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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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National food safety standard - Good manufacturing practice for milk products

1 Scope

This standard specifies the basic requirements and management criteria for the sites, facilities and personnel involved in the procurement, processing, packaging, storage and transportation of raw materials during the production of dairy products.

This standard applies to the production of dairy products using raw milk and its processed products as the main raw materials.

2 Terms and definitions

The terms and definitions defined in GB 14881 apply to this standard.

3 Site selection and factory environment

It shall comply with the relevant provisions of GB 14881.

4 Factory buildings and workshops

4.1 Basic requirements

It shall comply with the relevant provisions of GB 14881.

4.2 Work area zoning requirements

4.2.1 Reasonable zoning shall be carried out based on product characteristics, production technology and the requirements for cleanliness in the production process, combined with the actual conditions of the factory and workshop. Generally, the factory and workshop are divided into common work areas, quasi-cleaning work areas and cleaning work areas.

4.2.2 The commonly work area includes the milk collection room, raw material warehouse, packaging material warehouse, outer packaging workshop, post-sterilization room for post-filling sterilization process, finished product warehouse, etc.

4.2.3 The quasi-cleaning work area includes the workshop of raw material pre-treatment, weighing, blending, and temporary storage of inner packaging materials for subsequent sterilization or disinfection processes.

4.2.4 Cleaning work areas include workshops for weighing, batching, filling, etc. that are in contact with the air environment and without subsequent sterilization or disinfection processes, auxiliary areas with special cleaning requirements (such as temporary storage rooms for exposed inner packaging after cleaning and disinfection), workshops for storage and filling of exposed semi-finished products to be packaged, and the workshop for inner packaging that are in contact with the air environment and without subsequent sterilization, etc.

5 Facilities and equipment

5.1 Basic requirements

It shall comply with the relevant provisions of GB 14881.

5.2 Facilities

5.2.1 Water supply facilities

Safety and sanitation facilities shall be added at the entrances and exits of water supply facilities to prevent animals and other foreign objects from entering and causing food contamination.

5.2.2 Drainage facilities

5.2.2.1 Drainage facilities shall be sloped, unobstructed and easy to clean. The junction between the side and bottom of the drainage ditch shall have a certain curvature or take appropriate measures to prevent water accumulation. Drainage facilities in the work area shall avoid sewer backflow and turbid gas escape. If necessary, floor drains with water seals, check valves or backflow prevention shall be used.

5.2.2.2 There shall be no water supply pipelines for production water under the drainage facilities.

5.2.3 Personal hygiene facilities

5.2.3.1 Changing rooms (including changing shoes or wearing shoe covers), hand washing and drying facilities, and disinfection facilities shall be set up near the entrance of the production site or production workshop.

5.2.3.2 Necessary cleaning measures shall be taken before personnel enter the cleaning work area, and a dedicated changing room shall be set up at the personnel entrance. Hand disinfection facilities shall be set up at the entrance of the cleaning work area, and hand washing facilities may not be set up.

5.2.4 Ventilation facilities

5.2.4.1 Effective measures shall be taken at outdoor air inlets to prevent animals or other foreign objects from entering, and they shall be kept away from pollution sources and exhaust ports, and equipped with air filtration equipment. Exhaust ports shall be equipped with easy-to-clean, corrosion-resistant mesh covers to prevent animals from intruding.

5.2.4.2 Compressed air or other gases used in food production and cleaning of food contact surfaces and equipment shall be filtered and purified to prevent indirect contamination.

5.2.4.3 In areas where odors, gases (steam and harmful gases) or dust are generated and may contaminate food, appropriate removal, collection or control devices shall be installed.

5.2.4.4 Cleaning work areas shall be equipped with purification air conditioning systems to prevent steam condensation and keep the indoor air fresh; commonly work areas shall be equipped with ventilation facilities or ensure good ventilation to remove damp and dirty air in time. When air conditioning, air intake and exhaust or fans are used in the factory, the air shall flow from areas with high cleanliness requirements to areas with low cleanliness requirements to prevent food, production equipment and inner packaging materials from being contaminated. The pressure difference between the cleaning work area and the commonly work area shall be maintained at a positive pressure of more than 10 Pa.

5.2.5 Storage facilities

5.2.5.1 When automated warehouses store items of different nature in the same warehouse, effective control measures shall be established for the reliability of the automation system.

5.2.5.2 Refrigerated (frozen) warehouses shall be equipped with thermometers, temperature measuring devices or temperature automatic recorders that can correctly indicate the temperature inside the warehouse, and the temperature shall be monitored and recorded. The monitoring frequency shall be consistent with the characteristics of the stored products. Thermometers, temperature measuring devices or temperature automatic recorders shall be calibrated regularly.

5.3 Equipment

5.3.1 Production equipment

5.3.1.1 Storage, transportation and processing systems (including gravity, pneumatic, closed and automatic systems) shall be designed and manufactured so as to facilitate the maintenance of good sanitary conditions.

5.3.1.2 There shall be a special area to store equipment spare parts and necessary

7 Food raw materials, food additives and food related products

7.1 Basic requirements

Food raw materials, food additives and food-related products shall comply with the relevant provisions of GB 14881.

7.2 Food raw materials

7.2.1 A supplier management system shall be established to specify the supplier selection, review and evaluation procedures. Raw milk purchasing stations or ranches shall comply with relevant national and local regulations, conduct unified management of raw milk quality and safety throughout the entire process, and strengthen the construction of milk source bases.

7.2.2 Enterprises using raw milk shall conduct batch-by-batch inspections in accordance with relevant national regulations, record the inspection results, the supplier's name and contact information, date of purchase, etc., check the transport vehicles, and keep records of raw milk handovers.

7.2.3 Raw materials and packaging materials that are judged to be unqualified shall be marked, stored separately, notified to the supplier, and properly handled.

7.2.4 The transportation and storage of raw milk shall comply with the following requirements.

a) Containers used to transport and store raw milk shall comply with relevant national standards. Insulated milk tanks or milk storage containers used to transport raw milk shall be cleaned every time and disinfected regularly, free of milk stains and unpleasant odors. Enterprises shall establish an inspection mechanism.

b) Relevant records shall be checked to confirm that the temperature of raw milk has been cooled to 0 ℃~4 ℃ within 2 hours after milking. The storage and transportation of raw milk shall comply with the relevant regulations and standards of relevant national departments, the temperature shall be effectively controlled, the protection shall be well carried out, and the temperature shall be monitored and recorded.

c) The raw milk shall be processed promptly after arriving at the factory. If it cannot be processed promptly, it shall be stored in cold storage. Unless otherwise specified, the storage temperature shall not exceed 7 °C. At the same time, the temperature and microbial contamination level shall be monitored and records shall be kept.

7.3 Other raw materials

7.3.1 During transportation and storage, raw materials and packaging materials shall be protected from contamination and damage and quality degradation shall be minimized; raw materials and packaging materials with special requirements for temperature, humidity and other conditions shall be transported and stored in accordance with the specified conditions.

7.3.2 During storage, raw materials and packaging materials shall be stored in different areas according to their characteristics and marked with relevant information and quality status.

7.3.3 The raw materials and packaging materials in stock shall be checked regularly. For raw materials and packaging materials that have been stored for a long time and are prone to quality changes, samples shall be taken to confirm the quality before use; raw materials and packaging materials that have deteriorated or exceeded their shelf life shall be cleared out in a timely manner.

8 Food safety control during the production process

8.1 Basic requirements

8.1.1 It shall comply with the relevant provisions of GB 14881.

8.1.2 The relevant principles of the Hazard Analysis and Critical Control Point shall be followed to establish and effectively operate a strict food safety control system, identify the key links of food safety in the production process, and formulate control measures for the key links of food safety.

8.1.3 The temperature and humidity facilities in the cleaning work area for the production of powdered dairy products shall be adjustable and equipped with monitoring devices.

8.1.4 Before the products are packaged independently, effective temperature and time control measures shall be formulated according to product characteristics and process requirements. The basic requirements are as follows.

a) Specify the methods used to kill microorganisms or inhibit their growth and reproduction, such as heat treatment, freezing or refrigerated storage, and implement effective monitoring.

b) Establish temperature and time control measures and corrective measures, and conduct regular verification.

c) For processing links in which the temperature and time are controlled strictly,

the membrane filtration sterilization system shall be verified.

8.2.1.2 Sterile air should be used to implement positive pressure protection in storage tanks for sterilized semi-finished products.

8.2.1.3 A safety evaluation of the sterilization effect shall be conducted to verify the sterilization parameters and establish control measures and disposal measures.

8.2.1.4 The microbial monitoring procedures for pasteurized milk processing may be established with reference to the requirements in Table B.1, including microbial monitoring indicators, sampling points, monitoring frequency, sampling and testing methods, evaluation principles and corrective measures, etc.

8.2.1.5 After filling, the product sealing (soft packaging) or airtightness (hard packaging such as glass jars) test shall be carried out.

8.2.2 Sterilized milk

8.2.2.1 Cleaning, disinfection and sterilization of product processing equipment

8.2.2.1.1 In the aseptic filling process, high temperature pressurized water, filtered steam, sterile distilled water or other suitable treatment agents shall be used before production to clean and sterilize the high temperature sterilization parts for the product and all pipelines, valves, pumps, buffer tanks, filling equipment and other product contact surfaces downstream of the pipeline. Ultra-high temperature sterilized milk processing shall ensure that all surfaces in direct contact with the product meet the requirements of aseptic filling after product sterilization and maintain this state until the end of production.

8.2.2.1.2 The aseptic chamber of the filling and packaging equipment in the aseptic filling process shall be cleaned and sterilized to meet the production requirements of aseptic filling before the product begins to be filled, and this state shall be maintained until the end of production. During the sterilization process, key indicators such as time, temperature, and disinfectant concentration shall be monitored and recorded, and verification measures shall be established for the sterilization effect.

8.2.2.1.3 The cleaning and disinfection of processing equipment for the post-filling sterilization process shall comply with the process requirements.

8.2.2.2 Thermal sterilization of products

8.2.2.2.1 A sterilization process specification shall be developed and verified to ensure that commercial sterility requirements are met. When developing a sterilization process specification, the following key factors affecting thermal sterilization shall be considered: type of sterilization equipment, characteristics of food, container type and size, technical and sanitary conditions, water activity, etc. When the product process

technical conditions change, an analysis shall be conducted to assess whether they have an impact on the sterilization effect. If the original sterilization process is found to be no longer applicable, the sterilization process specification shall be re-established.

8.2.2.2.2 Sterilization operation procedures shall be formulated and strictly implemented. If deviations occur during the sterilization process, they shall be corrected according to the correction plan, and the products shall be isolated, the causes shall be identified, and corrective measures shall be proposed.

8.2.2.2.3 The product shall be tested for commercial sterility to determine whether it meets the commercial sterility requirements. If the batch of products does not meet the commercial sterility requirements, it shall be properly handled in accordance with relevant regulations. The determination process, results and handling methods shall be recorded.

8.2.2.3 Filling of products

8.2.2.3.1 Automatic mechanical devices shall be used and manual operation is not allowed.

8.2.2.3.2 For products that are sterilized after filling, the time from sealing to sterilization shall be controlled within the time range required by the process regulations.

8.2.2.3.3 After filling, the product shall be tested for sealing or airtightness quality.

8.2.3 Fermented milk

8.2.3.1 The temperature of fermented milk during the sterilization process shall be monitored.

8.2.3.2 The strains used for fermentation shall comply with relevant regulations.

8.2.3.3 In the process of fermented milk processing, post-sterilization products and other materials that need to be added (such as bacteria, jam and other non-re-sterilized materials) should be protected by the positive pressure of sterile air, nitrogen or inert gas in the storage tank (or sterile bag).

8.2.3.4 Water that comes into contact with sterilized materials shall be sterilized or disinfected.

8.2.3.5 Before production, high-temperature pressurized water, filtered steam, sterile distilled water or other suitable treatment agents shall be used to clean and sterilize the high-temperature sterilization area and all pipelines, valves, pumps, buffer tanks, filling equipment and other product contact surfaces downstream of the pipeline.

8.2.3.6 For products that do not undergo a sterilization process after fermentation, the

batching, mixing and filling in the dry mixing process) shall be carried out in a cleaning work area. The temperature and relative humidity of the cleaning work area shall be compatible with the production process of dairy products.

8.2.4.4.2 Materials shall be added according to the product formula ratio requirements and the measurement shall be accurate.

8.2.4.4.3 Key process parameters (such as mixing time) related to mixing uniformity shall be verified and the mixing uniformity shall be confirmed.

8.2.4.4.4 For raw materials or products transported through pneumatic ducts entering the cleaning work area, an appropriate air filtration system shall be designed and installed.

8.2.4.4.5 For key processing parameters, corresponding control measures shall be established.

8.2.4.5 Inner packaging

8.2.4.5.1 The inner packaging process shall be carried out in a cleaning work area, and packaging materials entering the cleaning work area shall be cleaned.

8.2.4.5.2 Effective foreign matter control measures shall be adopted to prevent and detect foreign matter, and process monitoring and effectiveness verification shall be implemented.

8.2.4.6 The microbial monitoring procedures for milk powder processing may be established with reference to the requirements in Table B.3, including microbial monitoring indicators, sampling points, monitoring frequency, sampling and testing methods, evaluation principles and corrective measures, etc.

8.2.5 Processed cheese

8.2.5.1 The raw cheese after cutting and before mixing shall be properly stored and refrigerated at 6 °C or below. The storage temperature shall be monitored and the material shall be used within the specified time.

8.2.5.2 The sterilization process specification shall be strictly followed. If a continuous sterilization process is adopted, an automatic recorder should be used for continuous monitoring and recording, and an alarm device should be provided. When the temperature or time deviates from the set value, correction shall be made in time.

8.2.5.3 The microbiological monitoring procedures for processed cheese processing may be established with reference to the requirements in Table B.4, including microbiological monitoring indicators, sampling points, monitoring frequency, sampling and testing methods, evaluation principles and corrective measures.

Appendix A

Requirements for computer system application in dairy product production enterprises

The computer system of dairy product production enterprises shall be able to meet the regulatory requirements of the *Food Safety Law of the People's Republic of China* and its related laws, regulations and standards on food safety, and shall form a complete information chain that helps to trace, track and locate food safety issues in all links from raw materials entering the factory to products leaving the factory, and shall be able to submit or remotely report relevant data in accordance with the requirements of the regulatory authorities. The computer system shall comply with (but not be limited to) the following requirements.

A.1 The system shall include data collection and record-keeping functions related to food safety in all links, including raw material procurement and acceptance, raw material storage and use, monitoring of key control links in production and processing, product factory inspection, product storage and transportation, and sales.

A.2 The system shall be able to assess and warn of food safety risks related to the company's raw materials, processing technology and products.

A.3 The system and its supporting database shall establish and use a complete permission management mechanism to ensure the mandatory use of staff accounts/passwords and ensure that there are no loopholes in the system and database that allow unauthorized access in the security architecture.

A.4 Based on the authority management mechanism, the system shall implement a complete security strategy and set corresponding policy groups for different staff members to ensure that users with specific roles only have corresponding permissions. All data accessed and generated by the system shall be saved in the corresponding database and shall not be stored in the form of files, so that it is ensured that all data access is subject to the authority management control of the system and database.

A.5 Special security policies are used for confidential information to ensure that only the information owner has the right to read, write and delete. If confidential information must be stored and transmitted outside the security control scope of the system and database, ensure that:

a) Encrypt and store confidential information to prevent unauthorized persons from reading the information;

b) Generate a check code before confidential information is transmitted. The

check code and information (after encryption) are transmitted separately. The check code is used at the receiving end to confirm that the information has not been tampered with.

A.6 If the system needs to collect data generated by automated testing instruments, the system shall provide a safe and reliable data interface to ensure the accuracy and high availability of the interface part and ensure that the data generated by the instrument can be collected by the system in a timely and accurate manner.

A.7 Comprehensive and detailed system and database log management functions shall be implemented, including:

a) System logs record every user-login to the system and database (user, time, login computer address, etc.);

b) Operation logs record every modification of data (including modifying user, modification time, modified content, original content, etc.);

c) System logs and operation logs shall have a preservation strategy. No user (excluding system administrators) can delete or modify them within the set time limit to ensure a certain time-limited traceability capability.

A.8 Establish a system usage and management system that must include at least the following:

a) A real-time recording system for the original data, intermediate data, generated data and processing flow in the workflow to ensure that the entire work process can be reproduced.

b) A detailed backup management system to ensure that the entire system and corresponding data can be fully restored as soon as possible after a disaster occurs.

c) The computer room shall be equipped with an intelligent UPS uninterruptible power supply connected to the working system to ensure that in the event of a power outage, the UPS will take over the power supply and notify the working system to save data and perform log operations (the UPS shall be able to provide enough power to ensure the system's emergency save operation time).

d) A sound data access management system shall be established. Confidential data must not be stored on shared devices. Data sharing within a department shall also adopt a permission management system to achieve authorized access.

e) A supporting system maintenance system, including regular storage organization and system testing, to ensure the long-term stable operation of the system.

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