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National food safety standard - Good manufacturing practice for formulae for infants and young children

食品安全国家标准　婴幼儿配方食品良好生产规范

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Table of Contents

Foreword 3
1 Scope 4
2 Terms and definitions 4
3 Site selection and factory environment 5
4 Factory buildings and workshops 5
5 Facilities and equipment 9
6 Health management 11
7 Food raw materials, food additives, and food-related products 13
8 Food safety control during production 13
9 Inspection 18
10 Storage and transportation of food 18
11 Product recall management 18
12 Training 18
13 Management system and personnel 19
14 Record and document management 19
Appendix A Guidelines for environmental monitoring of Salmonella, Cronobacter spp. (Enterobacter sakazakii) and other Enterobacteriaceae in cleaning work areas of powdered infant and young child formula foods 20

National food safety standard - Good manufacturing practice for formulae for infants and young children

1 Scope

This standard specifies the basic requirements and management guidelines for sites, facilities, and personnel in the production process of formula foods for infants and young children such as raw material procurement, processing, packaging, storage, and transportation.

This standard applies to the production of formula foods for infants and young children with milk and/or soybeans and their processed products as the main protein source.

2 Terms and definitions

The terms and definitions defined in GB 14881, GB 10765, GB 10766, and GB 10767 apply to this standard.

2.1 Wet (production) process

The production process of processing the ingredients of powdered infant and young child formula foods in a liquid state into the final product. This process usually includes batching, heat treatment, concentration, drying, packaging (filling), and other processes.

2.2 Dry (production) process

The production process of physically mixing the ingredients of powdered infant and young child formula foods in a solid state to produce the final product. This process usually includes batching, mixing (including premixing), packaging (filling), and other processes.

2.3 Dry-wet combined (production) process

A complete production process in which part of the ingredients of powdered infant and young child formula foods are processed in a liquid state, dried, and then another part of the solid ingredients is added by using a dry process, and then packaged (filled) to make the final product.

2.4 Liquid (production) process

The production process of processing the ingredients of infant and young child formula

food in a liquid state into the final liquid product. This process usually includes batching, homogenization, sterilization, filling, sealing, and other processes (also includes sterilization process after filling and sealing).

3 Site selection and factory environment

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

3.2 It shall be kept away from livestock and poultry farms, and animals shall not be raised in the factory area.

4 Factory buildings and workshops

4.1 Basic requirements

They shall comply with the relevant provisions of GB 14881.

4.2 Design and layout

4.2.1 Factory buildings and workshops shall be reasonably designed, planned, and constructed to be compatible with facilities and equipment to prevent microbial contamination and growth, especially contamination by Salmonella and Cronobacter spp. (Enterobacter sakazakii). The following shall be considered in the design:

a) Wet areas and dry areas shall be effectively separated; contamination caused by personnel, equipment, facilities, and material flow shall be effectively controlled to prevent microorganisms that are easily harmful to infants and young children from entering the cleaning work area, such as Salmonella, Cronobacter spp. (Enterobacter sakazakii).

b) The cleaning work area shall prevent the generation of condensation water.

c) The wet cleaning process shall be reasonably designed, and improper wet cleaning shall be prevented in dry areas.

d) All kinds of pipes, cables, and penetration gaps that pass through the floor, ceiling, and wall of the building shall be enclosed or sealed.

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

a) The common work areas include the milk collection room, raw material

warehouse, packaging material warehouse, outer packaging workshop and finished product warehouse, sterilization area for the sterilizing-after-filling liquid products after filling and sealing, etc.

b) The quasi-cleaning work areas include raw material pretreatment workshops, raw material inner packaging cleaning or packaging material disinfection or tunnel sterilization areas, wet processing areas for powdered products (such as weighing, batching, and concentration), areas for weighing, batching, heat treatment, disinfection or sterilization of liquid products, filling area for the sterilizing-after-filling liquid products, etc.

c) The cleaning work areas include workshops where food is in contact with the air environment and there are no subsequent disinfection or sterilization operations (such as weighing, batching, and mixing), filling areas for liquid aseptic filling products, and auxiliary areas with special cleaning requirements (such as temporary storage rooms for temporarily storing cleaned and disinfected inner packaging), storage areas for exposed semi-finished products to be packaged, filling and inner packaging workshops, etc.

4.2.3 Effective separation shall be set up between working areas with different cleanliness levels. An independent air purification system with a filter device shall be installed in the cleaning work area and positive pressure shall be maintained to prevent unpurified air from entering the cleaning work area and causing cross-contamination.

4.2.4 Reasonable and effective control measures shall be taken when entering and exiting the cleaning work area to avoid or reduce microbial and other contamination. For personnel, raw materials, packaging materials, waste, equipment, etc. that enter and exit the cleaning work area, measures shall be taken to prevent cross-contamination, such as setting up changing rooms for personnel to change work clothes, work shoes or shoe covers, dedicated logistics channels, and waste sealing protection. For materials transported through pipelines by using airflow as a carrier to enter the cleaning work area, an appropriate air filtration system shall be designed and installed for the carrier airflow.

4.2.5 The dynamic control requirements for the cleaning work area in the production of powdered infant and young child formula foods shall comply with the provisions in Table 1. The dynamic control requirements for the cleaning work area in the production of liquid infant and young child formula foods shall comply with the provisions in Table 2, and the inspection shall be carried out regularly. The number of settling microbes in the air in the quasi-cleaning work area shall be ≤50 CFU/dish (measured according to GB/T 16294 for 5 minutes) and shall be monitored and recorded.

4.2.7 Factory buildings, workshops, and warehouses shall have facilities to prevent pest intrusion.

5 Facilities and equipment

5.1 Basic requirements

They shall comply with the relevant provisions of GB 14881.

5.2 Drainage facilities

5.2.1 In the cleaning work area where powdered infant and young child formula foods are produced, drainage facilities shall be avoided. If necessary, appropriate measures shall be taken to keep the drainage facilities in a dry state during production.

5.2.2 Drainage facilities shall have a slope, be kept smooth, and be easy to clean. There shall be no dead corners for cleaning at the joints between the sides and bottom of the drainage ditch, or corresponding measures shall be taken to prevent the generation of water accumulation. Drainage facilities in the work area shall avoid sewage backflow and turbid gas escape, and hygienic clean floor drains shall be used when necessary.

5.2.3 There shall be no water supply pipelines for production water in and below the drainage facilities.

5.3 Personal hygiene facilities

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

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

5.4 Ventilation facilities

5.4.1 The temperature and humidity of the clean working area where powdered infant and young child formula foods are produced shall be adjustable, and a monitoring device shall be installed.

5.4.2 Effective measures shall be taken for outdoor air inlets to prevent animals or other foreign objects from entering, such as being more than 2 m away from the ground or roof, and setting up fences. They shall be far away from pollution sources and exhaust outlets, and shall be equipped with air filtering equipment. The exhaust outlet shall be

equipped with an easy-to-clean, corrosion-resistant mesh cover to prevent animal intrusion.

5.4.3 Compressed air or other gases used for food production and cleaning food contact surfaces and equipment shall be filtered and purified to prevent indirect pollution.

5.4.4 In areas where odors, gases (steam and harmful gases), or dust are generated that may contaminate food, there shall be appropriate elimination, collection, or control devices.

5.4.5 A purification air-conditioning system shall be installed in the cleaning work area to prevent steam condensation and keep the indoor air fresh; ventilation facilities shall be installed in the common work area or ensure good ventilation to remove moist and dirty air in a timely manner. When air conditioning, air intake and exhaust, or fans are used in the factory building, 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.

5.4.6 The ventilation facilities of the production area and the inspection room shall be kept independent of each other. The exhaust outlet of the ventilation facilities in the inspection room shall not pollute the fresh air supplementary inlet in the production area.

5.5 Equipment

5.5.1 Production equipment shall have obvious operating status signs to indicate its status of normal, repair, out-of-use, limited, etc., and shall be repaired and maintained regularly. Equipment installation, repair, and maintenance operations shall not affect the quality of the product. It shall be ensured that the performance of the repaired equipment meets the process requirements and it shall be verified if necessary. Equipment that is out of service for any reason shall be cleaned and protected, and clearly marked. Equipment operating status identification should be displayed by an automated control system or manually identified.

5.5.2 Compressed air or other inert gases used for food and food contact surfaces shall be filtered and purified at least to remove oil, water, bacteria, dust, etc. before use (outsourced qualified products that meet production requirements can be used directly).

5.5.3 The inner walls and welds of equipment in contact with materials shall be smooth, flat, without dead corners, easy to clean, and corrosion-resistant. The inner surface shall be made of materials that do not react with materials, release particles, or absorb materials. They shall not cause stagnation or accumulation of materials.

5.5.4 For the production of powdered and liquid infant and young child formula foods, after the sterilization equipment is installed, the sterilization effect of the materials shall

equipment and processing environment, and wet cleaning shall be avoided as much as possible. Wet cleaning shall be limited to equipment parts that can be moved to a dedicated room or the situation that drying measures can be taken immediately after wet cleaning.

6.2.2 The following measures shall be taken for cleaning work areas that need to be kept dry:

a) Adopt a dry-cleaning process suitable for the place and equipment. When using a disinfectant containing necessary moisture, it shall be able to ensure that the cleaning work surface is dry, or dry cleaning shall be carried out in a dry state without using disinfectants;

b) When using wet cleaning measures under controlled conditions, it shall be ensured that the equipment and environment can be restored to dryness in a timely and thorough manner so that the area is not contaminated;

c) Mixing cleaning tools in different work areas shall be avoided.

6.2.3 Effective supervision measures shall be developed to ensure that key processes such as manual cleaning, cleaning in place operations (CIP), and equipment maintenance comply with relevant regulations and standard requirements, especially to ensure the applicability of cleaning and disinfection plans, the type and concentration of cleaning agents and disinfectants are appropriate, and the CIP system meets the relevant temperature and time requirements.

6.2.4 A cleaning and disinfection plan shall be formulated for the cleaning work area to ensure that all zones of the cleaning work area are cleaned. A cleaning or disinfection plan shall be developed for quasi-cleaning work areas and common work areas based on needs to prevent cross-contamination.

6.2.5 Cleaning and disinfection records shall be kept.

6.3 Work clothes management

Employees in the cleaning work area shall wear work clothes (or disposable work clothes) that meet the hygiene requirements of the area, and be equipped with hats, masks, and work shoes. Employees in quasi-clean work areas and common work areas shall wear work clothes that meet the hygiene requirements of the corresponding areas, and be equipped with hats and work shoes. Work clothes (including hats and masks) and work shoes used in cleaning work areas and quasi-cleaning work areas shall not be worn outside designated areas.

7 Food raw materials, food additives, and food-related products

7.1 They shall comply with the relevant provisions of GB 14881.

7.2 The food raw materials and food additives used shall comply with the requirements of corresponding national standards and/or relevant regulations, and shall ensure the safety of infants and young children and meet their nutritional needs. The supplier management, transportation, storage, procurement, and acceptance of raw milk shall comply with the relevant requirements of GB 12693.

7.3 For raw materials and food additives that directly enter the dry mixing process, measures shall be taken to ensure that the microbial indicators meet the requirements of product standards. For raw materials containing soybeans or soy protein components, the urease activity shall be ensured to be negative.

7.4 Suppliers shall be evaluated, and if necessary, on-site reviews shall be conducted or the production process shall be monitored.

7.5 Food additives shall be strictly managed, special warehouses or storage areas shall be set up, clearly marked to avoid cross-contamination and misuse, and a special register (or warehouse management software) shall be used to record the food additive's name, manufacturer or supplier, production date or production batch number, purchase date, purchase quantity, and usage, etc.

7.6 The food raw materials, food additives, and packaging materials in stock shall be inspected regularly. For food raw materials, food additives, and packaging materials that have been stored for a long time or whose quality is prone to change, the quality and safety management shall be strengthened and samples shall be taken to confirm the quality before use; for nutritional supplements such as vitamins whose quality is prone to change during the storage period, the shelf life management and storage environment requirements shall be established, and inspections shall be conducted when necessary to ensure that they meet the requirements; food raw materials, food additives and packaging materials that have deteriorated or exceeded their shelf life shall be cleaned up in a timely manner.

7.7 When automated warehouses are used to store food raw materials and food additives, effective control measures shall be established for the reliability of the automation system.

8 Food safety control during production

8.1 Basic requirements

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

8.1.2 The relevant principles of hazard analysis and critical control points shall be followed to establish and effectively operate a strict food safety control system.

8.1.3 When different types of products are produced on the same production line, the site shall be cleared and records of clearance shall be kept when switching between different products to ensure that product switching does not affect the next batch of products.

8.2 Special requirements for the production process of powdered infant and young child formula foods

8.2.1 Heat treatment (wet and dry-wet combined production processes)

8.2.1.1 The heat treatment process shall be regarded as a key control point to ensure the safety of powdered infant and young child formula foods. The heat treatment temperature and time shall consider the impact of factors such as product attributes (including fat content, total solid content, etc.) on the heat resistance of the sterilization target microorganisms, and monitoring measures that can reflect the heat treatment temperature, time and related key factors that affect the heat treatment effect shall be formulated to ensure that there is no deviation from the process parameter limit requirements; if there is a deviation, appropriate corrective measures shall be taken for real-time monitoring, and corresponding monitoring records shall be retained.

8.2.1.2 If the raw materials containing soybeans or soy protein components are used and have not been heated to inactivate the enzyme (or the enzyme is not completely inactivated), the heat treatment shall be used to simultaneously kill pathogenic bacteria and completely eliminate the enzyme (urease activity is negative), and it shall be monitored.

8.2.1.3 Key process parameters such as time, temperature, and enzyme inactivation time during heat treatment shall be recorded.

8.2.2 Intermediate storage

8.2.2.1 In wet and dry-wet combined processes, corresponding measures shall be taken for the intermediate storage of liquid semi-finished products to prevent the growth of microorganisms.

8.2.2.2 If exposed raw material powder in dry production or powdery semi-finished products exposed in wet production need to be temporarily stored, it shall be done in a cleaning work area.

8.2.2.3 If powdery semi-finished products are placed outside the clean area, measures shall be taken to ensure that the requirements of the cleaning work area are met when they enter the clean area. At the same time, the storage period and storage conditions of powdery semi-finished products shall be specified, and the quality of semi-finished

screens, strong magnets, and metal detectors, to prevent and inspect foreign matter, and process monitoring and effectiveness verification shall be implemented.

8.2.7 Environmental monitoring requirements

Environmental monitoring measures shall be established for Salmonella, Cronobacter spp. (Enterobacter sakazakii) and other Enterobacteriaceae in the cleaning work area of powdered infant and young child formula foods, and the monitoring requirements shall comply with the requirements of Appendix A.

8.3 Special requirements for the production process of liquid infant and young child formula foods

8.3.1 Product technology

8.3.1.1 All process operations shall meet the process requirements, and the process method of heat sterilization and aseptic filling or final heat sterilization after sealing shall be selected to achieve the purpose of commercial sterility.

8.3.1.2 After batching, all material delivery pipelines and equipment shall be kept closed.

8.3.1.3 Control measures shall be formulated to prevent foreign matter from entering the product during the production process.

8.3.2 Washing, sterilization, and clean-keeping of packaging containers

8.3.2.1 Food containers, packaging materials, detergents, and disinfectants that comply with national food safety standards and are approved by the health administrative department shall be used.

8.3.2.2 Packaging materials, containers, and equipment after final cleaning shall be handled to avoid recontamination.

8.3.2.3 Packaging materials used in aseptic filling systems shall be sterilized by appropriate methods, and shall be cleaned and dried when necessary. After sterilization, they shall be placed in a cleaning work area for cooling before use. If the storage time exceeds the specified period, they shall be re-sterilized.

8.3.3 Washing, sterilizing, and clean-keeping of product processing equipment for aseptic filling processes

8.3.3.1 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 holding sterilization position for the product, all pipelines, valves, pumps, buffer tanks, and filling equipment downstream of the pipeline, and other

product contact surfaces. It shall be ensured that after product sterilization, all equipment surfaces that are in direct contact with the product meet the requirements for aseptic filling and remain in this state until the end of production.

8.3.3.2 The aseptic warehouse of the filling and packaging equipment shall be cleaned and sterilized, meet the requirements of aseptic filling before the product is filled, and remain in this state until the end of production. When sterilization fails or the aseptic state fails, the sterile warehouse shall be re-sterilized. During sterilization, key indicators such as time, temperature, and disinfectant concentration shall be monitored and recorded.

8.3.4 Filling of products

8.3.4.1 Automatic mechanical devices shall be used for product filling, and manual operation is not allowed.

8.3.4.2 For products that require sterilization after filling, the time from filling to sterilization shall be controlled within the time limit required by the process regulations. The monitoring standards of microbial contamination levels of the product before sterilization shall be determined based on the effect of the sterilization method used and monitored regularly.

8.3.5 Sterilization of products

8.3.5.1 A suitable sterilization process needs to be established based on the heating characteristics of the product and the death kinetics of specific target microorganisms. The product is heated to sterilization temperature and shall be maintained at that temperature for a certain period of time to ensure commercial sterility. All sterilization processes shall be verified to ensure process reproducibility and reliability.

8.3.5.2 For liquid products that are sterilized after filling, the loading method of the products and items to be sterilized in the chamber of the sterilization equipment shall be confirmed through verification. The time-temperature curve of the sterilization process shall be recorded for each sterilization. There shall be a clear method of distinguishing between sterilized products and products to be sterilized. Sterilization records shall be used as one of the bases for the release of this batch of products.

8.3.5.3 Commercial sterility testing shall be conducted on the product to determine whether it meets commercial sterility requirements. Once a deviation is found during the sterilization process, the deviation shall be corrected according to the correction plan, the product shall be isolated, the cause shall be identified, and corrective measures shall be proposed. If it is determined that the batch of products does not meet commercial sterility requirements, it shall be properly handled under strict supervision. The determination process, results, and processing methods shall be recorded in detail.

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