National Standards of People's Republic of China

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National Food Safety Standard

Good Manufacturing Practice of Foods for Special Medical Purposes

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National Standard for Food Safety

Good Manufacturing Practice of Foods for Special Medical Purposes

1. Scope

The standard specifies the basic requirements and administration rules for the sites, facilities and personnel during the raw material purchase, processing, packaging, storage and transportation of formulated foods for special medical purposes.

The standard is applicable to manufacturers of formulated foods for special medical purposes including infant formula foods for special medical purposes.

2. Terms and definitions

The following terms and definitions specified in GB 14881--National Standard for Food Safety, General Hygienic Regulation of Food Production are applicable to the standard.

2.1 Formulated foods for special medical purposes

As especially formulated foods that are produced to meet the special requirements for nutrient or meals of people who suffer from eating limitation, disorder of digestion and absorption, metabolic disorders or special disease state , these products shall be eaten individually or together with other foods under the guidance of doctors or clinical dietitians. Formulated foods for special medical purposes shall be based on the medical and/or nutritional research results with scientifically verified security and clinical effects.

2.2 Clean work area

Work areas with high requirements for cleanliness, such as the processes where liquid products are in contact with the air environment (such as the weighing and compounding), bottling rooms and workshops for storage, filling and inner packing of semi-finished products where powder products are exposed for packaging.

2.3 Sub-clean work area

Work areas with requirements for cleanliness lower than clean work area, such as the raw material pre-treatment plants.

2.4 Ordinary work area

Work areas with lower requirements for cleanliness than sub-cleaning work area, such as milk collection rooms, warehouses for raw materials and packaging materials, workshops for external packing and warehouses for finished products, etc.

2.5 Commercial sterilization

A condition where products, after proper sterilization, contain neither pathogenic microorganisms nor non-pathogenic microorganisms that can breed in the normal temperature.

2.6 Sterile filling

The process to put the foods which are sterilized and meet the commercial sterilization requirements into the pre-sterilized container (with a lid) before sealing it in an aseptic environment.

3. Site selection and the plant area environment

It shall be in accordance with GB 14881.

4. Workshop and factory

4.1 Design and layout

4.1.1 It shall be in accordance with GB 14881.

4.1.2 Facilities and equipment related to manufacture shall be properly designed, built and planned at the workshop and factory so as to prevent the breeding and pollution of microorganisms, especially the pollution of salmonella. As to infant products, pollution of enterobacter sakazakii (belonging to Cronobacter) shall be especially prevented. Their hideouts or breeding shall be prevented or reduced as much as possible. The following shall be considered during the design:

a) Dry area shall be separated from wet area. Cross contamination due to personnel, equipment and material flow shall be effectively controlled.

b) Work material shall be properly piled to prevent the sites from being untidy due to improper piling.

c) The enclosure and sealing between the perforations and various pipes cables which go through the building floors, ceilings and walls shall be ensured.

d) The wet cleaning procedure shall be properly designed to prevent the breeding and spreading of microorganisms in dry areas due to improper wet cleaning procedures.

e) Proper facilities or measures shall be utilized or taken to remain dry while avoiding and timely removing water residue, thus preventing relevant microorganisms from growing and spreading.

4.1.3 Cleanliness levels for work zones shall be determined according to the requirements for manufacturing techniques, sanitation and quality. In principle, work zones can be divided into ordinary zones, sub-clean zones and clean zones.

4.1.4 Work without follow-up sterilization in dry processing areas shall be done in clean work areas, such as the work from drying (or post-drying) processes to the filling and sealing of packages.

4.1.5 Work zones of different cleanliness levels shall be effectively separated. Independent air cleaning systems with filters shall be installed at the clean work zones. Furthermore, positive pressure in the areas shall be maintained so as to prevent the air that is not purified from going into the clean work areas and causing cross contamination.

4.1.6 There shall be proper limitation and control over the behaviors of entering and exiting the clean work areas so as to avoid or reduce microorganism pollution. There shall be relevant measures to prevent cross contamination due to the personnel, raw materials, packaging materials, waste and equipment that enter or exist the clean work area, such as the work clothes, shoes or shoe covers replaced in the changing rooms, special logistics channels and waste channels. Proper air filtration systems shall be designed and installed for powder materials or products which enter the clean work zones via pipelines.

4.1.7 The purification levels in every work zone shall meet the requirements of formulated foods for special medical purposes for air purification when being processed. The air cleanliness in clean work zones and sub-clean work zones for solid and liquid products shall be in accordance with Table 1 and Table 2, and be inspected on a regular basis.

Table 1 Requirements for control over the air cleanliness in clean and sub-clean work areas for solid products

Items		Requirements		Test method
		Sub-clean work areas	Clean work areas	
Dust count/m^3	≥0.5μm	—	≤7,000,000	To be tested in accordance with GB/T 16292. The test state is static state.
	≥5μm	—	≤60,000	
Ventilation rate [a] （per hour）		—	10～15	—
Total bacterial count（CFU/皿）		≤30	≤15	To be tested with the natural sinking method in accordance with GB/T 18204.1.
[a] Ventilation rate is applicable to clean work zones with floors lower than 4.0m.				

Table 2 Requirements for control over the air cleanliness in clean work areas for liquid products

Items		Requirements	Test method
		Clean work areas	
Dust count/m^3	≥0.5μm	≤3,500,000	To be tested in accordance with GB/T 16292. The test state is static state.
	≥5μm	≤20,000	
Ventilation rate [a] （per hour）		10～15	—
Total bacterial count（CFU/皿）		≤10	To be tested with the natural sinking method in accordance with GB/T 18204.1.
[a]Ventilation rate is applicable to clean work zones with floors lower than 4.0m.			

4.1.8 Clean work areas shall be dry. Water facilities and systems shall be prevented as much as possible there. If unable to avoid them, they shall not pass through the upper space of the production work area in case secondary pollution occurs. There shall also be preventive measures.

4.1.9 There shall be facilities to keep animals such as insects and rats away from plants, workshops and warehouses.

4.2 Interior structures and materials of the buildings

4.2.1 Ceilings

4.2.1.1 They shall be in accordance with GB 14881.

4.2.1.2 Internal ceilings and top corners in work sites such as workshops shall be easy to clean so as to avoid dust accumulation, dew formation, mold growth or exfoliation and other conditions. Smooth and cleanable ceilings shall be added where, in clean work zones, sub-clean work zones and other sites where foods are exposed, ceilings are apt to harbor dusts. Ceilings made of reinforced concrete shall be flat and gap-free.

4.2.1.3 Flat-topped ceilings in workshops shall be made of white or light-colored, non-toxic, odorless waterproof materials. Mold-proof, durable and cleanable coating shall be used when necessary.

4.2.2 Walls

They shall be in accordance with GB 14881.

4.2.3 Doors and windows

They shall be in accordance with GB 14881. Self-closing doors (with auto sensors or door closers) and/or air curtains shall be installed at the entrances and exits of clean work zones and sub-clean work zones.

4.2.4 Grounds

They shall be in accordance with GB 14881. Grounds, where drainage or waste water flows and which are often damp or washed with water during work, shall be acid- and alkali- resistant and slope at some angle for drainage.

4.3 Facilities

4.3.1 Water facilities

4.3.1.1 They shall be in accordance with GB 14881.

4.3.1.2 Water facilities and equipment shall be in accordance with relevant national administrative regulations.

4.3.1.3 Safety and health facilities shall be installed at the entrances of water facilities so as to prevent animals and other substances from entering and causing food pollution.

4.3.1.4 Secondary water supply facilities shall be in accordance with GB 17051-- Hygienic Regulations for Secondary Water Supply Facilities.

4.3.2 Drainage facilities

4.3.2.1 They shall be in accordance with GB 14881.

4.3.2.2 The drainage system shall slope at some angle and keep unobstructed so as to be cleaned and maintained. There shall be some curve at the junction of flanks and bottoms of the drainage ditches.

4.3.2.3 There shall not be water supply pipes for production water within the drainage systems and underneath.

4.3.3 Facilities for cleansing and disinfection.

They shall be in accordance with GB 14881.

4.3.4 Private sanitary facilities

4.3.4.1 They shall be in accordance with GB 14881.

4.3.4.2 Secondary dressing rooms shall be installed at the entrances of clean work areas. Hand disinfection facilities shall be installed at the entrances of clean work areas.

4.3.5 Ventilation equipment

4.3.5.1 They shall be in accordance with GB 14881. Environment temperature and, when necessary, air humidity shall be controlled at clean work areas where powder products are manufactured.

4.3.5.2 Air conditioning facilities shall be installed at the clean work areas so as to avoid devaporation and keep the indoor air fresh. Proper facilities for removal, collection or control shall be installed at the areas where odors, gas (steam, poisonous and hazardous gas) or powder may contaminate foods.

4.3.5.3 The air inlet shall be 2m above the ground or roof. It shall be away from the pollution sources and air outlets. Air filtering facilities shall be installed.

4.3.5.4 Compressed air or other inert gases that are used to transport or package foods, clean the food contact surfaces or facilities shall be filtered and purified.

4.3.6 Lighting facility

It shall be in accordance with GB 14881. The workshop daylight factor shall reach Standard Ⅳor higher. Mixing illumination in the quality control working plane shall reach 540 lx or higher. And the working plane in the processing sites shall reach 220 lx or higher and that in other sites shall reach 110 lx or higher. Beam-focusing sensitivity test zones are exceptions.

4.3.7 Warehousing facilities

4.3.7.1 They shall be in accordance with GB 14881.

4.3.7.2 Storage sites shall be divided according to the different characteristics of raw materials, semi-finished products, finished products and packing materials. Refrigerating (freezing) chambers shall be used when necessary. Different substances shall be properly separated or divided (classified or stored in different shelves or zones) and obviously marked when stored in the same warehouse.

4.3.7.3 Temperature monitoring facilities, such as thermometers, temperature measuring devices or automatic temperature recorders which can indicate the right temperatures in the refrigerating (freezing) chambers, shall be installed to carry out real time monitoring and keep records.

5. Facilities

5.1 Production equipment

5.1.1 General requirements

5.1.1.1 They shall be in accordance with GB 14881.

5.1.1.2 Operation specifications of special equipment (such as pressure vessels and pressure pipes) shall be formulated during the productive process.

5.1.2 Materials

Materials for production equipment shall be in accordance with GB 14881.

5.1.3 Design

5.1.3.1 It shall be in accordance with GB 14881.

5.1.3.2 The food contact surfaces shall be smooth, indentation- or crack-free so as to reduce the accumulation of food scraps, dirt or organic matters.

5.1.3.3 The facilities that are in contact with ingredients shall have smooth, complete, anti-corrosion, dead-zone-free interiors that are easy to clean. These interiors shall be made of materials that neither react with ingredients nor release particles nor absorb ingredients.

5.1.3.4 Storage, transportation and processing systems (including gravity, pneumatic, airtight and automatic systems) shall be designed and manufactured to facilitate the maintenance of their good sanitary conditions.

5.1.3.5 There shall be special zones for the storage of spare parts so as to provide necessary parts for equipment maintenance. Storage zones for spare parts shall be kept clean and dry.

5.1.3.6 Production equipment shall bear obvious labels for running status and be kept, maintained and verified on a regular basis. The product quality shall not be impaired during their installation and maintenance. Facilities shall be verified or determined to ensure that all their performance meets the requirements of the technology. Disqualified facilities shall be removed away from the production area. They shall have obvious labels before being removed.

5.1.3.7 Measuring instruments and key gauges for production shall be examined on a regular basis. Facilities for dry blending can ensure the mixing uniformity of products.

5.2 Monitoring equipment

5.2.1 It shall be in accordance with GB 14881.

5.2.2 See the related functions of computer systems and their network techniques in Appendix A when carrying out collection of key control points monitoring data and managing various records with these computer systems and their network techniques.

5.3 Maintenance and repair of facilities

5.3.1 They shall be in accordance with GB 14881.

5.3.2 Every time before production, facilities shall be checked to find if they are under normal conditions so as to ensure that the hygienic quality of products is not impaired. Failures shall be timely eliminated once they occur. Time and causes of failures, as well as the product groups that may be affected, shall be recorded.

6. Sanitary management

6.1 Sanitation management systems

They shall be in accordance with GB 14881.

6.2 Sanitary management of plants and facilities

6.2.1 It shall be in accordance with GB 14881.

6.2.2 Removable devices and tools which have been cleaned and sterilized shall be placed in a proper site where food contact surfaces will not be contaminated again so as to keep them applicable.

6.3 Cleaning and sterilization

6.3.1 Effective plans and procedures for cleaning and sterilization shall be formulated to ensure the sanitation and hygiene of food processing sites, equipment and facilities and to avoid food contamination.

6.3.2 In clean work zones where dry operation is needed (such as dry blend, powder product filling, etc), to perform the effective dry-clean process on the production equipment and processing environments is an effective way to prevent microorganisms from breeding. Wet-clean processes shall be avoided as much as possible. Wet-clean processes shall be limited to equipment components that can be carried to special rooms or conditions where dry-clean processes are not available. When dry-clean processes are not available, wet-clean processes under control shall be performed only if equipment and environments can be timely, thoroughly recovered to dryness in case the zone is contaminated.

6.3.3 Effective supervisory processes shall be formulated so as to ensure that key processes (such as manual cleaning, cleaning in place and facility maintenance) are in accordance with relevant regulations and standard requirements. In particular, applicability of cleaning and disinfection solutions shall be ensured. Concentration of disinfectants and detergents shall be appropriate. CIP System shall meet the relevant requirements for temperature and time and the equipment shall be properly rinsed when necessary.

6.3.4 The periodic chart to clean and sterilize all the workshops shall be formulated so as to ensure all the zones are cleaned and special cleaning are carried out on important zones, equipment and tools. The cycle and effectiveness to clean the equipment shall be verified or justified.

6.3.5 The amount of cleaning staff shall be guaranteed and their individual responsibilities shall be specified. All the cleaning staff shall be well trained and acquainted with the hazard of pollution and the importance to prevent it. Records on cleaning and sterilization shall be well made.

6.3.6 Cleaning tools for different clean zones shall be definitely marked and cannot be mixed.

6.4 Personnel health and sanitary requirements

6.4.1 General requirements

Management of food processing personnel health shall be in accordance with GB 14881.

6.4.2 Sanitary requirements for food processing personnel

6.4.2.1 It shall be in accordance with GB14881.

6.4.2.2 Personnel at sub-clean and ordinary work areas shall wear work clothes which are in accordance with the sanitary requirements of relevant areas. They shall also be equipped with caps and work shoes. Personnel at clean work areas shall wear work clothes (or disposable work clothes) that meet the sanitary requirements of the area. They shall also be equipped with caps (or hoods), masks and work shoes (or shoe covers).

6.4.2.3 Personnel shall enter the clean work areas after procedures such as secondary dressing and hand cleaning and sterilizing so as to ensure their hand sanitation. They shall wear work clothes, hoods or caps, work shoes or shoe covers. Work clothes and shoes designated for clean and sub-clean work areas shall not be worn outside designated areas.

6.4.3 Visitors

They shall be in accordance with GB 14881.

6.5 Insect pest control

It shall be in accordance with GB 14881.

6.6 Waste disposal

6.6.1 It shall be in accordance with GB 14881.

6.6.2 Containers for waste, by-products and inedible or hazardous substances shall be well-textured and waterproof with special marks on. When necessary, they shall be sealed so as to avoid food contamination.

6.6.3 Temporary storage facilities for waste shall be installed in appropriate places, where waste is classified and stored according to its characteristics. Corruptible waste shall be timely removed.

6.7 Management of poisonous and hazardous substances

Management of cleaning agents, disinfectants, pesticides and other poisonous and hazardous substances shall be in accordance with GB 14881.

6.8 Management of waste water

Waste water shall be properly dealt with before discharge so as to meet the national requirements for sewage discharge.

6.9 Management of work clothes

It shall be in accordance with GB 14881.

7. Requirements for raw and packaging materials

7.1 General requirements

It shall be in accordance with GB 14881.

7.2 Requirements for purchase and acceptance inspection of raw and packaging materials

7.2.1 Purchase of raw and packaging materials shall be in accordance with GB 14881.

7.2.2 Companies shall formulate regulations to manage suppliers and specify the procedures to select, examine and evaluate them.

7.2.3 Once found, food safety problems on raw and packaging materials shall be reported to the local food safety supervision department.

7.2.4 As to raw materials which directly go into the dry-mixing procedure, integrity of their packages shall be ensured and no traces of insect pests or other pollution shall be spotted.

7.2.5 As to raw materials which directly go into the dry-mixing procedure, the company shall take measures to ensure that the microbiological indicator meet the requirements for finished products. It shall be ensured that the urease activity of soybean raw materials is negative.

7.2.6 Procedures and safety precautions related to suppliers shall be evaluated. Site assessment or procedures shall be monitored on a regular basis when necessary.

7.3 Requirements for transportation and storage of raw and packaging materials

7.3.1 Companies shall transport and store the raw and packaging materials while meeting the requirements for quality safety.

7.3.2 During transportation and storage, raw and packaging materials shall avoid direct sunshine, rain, intensive temperature, humidity change and intensive impact. They shall not be transported together with poisonous, hazardous substances.

7.3.3 During transportation and storage, raw and packaging materials shall not be polluted and damaged, thus reducing quality deterioration to the minimum level. Materials and packaging materials which have special requirements for temperature, humidity or others shall be delivered and stored as specified.

7.3.4 During storage, different raw and packaging materials shall be separately stored according to their characteristics and labels shall be established to show relevant information and quality conditions.

7.3.5 Stored raw and packaging materials shall be checked on a regular basis. Those raw and packaging materials which have been stored for a long time and whose quality may have changed must be sampled to determine their quality. Spoiled or out-of-date raw and packaging materials shall be timely disposed of.

7.3.6 Qualified raw and packaging materials shall be used in accordance with the principle of first-in first-out (FIFO) or First Expiration First Out (FEFO) so as to be organized in a proper way.

7.3.7 Food additives and food nutritive fortifiers shall be managed by specially-assigned persons. Special warehouses or zones shall be used for storage and exclusive registers (or warehouse management software) shall be used to record the names, purchase time, purchase volume and usage amount of additives and nutrition enhancers. Furthermore, term of validity shall be paid attention to.

7.3.8 Raw material verification shall be done to ensure the qualification of vitamins and mineral substances which may change during the storage. When necessary, tests shall be done so as to ensure they meet the requirements for raw materials.

7.3.9 Raw materials which contain allergen shall be separately stored and well marked so as to avoid cross contamination.

7.4 Others

Relevant records on the purchase, acceptance inspection, storage and transportation of raw and packaging materials shall be kept.

8. Food safety control during the production

8.1 Risk control over product pollution

It shall be in accordance with GB 14881.

8.2 Control over microbial contamination

8.2.1 Temperature and time

8.2.1.1 The way to kill microorganisms or inhibit microorganism growth and breeding shall be specified according to the product characteristics, such as heat treatment, freezing or refrigerating storage. Effective monitoring shall be carried out.

8.2.1.2 Measures to control the temperature and time and to correct errors shall be formulated and verified on a regular basis.

8.2.1.3 Real time monitoring measures shall be formulated for processing procedures which require strict temperature and time control. Monitoring records shall be kept.

8.2.2 Humidity

8.2.2.1 Control over air humidity in places where it is required shall be carried out according to the product and technique characteristics so as to reduce the breeding of harmful microbe. Critical limit of air humidity shall be formulated and put into effective operation.

8.2.2.2 Real time control over air humidity and monitoring measures shall be formulated to make verification and keep records on a regular basis.

8.2.3 To avoid microbial contamination

8.2.3.1 Necessary measures shall be taken during the whole procedure from the inbound raw and packaging materials to the outbound finished products so as to avoid microbial contamination.

8.2.3.2 The operation, usage and maintenance of equipment, containers and tools which are used to deliver, carry or store the raw materials, semi-finished products and finished products shall avoid the contamination to the processed or stored foods.

8.2.4 Monitoring over the microorganisms during the manufacturing process

8.2.4.1 It shall be in accordance with GB14881.

8.2.4.2 Monitoring plans on microorganisms shall be formulated during the manufacturing process to carry out effective supervisory control in accordance with GB 14881-2013--Appendix A in combination with manufacturing techniques and requirements of National Standard for Food Safety--General Rule on Formulated Foods for Special Medical Purposes and GB 25596--National Standard for Food Safety--General Rule on Infant Formula Food for Special Medical Purposes. Total bacterial count and the

coli group shall be regarded as the indicator microorganisms for health standard. When the monitored results show deviations, proper corrective actions shall be taken to the control measures.

8.2.4.3 Powder foods for special medical purposes shall be in accordance with Appendix B. Environmental monitoring plans shall be formulated against the salmonella，enterobacter sakazakii and other enterobacterium in clean work zones. When the monitored results show deviations, proper corrective actions shall be taken to the control measures.

8.3 Control over chemical pollution

8.3.1 It shall be in accordance with GB 14881.

8.3.2 Chemical substances shall be separately stored with foods, definitely labeled and kept by specially-assigned persons.

8.4 Control over physical pollution

8.4.1 It shall be in accordance with GB 14881.

8.4.2 Work such as electric soldering, incision and polish cannot be done during the manufacture in case off-flavor and chippings appear.

8.5 Food additives and food nutritive fortifiers

8.5.1 Food additives and food nutritive fortifiers shall be rationally used according to the types, scope and dosage specified by National Standard for Food Safety.

8.5.2 When being used, food additives and food nutritive fortifiers shall be accurately weighed and recorded.

8.6 Packages

8.6.1 It shall be in accordance with GB 14881.

8.6.2 Packing materials shall be clean, non-toxic and in accordance with relevant national regulations.

8.6.3 Packaging materials or gas shall be non-toxic and shall not affect the food safety and product features under special storage and usage conditions.

8.6.4 Reusable packaging materials such as glass bottle and stainless steel containers shall be thoroughly rinsed and sterilized before being used.

8.7 Specific processing steps

8.7.1 General requirements

All treatment procedures in the manufacturing techniques of formulated foods for special medical purposes shall meet the requirements of corresponding specific processing steps and be in accordance with 8.7.2 to 8.7.9.

8.7.2 Heat treatment

The heat treatment procedure shall be the critical control point to ensure the safety of formulated foods for special medical purposes. As to the heat treatment temperature and time, the impact of factors such as product attributes (such as fat content, total solid content) on heat resistance of target microorganisms shall be considered. So relevant procedures shall be formulated to see if the temperature and time is deviated and proper corrective actions shall be taken.

When the purchased soybean raw materials fail to go through heated enzyme deactivation treatment (or the enzyme deactivation is incomplete), such soybean-based products shall go through the heat treatment while achieving the desired effect of pathogen killing and thorough enzyme deactivation (the urease shall be negative) and be monitored as a critical control point.

Records on critical process parameters such as the time, temperature and enzyme deactivation time in the heat treatment shall be kept.

8.7.3 Intermediate storage

During the production of formulated foods for special medical purposes, relevant measures shall be taken in the intermediate storage of liquid semi-finished products so as to prevent the growth of microorganisms. Raw material powder that is exposed during the dry production of powder formulated foods for special medical purposes or powder semi-finished products which are exposed during wet production shall be stored in the clean work zones.

8.7.4 Commercial sterile operation of liquid formulated foods for special medical purposes

It shall be in accordance with the operation guide in Appendix C.

8.7.5 Processing steps of powder formulated foods for special medical purposes from heat treatment to dryness

During the production of powder formulated foods for special medical purposes, the running pipes and equipment shall be airtight from heat treatment to dryness and be thoroughly cleaned and sterilized on a regular basis.

8.7.6 Cooling

The dry, exposed powder semi-finished products shall be cooled down in the clean work zone.

8.7.7 Key factor control over the dry blending in dry process of powder formulated foods for special medical purposes and dry-wet compound technology

8.7.7.1 The exposed powder process that is in contact with the air (such as premixing, sub-packaging and batch charging) shall be carried out in the clean work zone. The temperature and relative humidity in the clean work zones shall be in accordance with the manufacturing techniques of powder formulated foods for special medical purposes. When there is no special requirement, the temperature shall be 25℃or lower and the relative humidity shall be below 65%.

8.7.7.2 The batching shall be accurately calculated. There shall be review processes during the calculation of food additives and food nutritive fortifiers.

8.7.7.3 Critical process parameters (such as mixing time) related to mixing uniformity shall be verified. The mixing uniformity shall also be determined.

8.7.7.4 Compressed air which is needed to transfer materials with positive pressure shall only be used after the oil and water removal, cleaning, filtering and sterilization.

8.7.7.5 Sanitary control requirements for raw materials, packaging materials and personnel shall be strictly formulated. The raw materials shall enter the work zones via the necessary cleaning procedures and material channels. They shall be in accordance with the treatment procedure of outer package removal or outer package sterilization.

8.7.8 Key factor control over the inner packing of powder formulated foods for special medical purposes

8.7.8.1 Inner packing shall be carried out in clean work areas.

8.7.8.2 The wrapping room shall only be accessible to relevant personnel. Requirements for raw and packaging materials and the personnel shall be in accordance with 8.7.7.5 and 6.4.2.

8.7.8.3 The outer packages of the packaging materials shall be examined before use to see if they are intact so as to ensure that these materials are not contaminated.

8.7.8.4 Manufacturers shall take effective measures to control, prevent and inspect the extraneous substances. For example, screens, strong magnets and metal detectors shall be installed. Supervisory control or validation verification shall be carried out on the procedures of these measures.

8.7.8.5 When different types of products are produced on the same assembly line, they shall be cleaned in an effective way and site-clearing records shall be kept so as to ensure that product switch doesn’t affect the next group of products.

8.7.9 Control over production water supply

8.7.9.1 Production water supply, equipment cleaning water, ice and steam which is in direct contact with foods shall be in accordance with GB 5749--Hygienic Standard of Drinking Water.

8.7.9.2 Recycle-water from the steam or dry process in the food processing or water in cycle use can be reused, but they shall not jeopardize the food safety and product features. Water treatment and effective monitoring shall be carried out when necessary.

8.7.9.3 When liquid products are produced, production water in direct contact with the products shall be manufactured with the de-ionization method or ion exchange method, reverse osmosis method and other proper methods according to the characteristic of the products so as to ensure that the requirements for product quality and technology can be met.

9. Verification

9.1 The productive process shall be verified so as to ensure the reproducibility of the whole process and the controllability of the product quality. The production verification shall include the installation determination, operation determination, performance determination and product verification of plants, facilities and equipment.

9.2 Verification projects shall be put forward according to the verified objects. Verification schemes shall be formulated and implemented.

9.3 Manufacturing techniques and key facilities and equipment of the products shall be verified according to the verification schemes. When key factors which affect the product quality (including the nutrient content)

change, such as the technologies, quality control methods, main raw materials, main production equipment, or when the production has undergone a period, re-validation shall be carried out.

9.4 After the verification is done, test reports shall be written and then examined and approved by verifiers. Data and analytical content during the verification shall be recorded in files. Verifying files include verification schemes, verification reports, comments and Suggestions, approvers, etc.

10. Test

10.1 It shall be in accordance with GB 14881.

10.2 Representative samples shall be taken from finished products group by group. The samples shall be tested and kept in accordance with the relevant national regulations and standards.

10.3 Quality control over the labs shall be strengthened so as to ensure the accuracy and authenticity of verification results.

11. Storage and transportation of products

11.1 It shall be in accordance with GB 14881.

11.2 Storage and transportation of products shall be in accordance with the storage condition on their labels.

11.3 Products in the warehouses shall be checked on a regular basis. Temperature and/or humidity records shall be kept when necessary. Abnormal situations shall be immediately processed when occurring.

11.4 Quality conditions shall be marked on verified products.

11.5 Relevant records shall be made on the storage and transportation of products. Outbound products shall bear delivery records so that they can be recalled immediately when problems occur.

12. Product tracing and recall

12.1 Product tracing systems shall be formulated to ensure that products can be effectively traced during the whole process from raw material purchase to product distribution.

12.2 Product recall systems shall be formulated. When a group or a type of products are found to or be likely to jeopardize the consumers' health, product recall systems shall be launched according to the relevant national regulations. Relevant departments shall be immediately notified and relevant records shall be made.

12.3 Measures such as non-hazardous treatment and destruction shall be taken after the foods are recalled. Relevant departments shall be notified of the food recall and processing.

12.4 Customer complaint and processing systems shall be formulated. Relevant company management departments shall keep records of and find the reasons to the customers' written or oral advice and complaints before appropriately solving them.

13. Training

13.1 It shall be in accordance with GB 14881.

13.2 Annual training plans shall be formulated according to the different requirements for duties to carry out corresponding training. Special types of work require relevant work licenses.

14. Management system and personnel

14.1 It shall be in accordance with GB 14881.

14.2 Perfect food safety management systems shall be formulated and relevant management measures shall be taken to carry out safety quality control over the formulated foods for special medical purposes during the whole process from the inbound raw materials to outbound finished products so as to ensure that products are in accordance with laws and regulations and relevant standards.

14.3 Supervision organs of food safety shall be established to manage food safety.

14.4 Head of the above organ shall be the legal representative or a person-in-charge assigned by the legal representative.

14.5 Different departments within the organ shall have their definite management responsibilities to ensure that management responsibilities related to quality and safety are put in place. Every department shall have its effective division mechanism to avoid responsibility overlapping, repetition or absence. Corresponding management systems shall be formulated for the maintenance and management of the inside and outside plant environments, plant facilities and equipment, the quality safety management during the production, sanitary control and quality tracking. The managers and their responsibilities shall be clear and definite.

14.6 Supervision organs of food safety shall be equipped with especially trained food safety managers who are responsible for publicizing and implementing food safety regulations and relevant rules, as well as supervising the implementation of examination and keeping relevant records.

15. Management of records and files

15.1 Record management

15.1.1 It shall be in accordance with GB 14881.

15.1.2 All records shall be signed or stamped by executives or relevant supervisors for review. Once altered, the records shall be clear enough to show their original appearance. Modifiers shall sign or stamp the area near the words.

15.1.3 All production and quality management records shall be examined and verified by relevant departments so as to make sure all the processing is in accordance with regulation. When occurring, abnormal events shall be dealt with immediately.

15.2 File management

File management systems shall be formulated in accordance with GB 14881 and intact quality management files shall be established. Files shall be classified and stored. Files for distribution and use shall be approved current texts. The abolished or invalid files shall be only stored for inspection. They shall not appear at the working sites.

16. Monitoring and evaluation of the effectiveness of food safety control measures

Monitoring and evaluation measures in Appendix C shall be taken to ensure the effectiveness of food safety control measures for powder formulated foods for special medical purposes.

Appendix A

Computer system application guide for manufacturers of formulated foods for special medical purposes

A.1 Computer systems for manufacturers of formulated foods for special medical purposes shall be in accordance with Food Safety Law and relevant laws, regulations and standards on food safety. An integrated information link which supports the traceability, tracing and location of food safety during all processes from inbound raw materials to outbound products. Relevant data shall be submitted or reported from a long distant away according to the requirements of supervision departments. This computer system shall be in accordance with but not limited to the requirements of A.2 to A.11.

A.2 The system shall include the purchase and acceptance check of raw materials, storage and use of raw materials, supervisory control over the critical control links of production and processing, outbound product inspection, storage and transportation of products, distribution and other links, as well as the collection of data related to food safety and record retention.

A.3 The system shall be able to evaluate and send pre-warning about related raw materials, processing techniques and risks of food safety.

A.4 Perfect authorization management mechanisms shall be formulated in the system and the matched database so as to ensure the mandatory usage of workers' accounts/passwords. Bugs which allow unauthorized access shall not be allowed in the systems and database on the security architecture.

A.5 The system shall achieve perfect safety strategies based on the authorization management mechanism and ensure that specific role users only have their corresponding authorities by setting up strategy groups according the different workers. All data which the system is in contact with and produce shall be saved in the corresponding database. They shall not be saved as files so as to ensure access to all data is subject to the authority management control of the system and database.

A.6 Special security strategies taken to the confidential information ensure that only information owners have the right to read, write and cancel the information. If it is required that confidential information be saved and transmitted outside the safety control scope of the systems and database, the following shall be guaranteed:

a) To encrypt and save confidential information in case the information is read by unauthorized persons.

b) Check codes shall be generated before the transmission of confidential information; Check codes and information (encrypted) shall be separately transmitted; Check codes shall be used at the receiving end so as to ensure the information is not falsified.

A.7 If the system requires to collect data generated by automation detecting instruments, the system shall provide safe, reliable data interfaces and guarantee their accuracy and high availability, thus ensuring the data generated by instruments can be timely and accurately collected by the system.

A.8 Log management functions of complete, exhaustive systems and database shall be achieved, which includes:

a) Every user log-in on the system's logging system and database (users, time, locations of log-in computers)；

b) Every alteration of the logging data (including the altering users, altering time, altered content, original content, etc)；

c) Conversation strategies shall be in the system log and operation log. They shall not be canceled or altered by any user (except for the administrators) within the set time limit so as to guarantee some time traceability.

A.9 Detailed usage and management system shall be formulated and contain at least the following:

a) To formulate the real-time record system to record the original data, intermediate data, generated data and process flow during the work flow so as to reproduce the whole working process；

b) To formulate detailed backup management systems to ensure that the whole system and corresponding data can be recovered as soon as possible after failures occur；

c) The machine rooms shall be equipped with smart UPS to be linked with work systems and ensure that UPS can supply power and warn the work system to carry out data storage and log operation when power failures occur outside. (UPS can supply the power to guarantee the operation time of system emergency saving)；

d) Perfect data access management systems shall be formulated and restricted data shall not be saved on shared device. Authority management systems shall be applied to the internal data sharing to achieve authorized visit；

e) Matched system maintenance mechanisms including regular storage arrangement and system detection shall be formulated to ensure the long-term stable operation of the system；

f) Safety management systems shall be formulated. User passwords for the systems shall be replaced on a regular basis. Log-in sites of some users shall be restricted and unnecessary accounts shall be canceled.

g) It shall be specified that users who log in on outer nets shall not start and use the user/password memory function provided by the operating systems of outer computers so as to prevent the information from being embezzled.

A.10 When the data from the real-time monitoring of critical control points are inconsistent with the set standard values, the system can record the deviation dates, batches, the way to rectify the deviation and operator names.

A.11 Data and relevant records in the system shall be reproducible so as to be inspected and analyzed by supervisors.

Appendix B

Environmental monitoring guide on salmonella, enterobacter sakazakii and other Enterobacteriums in the clean work areas of formulated foods for special medical purposes

B.1 Monitoring purposes

B.1.1 There may be a small amount of Enterobacteriaece even in the sanitary production environments, including enterobacter sakazakii (belonging to Cronobacter). Pasteurized products may also be polluted by the environments, leading to the fact that a small amount of enterobacterium remains in the products. So enterobacterium in the production environments shall be monitored so as to determine whether the sanitation control procedure is effective. When deviation occurs, manufacturers shall take corrective actions and acquire the basic data of the hygiene status through continuous monitoring to trace the trend changes. According to relevant practices in the factory, reduction of the amount of enterobacterium in the environments can help decrease the enterobacterium in the final products (including enterobacter sakazakii and salmonella).

To prevent the contamination accidents and avoid the limitation of microbial sampling test in the final products, environmental monitoring plans shall be formulated as a food safety management tool and a basic procedure for Hazard Analysis and Critical Control Point（HACCP）to evaluate the sanitary conditions in clean work areas (dry areas).

B.1.2 Factors such as the ecological characteristics of salmonella, enterobacter sakazakii and other enterobacterium shall be considered when monitoring programs are formulated. Supervisory control over enterobacter sakazakii shall only be applicable to formulated infant foods for special medical purposes.

Salmonella can rarely be found in dry environments. Monitoring programs, however, shall be formulated to prevent its access. Effectiveness of hygiene control measures in the production environment shall be evaluated and relevant personnel shall be taught to prevent the salmonella from spreading when salmonella is found.

Enterobacter sakazakii is easier to be found in dry environments than salmonella and more likely to be detected with proper sampling and testing ways. Monitoring programs shall be formulated to appraise whether enterobacter sakazakii is increasing. Effective measures shall be taken to prevent its growth.

Enterobacterium, a common bacterium group in dry environments, is wide spread and easy to detect. Enterobacterium can be used as the indicator bacterium for environmental health conditions or during the production.

B.2 Factors which need considering in the design and sampling plans

B.2.1 Product category and technical process

The requirements and scope for sampling plans shall be determined according to the product feature, consumers' age and health conditions. In the standard, salmonella and enterobacter sakazakii are defined as pathogenic bacteria.

The emphasis of supervisory control shall be put on areas where microorganisms are likely to hide, such as the clean work area in the dry environments. Junctions between this area and the lower-level adjacent zones, as well as places that are close to the production line and equipment and are likely to be

contaminated, shall be paid more attention to, such as the opening of the enclosed equipment which is casually used for inspection. Areas that are known or may be contaminated shall be prioritized in supervisory control.

B.2.2 Two samples in the monitoring programs

B.2.2.1 Sampling from the surfaces which are in no touch with the food, such as equipment exteriors, ground around the production line, pipes and platforms. Under such circumstances, pollution risk degrees and pollutant content shall depend on the location and design of the production line and equipment.

B.2.2.2 Sampling from the surfaces which are in direct touch with the food, such as the equipment which may directly contaminate products from the spray tower to packaging. For example, microorganisms may breed at the sieve end due to the water absorption of clotting powdered formulas. Products are exposed to high contamination risks if indicator bacteria, enterobacter sakazakii or salmonella remain on the food contact surface.

B.2.3 Target microorganisms

Salmonella and enterobacter sakazakii are main target microorganisms. But the enterobacterium can be used as hygienic target bacteria. The enterobacterium content may show the possibility of salmonella to exist, as well as the conditions for salmonella and enterobacter sakazakii to grow.

B.2.4 Sampling location and sample amount

Sample amount shall be adjusted according to the complexity of techniques and the production line.

Sampling locations can be places where microorganisms may hide or go into so that contamination is caused. Sampling locations shall be determined according to relevant document literature or experience and expertise or historical data collected from factory pollution survey. Sampling locations shall be evaluated on a regular basis and necessary sampling locations shall be added to the monitoring programs according to special circumstances such as heavy maintenance, construction activities or worse sanitary conditions.

Sampling plans shall be comprehensive and representative. Scientific, rational sampling from various production shifts and different time frames in these shifts shall be considered. Sampling shall be carried out before production to verify the effect of cleaning measures.

B.2.5 Sampling frequency

The sampling frequency shall be determined according to B.2.1 and the data of existing microorganisms in different regions within the monitoring programs. If there are no such data, information shall be fully collected so as to determine the rational sampling frequency, including the long-term collection of the occurrence of salmonella or enterobacter sakazakii.

Implementation frequency of environmental monitoring plans shall be adjusted according to the testing results and severity of pollution risks. When pathogenic bacteria are detected in the final products or when the indicator bacteria increase, environmental sampling and investigation sampling shall be intensified so as to find the pollution source. When pollution risks increase (for example, after the maintenance, construction or wet cleaning), sampling frequency shall be properly increased.

B.2.6 Sampling tools and methods

Sampling tools and methods shall be selected according to the surface types and sampling locations. For

example, surface residues or powder in the dust collectors shall be directly chosen as samples. For larger surfaces,sponges or swabs shall be used for wiping sampling.

B.2.7 Analytical methods

Analytical methods shall be able to effectively detect target microorganisms with acceptable sensitivity and relevant records. On the basis of sensitivity, many samples can be detected together. If the outcomes are positive, the locations of positive samples shall be further determined. When necessary, information on the source of enterobacter sakazakii and pollution path of powder formulated foods for special medical purposes shall be analyzed with the genetic technology.

B.2.8 Data administration

Monitoring programs shall include data records and evaluating systems, such as the trend analysis. Constant evaluation must be made on data so as to properly alter and adjust monitoring programs. Effective management shall be carried out on the data of enterobacterium and enterobacter sakazakii. Neglected slight or discontinuous pollution may be found.

B.2.9 Corrective actions of positive results

Monitoring programs aim to find whether target microorganisms exist in the environments. Before the monitoring programs are formulated, acceptance standards and countermeasures shall be formulated. The concrete action strategies and relevant reasons shall be specified in the monitoring programs. Related measures include no actions (no pollution risks), to strengthen the cleaning and pollution source tracing (to intensify the environmental testing), to evaluate sanitary measures, to seize and detect products.

Action strategies shall be formulated by manufacturers after enterobacterium and enterobacter sakazakii are detected so as to accurately respond to the abnormal situations. Sanitation procedures and control measures shall be evaluated. Corrective actions shall be taken immediately after salmonella is detected. Enterobacter sakazakii trend and changes of enterobacter amount shall be evaluated. Actions to be taken shall depend on the possibility of products being contaminated by salmonella and enterobacter sakazakii.

Appendix C

Commercial sterile operation guide on liquid formulated foods for special medical purposes

C.1 General requirements

Besides the regulations which are applicable to liquid formulated foods for special medical purposes in the standard, the commercial sterile operation of liquid products shall also be in accordance with C.2 to C.6.

C.2 Product techniques

C.2.1 Operation of all techniques shall be performed under the good conditions which are in accordance with the technique requirements.

C.2.2 Processes which are in contact with the air (such as weighing and batching), bottling rooms and auxiliary areas with special requirements for cleanness shall meet the requirements for liquid formulated foods for special medical purposes.

C.2.3 All the delivery pipes and equipment for the products shall be airtight.

C.2.4 Liquid products shall be filtered during the production. Filter materials with no fiber exfoliating and meeting the sanitary requirements shall be used. Asbestos shall not be used as filters.

C.2.5 Control measures shall be formulated to prevent extraneous matters from entering the products during the production.

C.3 Washing, sterilization and clean-keeping of packaging containers

C.3.1 Food containers, packing materials, detergents and disinfectants which are in accordance with the national food safety standard and the permission of health administrative departments shall be used.

C.3.2 The washed packaging materials, containers and equipment shall not be contaminated for the second time.

C.3.3 Packaging materials used in sterile filling systems shall be sterilized in a proper way. They shall be washed and dried when necessary. After sterilization, they shall be stored in clean work areas for use. Sterilization shall be performed again when storage period exceeds the set time limit.

C.4 Washing, sterilization and clean-keeping of product processing equipment for aseptic filling technology

C.4.1 Before production, water, filtered steam, fresh distilled water or other proper treating agents under high temperature pressing shall be used to keep the products under high temperatures or clean and sterilize all the pipes, valves, pumps, feeding hoppers and other product contact surfaces in the lower reaches of the pipeline. It shall be ensured that all surfaces that are in direct contact with the products shall meet the requirements of sterile filling and remain until the production is over.

C.4.2 Sterile warehouses for filling and packaging equipment shall be cleaned and sterilized, and meet the requirements of aseptic filling before the production. They shall remain until the production is over. When sterilization fails, sterile warehouses shall be sterilized again. Key indicators such as the time, temperature and disinfectant concentration shall be controlled and recorded when sterilization is carried out.

C.5 Product filling

C.5.1 Automatic mechanical devices shall be used for product filling. No manual operation shall be allowed.

C.5.2 As to all products which need to be sterilized after filling, the time from bottling to sterilization shall be limited within the time required by the technological procedures.

C.5.3 As to the sterilized products, monitoring standards for pollution levels of product microorganisms before sterilization shall be determined according to the effects of the used sterilization methods and monitored on a regular basis

C.6 Heat treatment of products

C.6.1 Proper heat treatment processes shall be formulated according to the quality of product heating and the dynamics to kill specific target microorganisms. Products shall be heated to the sterilizing temperature and remain at the temperature for some time to achieve commercial sterilization. All the heat treatment processes are verified so as to ensure the reproducibility and reliability of the techniques.

C.6.2 Liquid products shall be sterilized with thermal sterilization as much as possible. Thermal sterilization is usually divided into damp-heat sterilization and dry-heat sterilization. The products to be sterilized in the chambers of sterilizing equipment and the way to carry materials shall be determined via verification. Time-temperature curve of every sterilization process shall be recorded. There shall be definite ways to distinguish sterilized products from products that are to be sterilized. Sterilization records shall be the basis to permit the group of products.

C.6.3 Constant flowing products which adopt the aseptic filling technique shall remain at the sterilizing temperature in the high temperature sterilization places or within the pipe flowing time so as to achieve commercial sterilization. So, product types, as well as the size and design of flow rate, pipeline length and high temperature sterilization places of every product shall be accurately determined. When steam injection or other steam filling way is used, product size increase due to the water caused by vapor condensation shall be considered.