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Report Name: China notifies Draft Good Manufacturing Practice for Formula Food for Infants and Young Children

Country: China - People's Republic of

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Report Highlights:

On March 4, 2021, China notified an addendum to the National Food Safety Standard: Good Manufacturing Practice for Powdered Infant Formula (GB23790-xxxx) to the WTO SPS Committee as G/SPS/N/CHN/1159/Add.1. This Draft Standard will replace the existing National Food Safety Standard: Good Manufacturing Practice for Powdered Infant Formula Food (GB23790-2010). Comments on the measure may be submitted to China's SPS Enquiry Point (sps@customs.gov.cn) by May 7, 2021. There is currently no published date for implementation of the final standard. This report contains an unofficial English translation of the draft standard.

Summary:

China's Ministry of Health implemented the National Food Safety Standard: Good Manufacturing Practice for Powdered Formula for Infants and Young Children (GB23790-2010) on December 1, 2010. It is a national, mandatory food safety standard that applies to both domestic and imported products. On March 4, 2021, China's National Health Commission (NHC) and the State Administration of Market Regulation (SAMR) notified an addendum to the previously issued updated draft to the WTO SPS Committee for comment as G/SPS/N/CHN/1159/Add.1.[1] Comments can be sent to China's SPS Enquiry Point at sps@customs.gov.cn. The deadline for comment submission is May 7, 2021. China has not announced a proposed date of entry into force for the standard. This report contains an unofficial English translation of the Draft Standard for Comment.

The preface of the draft standard lists a number of changes in the draft revision from the current standard. One of the most notable revisions is that liquid formula food is added to the scope of this updated draft standard so that the standard does not apply only to powdered formula food, but also to liquid formula food for infants and young children. In addition, the updated draft includes technical requirements related to liquid formula food. The draft standard includes changes related to food safety controls and testing for products and their manufacturing facilities and equipment.

Infant formula and dairy exporters should work with their Chinese importers and partners to closely monitor the standard revision process, provide their comments on issues of interest, and ensure compliance with the final standard.

[1] Editor's note: although the name of this standard China notified to WTO was National Food Safety Standard: Good Manufacturing Practice for Powdered Infant Formula (GB23790-xxxx), the actual name should be National Food Safety Standard: Good Manufacturing Practice for Formula Food for Infants and Young Children (GB23790-xxxx).

(Begin Translation)

National Food Safety Standard of the People's Republic of China

GB 23790 - 20XX

National Food Safety Standard

Good Manufacturing Practice for Formula Food for Infants and Young Children

(Draft for Comments)

Issued date: XX-XX, 201X Implementation date: XX-XX, 20XX

Published by the National Health Commission of the People's Republic of China and the State Administration for Market Regulation

Foreword

This standard will replace GB 23790-2010 Good manufacturing practice for powdered formula for infants and young children.

The main changes in this standard compared with GB 23790-2010 areas follows:

- The structure of the standard is modified;
- The basic requirements of each chapter are quoted from the relevant provisions of GB 14881

- “The terms and definitions in GB 14881 are applicable to this standard” are added, and the terms and definitions of “cleaning operation area”, “quasi-cleaning operation area” and “general operation area” are deleted in Chapter 2;

- The dynamic standard control requirements of cleaning operation area for production of powdered formulae for infants and young children are modified, and the dynamic standard control requirements of cleaning operation area for production of liquid formulae for infants and young children are added;
- " *E. Sakazakii*" is modified to "*Cronobacter*";
- The technical requirements of sterilization equipment are added;
- In chapter 8, the production practice and technical requirements for liquid formula for infants and young children are added;
- In chapter 9, "commercial sterility test shall be carried out according to GB 4789.26 for liquid formulae for infants and young children" is added;
- Training requirements for sterilization operators, filling and sealing operators and cleaning personnel are added.

National Food Safety Standard

Good manufacturing practice for formula food for infants and young children

1 Scope

This standard specifies the basic requirements and management guidelines of places, facilities and personnel in the process of raw material procurement, processing, packaging, storage and transportation and other aspects in the production of formula food for infants and young children.

This standard is applicable to production of formula food for infants and young children with the main raw materials of dairy or soybeans and its processing products.

2 Terms and definitions

The terms and definitions in GB 14881 are applicable to this standard.

2.1 Wet (production) process

It is a production process in which the ingredients of powdered infant formula food are processed in a liquid state. This process generally includes batching, heat treatment, concentration, drying, packaging (filling) procedures and other processes.

2.2 Dry (production) process

It is a production process in which the ingredients of powdered infant formula food are processed using the method of physical mixing in a solid state to produce the final product. This process generally includes batching, mixing (including pre-mixing), packaging (filling) procedures and other processes.

2.3 Dry Wet Composite (Production) process

It is a continuous and complete production process in which a portion of ingredients of the powdered infant formula food are processed in a liquid state, dried and followed by adding another portion of solid ingredients in a dry process to produce the final product.

2.4 Liquid (production) process

It is a production process in which the ingredients of powdered infant formula food are processed in a liquid state to produce the final product in liquid state. This process generally includes batching, homogenization, sterilization, filling and sealing (including sterilization after filling and sealing).

3 Site selection and factory environment

The site selection and factory environment shall meet the relevant specifications of GB 14881. This location should be away from livestock farms. Animals in the plant areas are also prohibited.

4 Plants and workshops

4.1. Basic requirements

It should comply with the relevant provisions of GB 14881.

4.2 Design and layout

4.2.1 Plants and workshops shall be rationally designed, built and planned, and should be compatible with production facilities and equipment, in order to prevent damage from microbial breeding and contamination, especially contamination caused by *Salmonella* and *Cronobacter* (*Cronobacterspp.*), and to and to avoid or minimize the breeding of these bacteria in hidden places at the same time. The following factors should be considered in the design to avoid microbial breeding:

a) The wet and dry areas should be segregated and separated; the design should effectively control contamination caused by personnel, equipment and material flow. The design should prevent *Salmonella* and *Cronobacter* from entering cleaning work area.

b) Cleaning operation areas should be protected from generating condensation water.

c) Improper accumulation of processing materials should be prevented from creating conditions unfavorable for cleaning.

d) Wet cleaning process should be properly designed and inappropriate wet cleaning process should be avoided in dry areas to prevent the breeding and spread of *Salmonella* and *Cronobacter*.

e) All types of pipes, cables and perforated gaps through floors, ceilings and walls of the building should be properly enclosed and sealed.

4.2.2 The production areas should be divided according to the product characteristics, production process and production characteristics, and quality requirements, combined with the actual situation of the factory building and workshop. In principle, the factory building and workshops are divided into common work areas, cleaning work areas, quasi-cleaning work areas.

4.2.3 Common work areas include dairy collection room, raw material warehouse, packaging material warehouse, outer packaging workshop and finished product warehouse, sterilization area for post-sterilization products after filling and sealing of liquid products, etc.

4.2.4 Quasi-cleaning work area includes raw material pre-treatment workshop, areas for cleaning the inner packaging of raw material or packaging material disinfection or tunnel sterilization, wet-mix process area of powdered products (such as weighing, batching, concentration, etc.), areas for weighing, batching, heat treatment, sterilization or disinfection of liquid products, filling area for post-sterilization products of liquid products, etc.

4.2.5 Cleaning work area includes workshops where food comes into contact with air environment and there is no subsequent sterilization or disinfection operation (such as weighing, batching, mixing, etc.), filling areas for liquid aseptic filling products, auxiliary areas with special cleaning requirements (such as temporary storage rooms for cleaned and sterilized inner packaging), storage areas for semi-finished products to be packaged, filling and inner packaging workshops, etc.

4.2.6 Effective physical separation shall be established between different levels of cleanliness. The cleaning work area shall be equipped with an separate air purification system with filtering device, to maintain a positive pressure differential and prevent cross-contamination caused by unpurified air entering the cleaning operation area.

4.2.7 There should be reasonable restriction measures and effective control measures for entering and leaving cleaning work area to avoid or minimize pathogenic bacteria contamination. In case that personnel, raw material, packaging material, waste, equipment enter the cleaning work area, measures shall be taken to avoid cross-contamination; such as setting up changing rooms for personnel to change work clothes, footwear or shoe covers, setting special material passage and waste passage, etc. For raw material or product that enters the cleaning work area transported by compressed air through pipeline, appropriate air filtration systems should be designed and installed

4.2.8 The level of purification in each operation area should meet the air purification requirements for powdered infant formula food processing for infants and young children. The dynamic standard control requirements of cleaning work area for powdered infant formula for infants and young children production should meet the requirements set out in Table 1, and the dynamic standard control requirements of cleaning work area for liquid formula for infants and young children

production should meet the requirements set out in Table 2, and regular inspection should be carried out. The aerobic bacterial count in the cleaning work area shall be controlled below 50 CFU/dish (the cleanliness shall be determined in accordance with the natural sedimentation method in GB/T 18204.3).

Table 1 The dynamic standard control requirements of cleaning work area for powdered formula for infants and young children

Item	Content	Test method	Control requirement	[a] Recommended monitoring frequency
Maximum allowable number of microorganisms	Planktonic bacteria	GB/T 16293	≤200 CFU/m^3	Once / week
	Sedimentated bacteria	GB/T 16294	≤100CFU/4h (φ90mm)	Once / week
	Surface microorganism	1. Use 55mm dish for direct sampling. [b]2. Refer to the sampling method in GB 15982, wipe 5cmx5cm with cotton swab, and count according to GB4789.2.	≤ 50 CFU / dish (φ55mm)	Once / week
Pressure difference	Between the cleaning work area and non-cleaning work area	Measured by differential pressure gauge	≥10Pa	Twice/shift
[C] Number of air exchanges	Verify the number of air exchanges by measuring wind speed	Measured by anemometer	≥12 /h	When replacing the high-efficiency filter, or once a month
[d] Temperature	-	Measured by thermometer	16-25°C	Twice/shift
Relative humidity	-	Measured by a hygrometer	≤65%	Twice/shift

a The monitoring frequency of the automatic monitoring system meets the control requirements.

b Method 2 is the reference method.

c The number of air exchanges is measured after being converted by the wind speed. The formula is: N=3600SV/A, which is calculated by the wind speed during monitoring. Where, N= Number of air exchanges, times/h; S= ventilation area of the air port, m^2; A= Workshop volume, m^3; V= Measured average wind speed at the air port, m/s. The number of air exchanges is suitable for cleaning work areas with a floor height less than 4.0m. The number of air exchanges can be adjusted appropriately in the

cleaning work area with a floor height of more than 4.0m, but the cleanliness of the cleaning work area shall be ensured.

d. Except for the open spray drying tower deployed in the cleaning work area, the enterprise shall specify the temperature of this area and submit an explanation.

Table 2 The dynamic standard control requirements of cleaning work area for liquid formula for infants and young children

Item	Content	Test method	Control requirement	[a] Recommended monitoring frequency
Maximum allowable number of microorganisms	Planktonic bacteria	GB/T 16293	≤100 CFU/m^3	Once / week
	Sedimentated bacteria	GB/T 16294	≤24CFU/4h (φ90mm)	Once / week
	Surface microorganism	1. Use 55mm dish for direct sampling. [b]2. Refer to the sampling method in GB 15982, wipe 5cmx5cm with cotton swab, and count according to GB4789.2.	≤ 10 CFU / dish (φ55mm)	Once / week
Pressure difference	Between the cleaning work area and non-cleaning work area	Measured by differential pressure gauge	≥10Pa	Twice/shift
[C] Number of air exchanges	Verify the number of air exchanges by measuring wind speed	Measured by anemometer	≥12 /h	When replacing the high-efficiency filter, or once a month
Temperature	-	Measured by thermometer	16-25 °C	Twice/shift

Relative humidity	-	Measured by a hygrometer	≤65%	Twice/shift

a The monitoring frequency of the automatic monitoring system meets the control requirements.

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4.2.9 Cleaning work area should be kept dry and water supply facilities and systems should be minimized; if unavoidable, protective measures should be taken and passing through the upper space of the main production operation surface is not allowed in order to prevent secondary contamination.

4.2.10Plants, workshops and warehouses should have facilities that can prevent pest infestation.

5 Facilities and equipment

5.1. Basic requirements

It should comply with the relevant provisions of GB 14881.

5.2 Drainage system

5.2.1 Unnecessary drainage facilities should be avoided, if necessary, appropriate measures should be taken to keep the drainage facilities dry during production.

5.2.2 Drainage facilities shall be sloped, kept unobstructed and easy to clean, and the joint between the side and bottom of drainage ditch shall have a certain radian. The drainage facilities in the quasi-cleaning and cleaning work areas should avoid the return air from the sewer, and if necessary, it shall use sanitary floor drain.

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

5.3 Heath facilities

A designated dressing room for cleaning work area should be set at the entrance of cleaning work area. Hand disinfection facilities should be set before entering the cleaning work area, and hand washing facilities can be set if necessary. The designated changing room and hand-washing disinfection room in the clean work area for producing powdered formulae for infants and young children can be set according to the needs of microbial control, and the production enterprises can choose to set up hand-washing facilities when necessary.

5.4 Ventilation facilities

5.4.1 The cleaning work area for producing powdered formula for infants and young children shall be equipped with temperature and humidity adjustment facilities and monitoring devices.

5.4.2 The outdoor air inlet should be more than 2 meters away from the ground or roof below, away from pollution sources and air outlets, and be equipped with air filtration equipment. The exhaust port should be equipped with an easy-to-clean and corrosion-resistant net cover to prevent animals from invading.

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

5.4.4 Appropriate removal, collection or control devices shall be provided in areas where there are odors and gas (steam as well as toxic and harmful gases) or dust that may pollute food.

5.4.5 Cleaning work area shall be equipped with purified air conditioning system to prevent steam condensation and keep indoor air fresh. Ventilation facilities shall be installed or well ventilated in the common work area, to remove damp and unpurified air. When air conditioning, air intake and exhaust or fans are used in the workshop, the air should flow from the areas with high cleanliness requirements to the areas with low cleanliness requirements, to prevent food, production equipment and inner packaging materials from being contaminated.

5.5 Equipment

5.5.1 Production equipment should be visibly marked with operating status, which shall be displayed by automatic control system or manually marked, and shall be repaired and maintained on a regular basis. Installation, maintenance and care of equipment shall not affect product quality. The repaired equipment should be validated to ensure the performance meets the process requirements. Substandard and unused equipment should be hygienically cleaned and protected, and clearly marked.

5.5.2 Compressed air or other inert gas used for food, cleaning food contact surface should at least be treated with oil removal, water removal, sterilization and filtration before being used.

5.5.3 The inner wall of equipment in contact with materials shall be smooth, flat, no dead space, easy to clean and corrosion resistant, and its inner surface layer shall be made of materials that do not react with materials, do not release particles and do not adsorb materials.

5.5.4 For the production of powdered and liquid formula for infants and young children, after the sterilization equipment is installed, the sterilization effect of the materials should be verified, and the equipment shall not be put into use until it has been confirmed as compliant.

5.5.5 Liquid formulae for infants and young children shall also meet the following requirements:

a) For continuously flowing products using aseptic filling process, the sterilization temperature shall be maintained during the time when the sterilization area or pipeline flows at high temperature to achieve commercial sterility. The material type, material flow rate, pipeline length, and the size of high-temperature reserved sterilization area should be confirmed. If steam injection or steam filling is used, the increase of product volume due to the water brought in by steam condensation should also be considered, and the steam water should comply with relevant provisions of GB 5749. Before steam is injected or filled into the product, it should pass through the steam filtering device.

b) All kinds of sterilization equipment in the production process of sterilized products after filling shall meet the requirements of sterilization process and relevant national standards such as pressure vessels. After the sterilization equipment is installed, it should be tested for heat distribution, and it shall not be put into use until it is confirmed that the heat distribution is uniform. On the premise of ensuring smooth heat supply and heat transfer medium, the heat distribution test shall be conducted at least once every three years. If the structure, pipes, valves and procedures of the equipment change and if it is necessary, the heat distribution test shall be conducted again. For the final sterilized product, the monitoring standard of microbial contamination level of the product before sterilization should be determined according to the effect of sterilization method used, and it should be monitored on a regular basis.

6 Sanitation management

6.1. Basic requirements

It should comply with the relevant provisions of GB 14881.

6.2 Cleaning and disinfection

6.2.1 In cleaning operation areas where dry cleaning is required (e.g., dry mixing, filling and packaging, etc.), an effective dry cleaning process should be implemented for production equipment and processing environment, wet cleaning should be avoided as much as possible. Wet cleaning should be limited to cases where equipment parts that can be moved to designated room or where e drying measures can be taken immediately after wet cleaning.

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

a) Adopt dry cleaning process suitable for the place and equipment (water is prohibited). If disinfectant containing water is used, it should be able to ensure the quick drying of the cleaning work surface, or implement dry cleaning in a dry status without disinfectant.

b) When wet cleaning measure is adopted under controlled conditions, it shall ensure that the dryness of equipment and environment can be completely restored in time, so that the area will not be polluted.

c) It shall avoid mixing cleaning tools in different operation areas.

6.2.3 Effective monitoring process or scheme should be established to ensure that the key procedures (such as manual cleaning, cleaning in place (CIP) and equipment maintenance) conform to the relevant provisions and standard requirements, in particular to ensure the applicability of cleaning and disinfection programs, the appropriate concentration of cleaning agents and disinfectants, and the CIP system meets the relevant temperature and time requirements.

6.2.4 Cleaning and disinfection plans shall be made for all areas in the cleaning work area to ensure that all areas in the clean area are cleaned. For the purpose of preventing cross-contamination in quasi-cleaning work areas and common work areas, the cleaning or disinfection plan shall be prepared according to the requirements.

6.2.5 Records shall be kept for cleaning and disinfection.

6.3 Work clothes management

Employees in cleaning work area should wear work clothes (or disposable work clothes) that meet the sanitary requirement of this area, and wear cap, gauze mask (only applicable to exposed areas of products) and work shoes. Employees working in quasi-cleaning work area and common work area should wear work clothes that meet the sanitary requirement of the respective area, and wear cap and work shoes. Work clothes and shoes for use in the cleaning work area and quasi-cleaning work area should not be worn at the place other than designated area.

7 Raw materials of food, food additives and food-related products

7.1 Basic requirements

7.1.1 It should comply with the relevant provisions of GB 14881.

7.1.2 Raw materials used shall meet the requirements of the corresponding national standards and related regulations. Infant and young children's safety should be guaranteed, and their requirement for nutrition should be satisfied. Supplier management, transportation, storage, procurement and acceptance of raw milk shall comply with relevant requirements of GB 12693.

7.2 Other requirements

7.2.1 Enterprise shall take measures for raw material and food additives that directly enter dry-mix process to ensure that the microbiological indicators of raw materials meet the requirements of product standards, and for soybean raw materials, they should ensure that urease activity is negative. Processes and safety measures adopted by suppliers should be evaluated. When necessary, field inspection or the monitor of the process should be carried out periodically.

7.2.2 Food additives and nutritional supplements should be used in strict accordance with food safety standards, stored in a designated warehouses or at a designated areas, clearly marked as food additives, and designated registers (or warehouse management software) should be used to record the names, manufacturers, production dates, purchase time, purchase quantity and usage amount of additives and nutritional supplements, and also attention should be paid to the expiry date.

7.2.3 Food nutrition enhancers, such as vitamins, trace elements, etc., that are susceptible to changes in quality during storage should be subject to shelf-life management and storage environmental requirements and, if necessary, inspection should be conducted to ensure that they meet the requirements specified for the raw materials.

8 Food safety control in production process

8.1. Basic requirements

It should comply with the relevant regulations stipulated in GB 14881. Hazard Analysis and Critical Control Point System (HACCP) should be adopted to control food safety in production process. Effective control measures should be established for key processing parameters, such as critical control points and formula. Environmental monitoring measures should be established for *Salmonella*, *Cronobacter* and other *Enterobacteriaece* in the cleaning work area of powdered

formulae for infants and young children, and the monitoring guidelines should meet the requirements of Appendix A.

8.2 Special requirements for the production process of powdered formula food for infants and young children

8.2.1 Heat treatment (wet process and dry-wet composite production process)

Heat treatment should be the key control point to ensure the safety of powdered formula foods for infants and young children. Temperature and time for heat treatment should take account of the influence of product attributes or other factors on heat resistance of microbiological indicator, such as fat content, total solids content, etc. Therefore, the monitoring measures of heat treatment temperature and time and related key factors affecting heat treatment effect should be established to ensure that the requirements of process parameter limits are not deviated; In case of deviation, appropriate corrective measures shall be taken for real-time monitoring, and corresponding monitoring records shall be kept.

If the purchased soybean raw materials have not been conducted heating enzyme deactivation treatment (or the enzyme deactivation treatment is incomplete), such bean-based products should achieve the effect of killing pathogenic bacteria and complete enzyme deactivation by heat treatment (urease is negative), and serve as the critical control point for monitoring.

The key process parameters such as time, temperature and enzyme deactivation time during heat treatment should be recorded.

8.2.2 Intermediate storage

In the wet process and dry-wet composite process, related measures should be taken for intermediate storage of liquid semi-finished product to prevent from growth of microorganism. Bare raw material powder in dry process production or powdered semi-finished products in wet process production should be kept in the cleaning operation area. The storage period and conditions shall be specified for powdery semi-finished products, and the quality of semi-finished products shall be confirmed to meet the production requirements.

8.2.3 Process steps from heat treatment to drying

All running pipes and equipment should be kept tightly closed from heat treatment to drying, and should be thoroughly cleaned and disinfected on a regular basis.

8.2.4 Cooling

In the wet process and dry-wet composite process production, the monitoring measures of powder temperature should be established for semi-finished products passing through fluidized bed. If the dried bare semi-finished powder needs cooling, it should be air-tightly stored and cooled in cleaning work area.

8.2.5 Dry mixing

8.2.5.1 The bare powder process in contact with the air environment (such as feeding, batching, mixing and filling of dry mixing) shall be carried out in the cleaning work area. The temperature and relative humidity in cleaning work area shall be compatible with production process of powdered formula food for infants and young children. When there is no special requirement, temperature should be controlled at 16 - 25°C, and relative humidity should be controlled below 65%.

8.2.5.2 Enterprises should conduct feeding according to the requirements of product formula ratio, and materials should be accurately batched.

8.2.5.3 Key process parameters related to mixing homogeneity (such as mixing time, etc.) should be validated and confirmed, and the mixing homogeneity should be confirmed.

8.2.5.4 For raw materials or products that enter the cleaning work area transported by air-driven pipelines, it is necessary to design and install an appropriate air filtration system.

8.2.5.5 Strict sanitation control requirements should be established for raw and packaging materials and personnel. Raw materials should enter the work area with higher cleanliness through necessary cleaning procedures and material channels, and should follow the treatment procedures of removing the outer packaging or sterilizing the outer packaging.

8.2.6 Inner packaging procedure

8.2.6.1 Inner packaging procedure should be carried out in cleaning work area.

8.2.6.2 Only related working personnel should be allowed to enter package room. Refer to specification of Clause 8.2.5.5 for requirements for raw and packaging materials and personnel.

8.2.6.3 Production enterprises should adopt effective foreign matter control measures to prevent and inspect foreign matters, such as screens, strong magnets, metal detectors, etc.

8.2.6.4 When products of different varieties are produced on the same production line, site clearing should be conducted and site clearing records should be kept to ensure that the product changing does not affect the next batch of products.

8.3 Special requirements for the production process of liquid formula food for infants and young children

8.3.1 Product process

8.3.1.1 All process operations should be carried out in good condition to meet the process requirements, and the process method of thermal sterilization, aseptic filling or final thermal sterilization after sealing should be selected to achieve the purpose of commercial sterility.

8.3.1.2 Workshop (such as weighing, batching, mixing, etc.), filling room and auxiliary area with special cleaning requirements where the food is in contact with air environment and there is no subsequent sterilization or disinfection shall meet the requirements of liquid product cleaning work area.

8.3.1.3 After batching, all pipelines and equipment for conveying products shall be kept closed.

8.3.1.4 Control measures to prevent foreign matters from entering the products in the production process should be established.

8.3.2 Washing, sterilization and cleaning of packaging containers

8.3.2.1 It should use food containers, packaging materials, detergents and disinfectants that meet the national food safety standards and are permitted by the health administrative authorities.

8.3.2.2 The disposal of packaging materials, containers and equipment after final cleaning should avoid re-contamination.

8.3.2.3 Packaging materials used in aseptic filling system should be sterilized by appropriate methods, and cleaned and dried when necessary. After sterilization, it should be placed in a cleaning work area and cooled for later use. If the storage time exceeds the specified time limit, it should be sterilized again.

8.3.3 Washing, sterilization and cleaning of product processing equipment in aseptic filling process

8.3.3.1 Before the production, high-temperature pressurized water, filtered steam, fresh distilled water or other suitable treatment agents should be used to clean and disinfect all pipelines, valves,

pumps, buffer tanks, feeding hoppers and other contact surfaces of products at the high-temperature sterilization area or downstream of pipelines. It shall ensure that all surfaces in direct contact with products meet the requirements of aseptic filling, and keep this state until the end of production.

8.3.3.2 The aseptic warehouse for filling and packaging equipment should be cleaned and sterilized, and meet the requirements of aseptic filling before the product begins to be filled, and keep it in this state until the end of production. When sterilization fails, the sterile warehouse should be sterilized again. During sterilization, key indicators such as time, temperature and disinfectant concentration need to be monitored and recorded.

8.3.4 Filling of products

8.3.4.1 The of products should be filled by automatic mechanical devices, no manual operations.

8.3.4.2 For products that need to be sterilized after filling, the time from filling and sealing to sterilization should be controlled within the time limit required by the process regulations.

8.3.4.3 For the final sterilized product, the monitoring standard of microbial contamination level of the product before sterilization should be determined according to the effect of sterilization method used, and it should be monitored on a regular basis.

8.3.5 Sterilization of products

8.3.5.1 A suitable sterilization process should be established according to the heating characteristics of products and the lethal kinetics of specific target microorganisms. The product shall be heated to sterilization temperature, and shall be kept at this temperature for a certain time to ensure commercial sterility. All sterilization technologies and processes should be verified to ensure the reproducibility and reliability of the process.

8.3.5.2 The sterilized liquid products after filling shall be verified to confirm the loading method of products and articles to be sterilized in the chamber of sterilization equipment. Time-temperature curve of sterilization process should be recorded for each sterilization. There should be a clear method to distinguish sterilized products from products to be sterilized. Sterilization records should be taken as one of the basis for releasing this batch of products.

8.3.5.3 It should carry out commercial sterility test on products to determine whether they meet the commercial sterility requirements. Once any deviation is found during sterilization, it should be corrected according to the correction plan, and the products should be isolated, the reasons should be found out, and corrective measures should be proposed. If it is determined that this batch of products does not meet the commercial aseptic requirements, it should be properly treated under

strict supervision. The determination process, results and treatment methods shall be recorded in detail.

8.3.6 Verification of sterilization effect

8.3.6.1 It should comprehensively determine the sterilization process parameters (such as sterilization temperature, sterilization time, sterilization pressure, etc.) according to the product characteristics of liquid formula food for infants and young children and verify the sterilization process effect.

8.3.6.2 It should measure (or calculate) the F value of sterilization intensity to ensure that the sterilization parameters and sterilization intensity are reasonable. Before leaving the factory, the commercial sterility effect of the product should be verified by heat preservation experiment, and the parameters of heat preservation experiment can be set according to the product characteristics and sterilization process to ensure that the product meets the requirements of commercial sterility.

9 Test

9.1 General requirements

It should conduct the all-items inspection in accordance with relevant regulations.

9.2 Commercial sterility test

The liquid formula food for infants and young children should be tested for commercial sterility according to GB 4789.26.

10 Food storage and transportation

It should comply with the relevant provisions of GB 14881.

11 Product recall management

It should comply with the relevant provisions of GB 14881.

12 Training

It should comply with the relevant provisions of GB 14881. A training plan should be developed for sterilization operators and cleaning staff to ensure effective implementation.

13 Management system and personnel

It should comply with the relevant provisions of GB 14881.

14 Records and document management

It should comply with the relevant provisions of GB 14881.

Appendix A

Environmental Monitoring Guidelines for *Salmonella, Cronobacter* and Other *Enterobacteriaece* in the Cleaning Work Area of Powdered Formula food for Infants and Young Children

A.1 Monitoring plan objectives and key factors to be considered

A.1.1 Monitoring plan objectives

Since there may be a small amount of *Enterobacteriaece* (referred to as EB) in the production environment with good sanitary conditions, including Cronobacter (*Cronobacter Spp.*), the pasteurized products may be environmentally contaminated, causing traces of *Enterobacteriaece* in the final product. Therefore, *Enterobacteriaece* in the production environment should be monitored in order to confirm whether the sanitation control procedures are effective, and production enterprises should take corrective measures in time when deviations occur. Through continuous monitoring, basic data can be obtained on the health situation to track changes in trends. According to relevant factory practice, reducing the number of *Enterobacteriaece* in the environment can reduce the number of *Enterobacteriaece* (including Cronobacter and *Salmonella*) in the final product.

In order to prevent the occurrence of pollution and avoid the limitations of sampling and testing the microorganisms in the final product, an environmental monitoring plan should be formulated. The monitoring plan can be used as a food safety management tool to evaluate the sanitation status of the cleaning operation area (drying area) and as the basic procedure of HACCP.

A.1.2 Key factors to be considered

A.1.2.1 *Salmonella* is rarely found in dry environment, whereas monitor plan should be developed to prevent the entry of *Salmonella*, evaluate the effectiveness of sanitation control measures in production environment and guide for related personnel to prevent from further spread when Salmonella is detected.

A.1.2.2 Compared with *Salmonella*, it is easier to discover *Cronobacter* in dry environment. If suitable sampling and testing method is adopted, *Cronobacter* can be more easily detected. Monitor plan should be developed toassess whether the number of *Cronobacter* has increased, and effective measures should be taken to prevent from its growth and pollution.

A.1.2.3 *Enterobacteriaece* is widely spread as it is a common colony in dry environment. It can be easily detected. *Enterobacteriaece* may serve as the indicator bacteria for sanitation status and production process.

A.2 Factors that should be considered while designing the sampling scheme

A.2.1 Product category and process

The demand and scope of sampling scheme should be determined according product characteristics, customers' age and health status. In this standard, *Salmonella* is considered as pathogenic bacteria in all products, and *Cronobacter* is considered as pathogenic bacteria in some products.The focus of monitoring should be placed on areas where it is easy for microorganisms to hide and grow, such as cleaning work area in dry environment. Particular attention should be paid to the boundary of such areas and their adjacent areas with lower clean level, areas close to production line and equipment that are prone to be contaminated, such as opening on the enclosed equipment for occasional inspection. Priority should be given to monitoring areas that are known or likely to be contaminated.

A.2.2 **Types of Samples**

The monitor plan should include the following two types of samples:

A.2.2.1Take samples from the surfaces that is not in contact with food, such as outside of equipment and ground of around production line, pipe and platform. In these cases, contamination risk degree and pollutants content depends on the location and design of production line and equipment.

A.2.2.2 Take samples drawn from surface directly contacting food, such as equipment that may directly contaminate the product from the powder spray tower to the packing, such as the agglomerated formula powder at the end of the screen, which absorbs moisture and causes microorganisms prone to breed. If indicator bacteria *Cronobacter* or *Salmonella* exists on food-contacting surface, it indicates a high risk of product contamination.

A.2.3 Target microorganisms

Salmonella and *Cronobacter* are the main target microorganisms, and *Enterobacteria* can serve as a health indicator.

A.2.4 Sampling locations and sample size

Sample size should vary with complexity of process and production line.

Sampling locations should be the places that may be contaminated by hidden or invaded microorganisms, such as raw materials, parts of movable equipment contacting the ground, air conditioner return vents, employees' work clothes and shoe soles, ground, the vacuum cleaner, powder blocks on vibrating screens, etc. Sampling locations may be determined according to relevant literatures, or experience and professional knowledge or historical data collected in factory contamination investigation. Sampling locations should be evaluated on a regular basis, and necessary sampling points should be added in the monitoring plan in special cases, such as major maintenance, construction activities, or worsening sanitary conditions.

The sampling plan should be comprehensive and representative, and different types of production shifts and different time periods within these shifts should be considered for scientific and reasonable

sampling. To verify the effectiveness of cleaning measures, samples should be taken before starting the production.

A.2.5 Sampling frequency

Sampling frequency shall be determined according to the factors stipulated in A.2.1 and based on existing microorganism data in each existing area in the monitor plan. In the case of no such data, sufficient information should be collected to determine a reasonable sampling frequency, including long-term collection of the occurrence of *Salmonella* or *Cronobacter*.

Implementation frequency of environment monitor plan should be adjusted according to test results and severity of pollution risks. When the number of pathogenic bacteria or indicator bacteria detected in the final product increases, environmental sampling and investigation sampling should be strengthened to determine the contamination source. When contamination risk increases (such as after maintenance, construction or wet cleaning), sampling frequency should be increased appropriately.

A.2.6 Sampling tool and method

Sampling tool and method should be selected according to surface type and sampling location, for example, directly scrape surface residues or dust in cleaner as sample. For larger surfaces, a suitable sampling tool such as sponge (or cotton swab) should be used to conduct wipe sampling.

A.2.7 Analysis method

The analysis method should be capable of effectively detecting target microorganisms, with an acceptable sensitivity and related records. Under the premise of ensuring sensitivity, multiple samples may be mixed together for detection. If a positive result is detected, the location of the positive sample should be further determined. If necessary, genetic technology may be applied to analyze information related to source of *Cronobacter* and contamination path of powdered formula food for infants and young children.

A.2.8 Data management

The monitor plan should include data records and evaluation system, such as trend analysis. Data must be subject to continuous evaluation in order to modify and adjust the monitor plan accordingly. Implementation of effective management for *Enterobacteriaece* and *Cronobacter* may help discover mild or intermittent contamination that may be ignored.

A.2.9 Corrective measure for positive results

The purpose of monitor plan is to discover the existing target microorganisms in environment. Before the monitor plan is developed, acceptance criteria and countermeasures should be established. The monitor plan should specify the specific actions and clarify the corresponding reasons. Related measures include: taking no action (there is no contamination risk), strengthening cleaning, tracking

contamination source (increasing environmental tests), evaluating sanitary measures, detaining and testing products.

The manufacturing enterprises should formulate actions after *Enterobacteriaece* and *Cronobacter* are detected to make accurate response when there is an over-standard Corrective actions should be taken immediately when Salmonella is detected. In addition, *Cronobacter* trend and change in *Enterobacteriaece* number should be evaluated; Which kind of action should be taken depends on possibility of product contaminated by *Salmonella* and *Cronobacter*.

(End Translation)

Attachments:

No Attachments.