USDA United States Department of Agriculture
Foreign Agricultural Service

GAIN Global Agricultural Information Network

Voluntary Report – Voluntary - Public Distribution **Date:** December 01, 2021

Report Number: CH2021-0148

Report Name: Powdered Infant Formula Good Manufacturing Practices Draft Standard Notified

Country: China - People's Republic of

Post: Beijing

Report Category: Agricultural Situation, Dairy and Products, FAIRS Subject Report, Sanitary/Phytosanitary/Food Safety, WTO Notifications

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Report Highlights:

On November 17, 2021, China notified 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.2. 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 January 16, 2022. 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. China has notified updated drafts to the WTO SPS Committee for comment as G/SPS/N/CHN/1159 on May 12, 2020 and G/SPS/N/CHN/1159/Add.1 on March 8, 2021 respectively.

On November 17, 2021, China notified an updated draft to the WTO SPS Committee for comment as G/SPS/N/CHN/1159/Add.2. One of the most notable revisions from G/SPS/N/CHN/1159/Add.1 is the addition of requirements related to liquid infant formula food. Additional changes from the current standard may be found in the preface of the draft standard. This report contains an unofficial English translation of the Draft Standard for Comment.

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.

(Begin Translation)

National Standard of the People's Republic of China

GB 23790-XXXX

National Food Safety Standard

Good Manufacturing Practice for Infant Formula Food

(Draft for Comments)

Issued date: XX-XX-XXXX

Implementation date: XX-XX-XXXX

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

Preface

This standard replaces GB 23790-2010 *National Food Safety Standard - Good Manufacturing Practice for Powdered Infant Formula Food.*

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

-The standard structure 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 infant formula food are modified, the dynamic standard control requirements of cleaning operation area for production of liquid infant formula food are added;

- " *E. Sakazakii*" is modified to "*Cronobacteria*".

- The technical requirements of sterilization equipment are added.

- In chapter 8, the production specification and technical requirements for liquid infant formula food are added.

- In chapter 9, "commercial sterility test shall be carried out according to GB 4789.26 for liquid infant formula food" is added.

- The training requirements for sterilization operators, filling and sealing operators and cleaning staff are added.

National Food Safety Standard

Good Manufacturing Practice for Infant Formula Food

1 Scope

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

This standard is applicable to the production of infant formula food with dairy or soybean ingredients and processed products as the main raw materials.

2 Terms and definitions

The terms and definitions specified in GB 14881 is 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 into the final product, which usually includes batching, heat treatment, drying, packaging (filling) and other processes.

2.2 Dry (Production) Process

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

2.3 Dry-Wet Composite (Production) Process

It is a 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 final product after packaging (filling).

2.4 Liquid (production) process

The production process of processing the ingredients of infant formula food in a liquid state to produce the final liquid product in liquid state. This process generally includes batching,

homogenization, sterilization, filling, sealing and other processes (including sterilization after filling and sealing).

3 Site Selection and Factory Environment

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

3.2 The factory should be located away from livestock farms. Animals are not allowed to be kept in the factory.

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 should be rationally designed, constructed and planned and should be compatible with production facilities and equipment in order to prevent damage from microbial breeding and contamination, in particular contamination from *Salmonella* and *Cronobacter* (*Cronobacterspp*.). The following factors should be considered in the design:

a) The wet and dry areas should be separated; contamination caused by the movement of personnel, equipment and materials should be effectively controlled to prevent pathogenic bacteria or conditional pathogenic bacteria that could cause harm to infants (such as *Salmonella* and *Cronobacter*) from entering the clean operation areas.

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

c) Wet cleaning processes should be properly designed and inappropriate wet cleaning processes should be avoided in dry areas.

d) 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 plants and workshops should be divided into general operation area, quasi-cleaning operation area and cleaning operation area according to the product characteristics, production process, production characteristics and the requirements for cleaning in the production process, combined with the actual situation of the plants and workshops.

4.2.3 The general operation area includes the dairy collecting room, raw material warehouse, packing material warehouse, outer packing workshop as well as the final product warehouse

and the sterilization area for post-sterilization products after filling and sealing of liquid products, etc.

4.2.4 The quasi-cleaning operation area includes the raw material pre-treatment workshop, areas for cleaning the inner packaging of raw material or packaging material disinfection or tunnel sterilization, wet processing 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 The cleaning operation area includes the workshop where the food comes into contact with the air environment without subsequent sterilization or sterilization operations (e.g., weighing, batching, mixing, etc.), filling areas for liquid aseptic filling products, auxiliary areas with special cleaning requirements (e.g., temporary storage room for cleaned and sterilized inner packaging, etc.), storage area for bare semi-finished products to be packed, filling and inner packing workshop, etc.

4.2.6 Effective physical separation should be set between operation areas with different levels of cleanliness. A separate air purification system with a filter should be installed in the cleaning operation area to maintain positive pressure on other areas and prevent cross-contamination caused by unpurified air entering the cleaning operation area.

4.2.7 There should be reasonable and effective control measures for entering and leaving cleaning operation areas to avoid or reduce microbial and other contamination. There should be facilities and measures for personnel, raw materials, packaging materials, waste, equipment, etc., entering and leaving the cleaning operation areas to prevent cross-contamination, such as setting up personnel changing rooms to change working clothes, working shoes or shoe covers, special logistics channels and waste sealing protection, etc. For raw materials or products transported by compressed air through pipelines entering into the cleaning operation areas, appropriate air filtration systems need to be designed and installed.

4.2.8 The level of purification in each operation area should meet the air purification requirements for infant formula food processing. The dynamic standard control requirements for cleaning operation areas in powdered infant formula food production should be in accordance with Table 1, and the dynamic standard control requirements for cleaning operation areas in liquid infant formulae food production should meet the requirements set out in Table 2, and regular inspection should be carried out. The aerobic bacterial count in the quasi-cleaning operation area shall be controlled below 50 CFU/dish (test according to GB/T16294 for 5 min, static).

Table 1 Dynamic Control Requirements for Cleaning Operation Areas in Powdered Infant Formula Food Production

Item	Content	Detection method	Control requirement	Minimum frequency of monitoring
Maximum number of microorganisms allowed	Planktonic bacteria	GB/T 16293	≤200 CFU/m^3	Once / week
	Sedimentated bacteria	GB/T 16294	≤100CFU/4h (φ90mm)	Once / week
	Surface microorganism	[a] 1. Direct sampling is measured using a φ55mm vessel	≤ 50 CFU / dish (φ55mm)	Once / week
		[b]2. Count according to GB 4789.2 with reference to the GB 15982 sampling method.	≤50CFU/25cm^2	
Pressure difference	Between the cleaning operation area and non-cleaning operation area	Measured by differential pressure gauge	≥10Pa	Twice/shift
[C] Number of air changes	Verify the number of air changes 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 Method 1 is not suitable for sampling irregular surfaces.

b Method 2 is the reference method.

c The number of air changes 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 operation areas with a floor height less than 4.0m. The number of air exchanges can be adjusted appropriately in the cleaning operation area with a floor height of more than 4.0m, but the cleanliness of the cleaning operation area shall be ensured.

d In the case that the temperature in the area for spray drying tower deployed in the cleaning operation area is out of this scope, the enterprise shall specify the temperature of this area and make an explanation.

Table 2 The Dynamic Control Requirements for Cleaning Operation Areas in Liquid Infant Formula Food Production

Item	Content	Detection method	Control requirement	Minimum frequency of monitoring
Maximum number of microorganisms allowed	Planktonic bacteria	GB/T 16293	≤100 CFU/m^3	Once / week
	Sedimentated bacteria	GB/T 16294	≤50CFU/4h (φ90mm)	Once / week
	Surface microorganisms	[a] 1. Direct sampling is measured using a φ55mm vessel.	≤ 25 CFU / dish (φ55mm)	Once / week
		[b]2. Count according to GB 4789.2 with reference to the GB 15982 sampling method.	≤25 CFU/25m^2	
Pressure difference	Between the cleaning operation area and non-cleaning operation area	Measured by differential pressure gauge	≥10Pa	Twice/shift
[C] Number of air changes	Verify the number of air changes 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

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4.2.9 Cleaning operation areas for powdered infant formula food should be kept dry and water supply facilities and systems should be minimized; the water supply facilities and

systems should avoid passing through the upper space of the main production operation surface. If unavoidable, protective measures should be taken to prevent contamination.

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

5 Facilities and Equipment

5.1. Basic requirements

It should comply with the relevant provisions of GB 14881.

5.2 Drainage systems

5.2.1 In the cleaning operation area for powdered infant formula production, unnecessary drainage facilities should be avoided. If necessary, appropriate measures should be taken to keep them dry during production.

5.2.2 Drainage facilities should be sloped, kept unobstructed and easy to clean, and the joint between the side and bottom of drainage ditch should have no dead spots for cleaning, or corresponding measures should be taken to prevent water accumulation. The drainage facilities in the quasi-cleaning and cleaning operation areas should avoid the return air from the sewer, and if necessary, these facilities should use sanitary floor drains.

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

5.3 Personnel Facilities

5.3.1 A changing room (including changing shoes or wearing shoe covers), hand washing, hand drying facilities and disinfection facilities should be set near the entrance of production place or production workshop. Necessary cleaning measures should be taken before personnel and goods enter the clean operation area.

5.3.2 Personnel should take necessary cleaning measures before entering the cleaning operation area. The entrance to the cleaning operation area should be equipped with a private changing room for the cleaning operation area and hand sanitizing facilities should be set up before entering the cleaning operation areas.

5.4 Ventilation facilities

5.4.1 The cleaning operation area for producing powdered infant formula food should be equipped with temperature and humidity regulation facilities and monitoring devices.

5.4.2 Effective measures should be taken at the outdoor air inlet to prevent animals or other foreign bodies from entering. For example, it should be more than 2m away from the ground or roof below, fence should be set, etc., 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 entering.

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

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

5.4.5 Cleaning operation areas shall be equipped with purified air conditioning systems to prevent steam condensation and keep indoor air fresh. Ventilation facilities should be installed or the general operation areas should be well ventilated, to remove damp and dirty air. When air conditioning, air intake and exhaust or fans are used in the plant, 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 polluted.

5.5 Equipment

5.5.1 Production equipment should be visibly marked with operating status, with regular repair and maintenance. The operation of equipment installation, repair and maintenance should not affect the quality of the product. All performance indicators of the repaired equipment should meet the process requirements, conduct validation if necessary. Equipment not in use should be cleaned and protected and shall have obvious markings.

5.5.2 Compressed air or other inert gases used for food, food contact surfaces, should at least be treated with oil removal, water removal, sterilization, filtration and purification.

5.5.3 The inner wall and welding seam of equipment in contact with the material should be smooth, flat, no dead space, easy to clean, corrosion resistant, and its inner surface should be made of materials that do not react with the material, do not release particles and do not absorb materials. Materials should not be stranded or accumulated. When welding pipes, automatic welding equipment should be used if the position permits.

5.5.4 In powdered and liquid infant formula food production areas, after the installation of sterilization equipment, the sterilization of the equipment should be confirmed, and the equipment will not be put into use until it has been confirmed as compliant.

5.5.5 Liquid infant formula food equipment should also meet the following requirements:

a) For continuously flowing products using aseptic filling process, the sterilization temperature should 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 regulations of GB 5749. Before steam is injected or filled into the product, it should pass through steam filtering device or other effective control measures, to ensure that the steam injected into the product meets the food safety requirements.

b) All kinds of sterilization equipment in the production process of sterilized products after filling should meet the requirements of sterilization process. 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, pipe size 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, and wet cleaning should be avoided as much as possible. Wet cleaning should be limited to cases where equipment parts can be carried to a dedicated room or where drying measures can be taken immediately after wet cleaning.

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

a) Adopt dry cleaning process suitable for the place and equipment, if disinfectant containing necessary water is used, it should be able to ensure 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 developed 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 cleaning and disinfection solutions are suitable, the appropriate concentration of cleaning agents and disinfectants, and the CIP system meets the relevant requirements.

6.2.4 Cleaning and disinfection plans shall be made for all areas in the cleaning operation area to ensure that all areas in the cleaning operation area are cleaned. For quasi-cleaning operation areas and general operation areas, the cleaning or disinfection plan shall be prepared as needed based on the purpose of preventing cross-contamination.

6.2.5 Cleaning and disinfection should be well recorded.

6.3 Working Clothes Management

Employees in cleaning operation areas should wear working clothes (or disposable working clothes) that meet the sanitary requirements for the area and should have hats, masks (only applicable to bare product areas) and working shoes. Employees in quasi-cleaning operation areas and general operation areas should wear working clothes that meet the sanitary requirements for the appropriate area and, should have hats and working shoes. Working clothes (including hats and masks) and working shoes for use in cleaning operation areas and quasi-cleaning operation areas should not be worn outside the designated areas.

7 Raw Materials of Food, Food Additives and Food-Related Products

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

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

7.3 For raw materials and food additives that directly enter the dry mixing process, enterprises should take measures to ensure that the microbiological indicators of raw materials meet the requirements of product standards, and for soybean or soybean protein raw materials, they should ensure that urease activity is negative. The process and safety measures adopted by suppliers should be evaluated, if necessary, on-site review or process monitoring should be conducted.

7.4 Food additives and nutrition enhancers should be used in strict accordance with food safety standards, a special warehouse or special area for storage should be set up, marking with the word food additives, and a special register (or warehouse management software) should be used to record the name of the additives and nutrition enhancers, manufacturer or supplier, production date or batch number, the time of purchase, the amount of purchase and usage, etc., and also attention should be paid to the expiry date. When using the automated warehouse to store food additives, it is not necessary to set up a special warehouse or special area and mark the word food additives, but effective control measures should be established for the reliability of the automated system.

7.5 The raw materials and packaging materials in stock should be inspected regularly. For raw materials and packaging materials with long storage time that are easy to change in quality, samples should be taken to confirm the quality before use. 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. Raw materials and packaging materials that have spoiled or exceeded the shelf life should be cleaned up in time.

8 Food Safety Control in the Production Process

8.1 Basic requirements

8.1.1 It should meet the relevant regulations stipulated in GB 14881.

8.1.2 The food safety control system should be established and operated effectively based on the basic principles of hazard analysis and critical control point system.

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

8.2 Special Requirements for the Production Process of Powdered Infant Formula Foods

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

The heat treatment process should be used as a critical control point to ensure the safety of powdered infant formula foods. The heat treatment temperature and time should consider the impact of product attributes and other factors (such as fat content, total solid content, etc.) on the heat resistance of the sterilization target microorganisms, and measures monitoring key factors that can reflect the temperature of heat treatment, time and heat treatment effect should be established to ensure that the limit requirements of process parameters are not

deviated. Appropriate corrective measures should be taken for monitoring in real time, and corresponding monitoring records should be kept.

If the purchased soybean raw materials have not been conducted heating enzyme deactivation treatment (or the enzyme deactivation treatment is incomplete), they 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, appropriate measures should be taken for intermediate storage of liquid semi-finished products to prevent the growth of microorganisms. 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. If the powdered semi-finished products are placed outside the clean area, measures should be taken to ensure that they meet the requirements of the cleaning operation area when entering the clean area. At the same time, the storage period and storage conditions should be specified for powdered semi-finished products, and the quality of the powdered semi-finished products should be confirmed to meet the production requirements.

8.2.3 Process steps from heat treatment to drying

All running pipes and equipment from heat treatment to drying should be kept tightly closed and regularly cleaned and disinfected.

8.2.4 Cooling

In the wet process and dry-wet composite process production, measures for temperature monitoring should be established for semi-finished products passing through fluidized beds or storage tanks of the semi-finished product before dry mixing. If the dried bare semi-finished powder needs cooling, it should be air-tightly stored and cooled in the cleaning operation area.

8.2.5 Dry mixing

8.2.5.1 The bare powder process in contact with the air environment (such as feeding, batching, and canning of dry mixing) should be carried out in the cleaning operation area. The temperature and relative humidity of the cleaning operation area should be compatible with the production process of powdered infant formula foods. When there is no special requirement, the temperature should be below 25 ºC, and the relative humidity should be below 65%.

8.2.5.2 The enterprise should conduct feeding according to the requirements of product formula ratio and ensure accurate measurement.

8.2.5.3 The key process parameters (such as mixing time, etc.) related to the mixing uniformity should be verified and the mixing uniformity should be confirmed.

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

8.2.5.5 Strict hygiene control requirements should be established for raw materials, packaging materials, and personnel. The raw materials should enter the operation area with higher cleanliness through necessary cleaning procedures and material channels, and the treatment procedures for removing the outer packing or sterilizing the outer packing should be followed.

8.2.6 Inner packing process

8.2.6.1 The inner packing process should be carried out in the cleaning operation area.

8.2.6.2 Only relevant staff should be allowed to enter the packing room. The requirements of raw materials, packing materials and personnel should refer to the provisions stipulated in 8.2.5.5.

8.2.6.3 The production enterprise should adopt effective foreign matter control measures to prevent and inspect foreign matters, such as setting screens, strong magnets, metal detectors, etc. For these measures, process monitoring or effectiveness verification should be implemented.

8.2.7 Environmental monitoring requirements

Environmental monitoring measures should be established for *Salmonella*, *Cronobacillus* and other *enterobacteriaceae* in the cleaning operation area of powdered infant formula food, and the monitoring requirements should meet the requirements of Appendix A.

8.3 Special requirements for the production process of liquid infant formula food

8.3.1 Product process

8.3.1.1 All process operations should be carried out in good condition in compliance with 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 After batching, all pipelines and equipment for conveying products shall be kept closed.

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

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 it should be cleaned and dried when necessary. After sterilization, it should be placed in a cleaning operation 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, filling equipment 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 it should 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 product 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 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 method to clearly 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 infant formula food and verify the sterilization process effect.

8.3.6.2 It should measure (or calculate) the F_0 value of sterilization intensity to ensure that the sterilization parameters and sterilization intensity meet the necessary sterilization requirements. If new sterilization equipment is used or the sterilization equipment is under maintenance and adjustment, and the key technical parameters change, the commercial aseptic effect should be verified by batch heat preservation experiments of all products.

9 Test

9.1 General requirements

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

9.2 Commercial sterility test

The liquid infant formula food 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 meet the relevant regulations stipulated in GB 14881. A training plan should be developed for sterilization operators, filling and sealing 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 Documents Management

It should comply with the relevant provisions of GB 14881.

Appendix A

Environmental Monitoring Guidelines for *Salmonella, Cronobacter* and Other *Enterobacteriaece* in Cleaning Operation Areas of Powdered Infant Formula Foods

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

A.1.1 Monitoring plan objectives

Enterobacteriaece, including *Cronobacter* (*Cronobacter Spp*.), which may exist in production environment with good sanitary conditions, may pollute the products without other sterilization processes after pasteurization, causing traces of *Enterobacteriaece* in the final product. In order to prevent the occurrence of infant formula food contamination, an environmental monitoring plan should be made for the sanitary conditions in cleaning operation areas (dry areas). By reducing the number of *Enterobacteriaceae* in the environment, the number of *Enterobacteriaceae* (including *Cronobacillus* and *Salmonella*) in the final products can be reduced.

A.1.2 Key factors to be considered

A.1.2.1 *Salmonella* is rarely found in the dry environment, but a plan should be developed to prevent the entry of *Salmonella*, evaluate the effectiveness of sanitary control measures in production environment, and provide instructions to personnel to prevent from further spread when *Salmonella* is detected.

A.1.2.2 *Cronobacter* is easier to be found in dry environment than *Salmonella*. If proper sampling and testing methods are used, *Cronobacter* is more likely to be detected. A monitoring plan should be formulated to evaluate if the number of *Cronobacteria* has increased, and effective measures should be taken to prevent further growth and contamination.

A.1.2.3 *Enterobacteriaece* is widely spread as it is a common in the dry environment, and it is easy to be detected. *Enterobacteriaece* testing can be used as an indicator of the production process and environmental sanitary conditions.

A.2 Factors to be Considered when Designing a Sampling Scheme

A.2.1 Product Type and Process

The demand and scope of the sampling scheme should be determined based on product characteristics, consumer age and health status. *Salmonella* is considered as pathogenic bacteria among all products and *Cronobacter* is considered as pathogenic bacteria in some products as described in this standard.

The focus of monitoring should be placed in areas where microorganisms are easy to contaminate and retain, such as the cleaning operation area in a dry environment. Particular attention should be paid to the boundary between this area and the adjacent area of lower sanitary level and the areas close to production lines and equipment that are prone to contamination, such

as the 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

A.2.2.1 Take samples from the surfaces that are not in contact with food, such as the outside of the equipment, the ground around the production line, pipes and platforms. In these cases, the degree of pollution risk and the content of pollutants will depend on the location and design of the production line and equipment.

A.2.2.2 Take samples from the surface that are directly in contact with 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 the indicator bacteria, *Cronobacter*, or *Salmonella* exists on the food contact surface, it indicates a high risk of product contamination.

A.2.3 Target Microorganisms

Salmonella and *Cronobacter* are the main target microorganisms, and *Enterobacteria* is a sanitation indicator.

A.2.4 Sampling locations and Number of Sample

The number of samples should vary with the complexity of the process and production line.

Sampling locations should be the places where microorganisms may hide or enter to cause pollution, such as raw materials, parts of the mobile equipment that contact the ground, air-conditioning return air outlet, employees' work clothes and shoe soles, the ground, the vacuum cleaner, and the powder agglomates on the vibrating screen. The sampling locations can be determined according to relevant literature or based on experience and professional knowledge or historical data collected in the factory pollution survey. The sampling locations should be regularly evaluated, and necessary sampling points should be added in the monitoring plan based on special circumstances, such as major maintenance, construction activities, or worsening sanitary conditions.

The sampling plan should be comprehensive and representative, and samples should be drawn scientifically and reasonably by taking account of different types of production shifts and different time periods within these shifts. To verify the effectiveness of cleaning measures, samples should be taken before starting the production.

A.2.5 Sampling Frequency

The sampling frequency should be determined according to the factors stipulated in A.2.1, and confirmed according to the available data of the existence of microorganisms in each area in the monitoring plan. If there is no such data, sufficient information should be collected to determine a reasonable sampling frequency, including long-term collection of the contamination of *Salmonella* or *Cronobacteria*.

The implementation frequency of the environmental monitoring plan should be adjusted according to the test results and the 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 source of pollution. When the risk of contamination increases (such as after maintenance, construction, or wet cleaning), the sampling frequency should also be increased appropriately.

A.2.6 Sampling tool and method

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

A.2.7 Analysis Method

The analysis method should be able to effectively detect the target microorganism, with acceptable sensitivity, and relevant records. Under the premise of ensuring sensitivity, multiple samples can be mixed together for detection. If a positive result is detected, the location of the positive sample should be further determined. If necessary, gene technology may be applied to analyze the source of *Cronobacteria* and trace to the contamination path of powdered infant formula foods.

A.2.8 Data Management

The monitoring plan should include data recording and evaluation system, such as trend analysis. The data must be continuously evaluated in order to appropriately modify and adjust the monitoring plan. Effective data management for *Enterobacteriaece*, *Cronobacteria*, *and Salmonella* may help the detection of neglected mild or intermittent contamination.

A.2.9 Corrective Measures for Positive Results

The purpose of the monitoring plan is to discover whether target microorganisms exist in the environment. Before a monitoring plan is developed, acceptance criteria and response measures should be established. The monitoring plan should specify specific action measures and clarify the corresponding reasons. Relevant measures include taking no action (no pollution risk), enhancing cleaning operation, tracking pollution source (increasing environmental testing), assessing sanitary measures, detention and testing of products.

The manufacturing enterprise should formulate corrective measures after the detection of *Enterobacteriaece* and *Cronobacter* to make accurate response when there is an over-standard. Health procedures and control measures should be evaluated. When *Salmonella* is detected, corrective action should be taken immediately, and the trend of *Cronobacter* and changes in *Enterobacteriaece* numbers should be evaluated. The specific action to be taken depends on the possibility of the product being contaminated by *Salmonella* and *Cronobacter*.

(End Translation)

Attachments:

No Attachments.