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Report Name: China Notifies Draft National Food Safety Standard on Good Manufacturing Practice for Powdered Infant Formula Food

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Report Highlights:

On May 12, 2020, 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. 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 July 11, 2020 . 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 May 12, 2020, China's National Health Commission (NHC) and the State Administration of Market Regulation (SAMR) notified an updated draft to the WTO SPS Committee for comment as G/SPS/N/CHN/1159. Comments can be sent to China's SPS Enquiry Point at sps@customs.gov.cn. The deadline for comment submission is July 11, 2020. 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 the incorporation of the National Food Safety Standard of General Hygiene Regulations for Food Production (GB14881-2013). Instead of listing specific requirements, it incorporates the requirements in GB14881 by reference. Another notable revision is that references to "Enterobacter Sakazakii" are modified as "Cronobacter." Please see the Preface Section of the translation below for a more complete list of revisions.

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—20XX

National Food Safety Standard **Good Manufacturing Practice for Powdered Infant Formula** **Food**

(Draft for Comments)

Issued by 201X-XX-XX

Implemented on 20XX-XX-XX

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 *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 for the cleaning operation area of infant formula food production are modified;
- The “*Enterobacter Sakazakii*” is modified as “*Cronobacter*”;
- The technical requirements for “food safety control in the production process using the Hazard Analysis and Critical Control Point System (HACCP)” are emphasized;
- The technical requirements for sterilization equipment are added;
- The training requirements for sterilization operators and cleaning staff are added.

National Food Safety Standard

Good Manufacturing Practice for Powdered 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 powdered infant formula food.

This standard is applicable to the production of powdered infant formula food with dairy or soybean and its 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, which usually includes ingredients, heat treatment, concentration, drying, 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, which usually includes the ingredients, mixing (including pre-mixing), packaging (filling) 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.

3. Site Selection and Factory Environment

It should comply with the relevant provisions of GB 14881.

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 the contamination from Salmonella and Cronobacter (*Cronobacterspp.*), 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 designed to be segregated and separated; contamination caused

by the movement of personnel, equipment and materials should be effectively controlled to prevent Salmonella and Cronobacter from entering the cleaning operation 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 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.

4.2.3 The general operation area includes the dairy collecting room, raw material warehouse, packing material warehouse, outer packing workshop, finished product warehouse, etc.

4.2.4 The quasi-cleaning operation area includes the raw material pre-treatment workshop, wet processing area (e.g. weighing, batching, etc.), inner packing cleaning of raw materials and tunnel, disinfection of packaging materials, 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, filling, etc.), 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 restriction measures and effective control measures for entering and leaving cleaning operation areas to avoid or reduce pathogenic bacteria contamination. There should be measures for personnel, raw materials, packaging materials, waste, equipment, etc. entering and leaving the cleaning operation area 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 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 powdered 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 should be detected periodically.

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

Item	Content	Detection method	Control requirement	Recommended frequency of monitoring
Maximum number of microorganisms allowed	Planktonic bacteria	GB/T 16293	≤ 200 cfu/m ³	Once/week
	Sedimentated bacteria	GB/T 16294	≤ 100 cfu/ IIII ($\phi 90$ mm)	Once/week
	Surface microorganisms	Direct sampling is measured using a $\phi 55$ mm vessel or wiped with a cotton swab 5 cm x 5 cm to count according to GB 4789.2 with reference to the GB 15982 sampling method.	≤ 50 cfu/vessel ($\phi 55$ mm), with an area of about 25cm ²	Once/week
Pressure difference	Between cleaning operation areas and general operation areas	Measured by differential pressure gauge	Positive pressure or ≥ 10 Pa	Twice/shift
Temperature	-	Measured by thermometer	16-25°C	Twice/shift
Relative humidity	-	Measured by hygrometer	$\leq 65\%$	Twice/shift

Note: The monitoring frequency of the automatic monitoring system meets the control requirements.

4.2.9 Cleaning operation areas 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.

4.2.10 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 System

Unnecessary drainage facilities should be avoided in cleaning operation areas and, if necessary, appropriate measures should be taken to keep them dry during production.

5.3 Cleaning Facilities

The following measures should be applied in cleaning operation areas that need to be kept dry:

- a) A dry cleaning process (no water used) suitable for the site and equipment is adopted. For example, disinfectants containing necessary moisture are used to ensure rapid drying of the cleaning operation surface or dry cleaning is conducted without using disinfectants in a dry state.
- b) If dry cleaning measures are not available, wet cleaning may be used under controlled conditions, but it should ensure that the equipment and environment can be restored to dryness in a timely and thorough manner so that the area is not contaminated.
- c) Mixing of cleaning tools in different operation areas should be avoided.

5.4 Sanitation Facilities

The entrance to the cleaning operation area should be equipped with a private changing room in the cleaning operation area and hand sanitizing facilities should be set up before entering the cleaning operation area. The private changing rooms and hand sanitizing rooms in the cleaning operation area for the production of powdered infant formula food can be used without setting hand-washing facilities according to the control requirements of microorganisms.

5.5 Equipment

- 5.5.1 Production equipment should be visibly marked with operating status, which should be displayed by an automation control system with regular repair and maintenance. The operation of equipment installation, repair and maintenance should not affect the quality of the product. The repaired equipment should be validated to ensure that 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 gases used for food, food contact surfaces should at least be treated with sterilization, filtration and purification.
- 5.5.3 The inner wall of the 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.
- 5.5.4 After the installation of sterilization equipment, material sterilization effect should be confirmed, and the equipment will not be put into use until it has been confirmed as compliant.

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 Effective monitoring process should be formulated to ensure that key processes (e.g. manual cleaning, cleaning-in-place operations (CIP) and equipment maintenance) comply with regulations and standards, in particular to ensure that cleaning and disinfection solutions are suitable, that the concentration of detergent and disinfectant is appropriate and that CIP systems meet relevant temperature and time requirements.
- 6.2.3 A cleaning and disinfection periodic table should be established for all cleaning operation areas to ensure that all areas in the clean area are cleaned. The periodic table for cleaning or disinfection of quasi-cleaning operation areas and general operating areas is formulated as needed based on the purpose of preventing cross-contamination.
- 6.2.4 The number of cleaning staff should be ensured, and post responsibilities should be identified as needed; 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 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 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 Basic Requirements

- 7.1.1 It should comply with the relevant provisions of GB 14881.
- 7.1.2 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.

7.2 Other Requirements

- 7.2.1 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 raw materials, they should ensure that urease activity is negative.
- 7.2.2 Food additives and nutrition enhancers should be managed by a specific person, a special warehouse or special area for storage should be set up, and a special register (or warehouse management software) should be used to record the name of the additives and nutrition enhancers, the time of purchase, the amount of purchase and usage, etc., and also attention should be paid to the expiry date.

7.2.3 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 the Production Process

8.1 Basic Requirements

It should meet the relevant regulations stipulated in GB 14881. Hazard Analysis and Critical Control Point System (HACCP) should be used to control food safety in the production process. For key processing parameters, such as critical control points, formula, etc., effective control measures should be established. Environmental monitoring measures should be established for Salmonella, Cronobacter, and other Enterobacteriaceae in cleaning operation areas of powdered infant formula foods. The monitoring guidelines should meet the requirements of Appendix A.

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. Therefore, the heat treatment temperature and time should be established and deviations of related key factors that affect the heat treatment effect should be checked. 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), 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, 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.

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 powder temperature monitoring should be established for semi-finished products passing through fluidized beds. 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 controlled at 16 °C ~ 25 °C, 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. Compressed air required for positive pressure materials conveying can be used after degreasing, dewatering, clean filtration or sterilization treatment.

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.

8.2.6.4 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.

9. Inspection

It should meet the relevant regulations stipulated in GB 14881.

10. Food Storage and Transportation

It should meet the relevant regulations stipulated in GB 14881.

11. Product Recall Management

It should meet the relevant regulations stipulated in GB 14881.

12. Training

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

14. Records and Documents Management

It should meet the relevant regulations stipulated in GB 14881.

Appendix A

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

A.1 Since there may be a small amount of Enterobacteriaceae (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 Enterobacteriaceae in the final product. Therefore, Enterobacteriaceae 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 Enterobacteriaceae in the environment can reduce the number of Enterobacteriaceae (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.

The following ecological characteristic factors of Salmonella, Cronobacter, and other Enterobacteriaceae should be considered when a monitoring plan is formulated:

- A.1.1 Salmonella is rarely found in dry environment, but a monitoring plan should be developed to prevent the entry of Salmonella, evaluate the effectiveness of sanitary control measures in the production environment, and guide relevant personnel to prevent the further spread of Salmonella if it is detected.
- A.1.2 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 developed to assess whether the number of Cronobacter has increased and effective measures should be taken to prevent its growth.
- A.1.3 Enterobacteriaceae is widely distributed and is a common flora in a dry environment, and it is easy to be detected. Enterobacteriaceae 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 hide and breed, 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

The monitoring plan should include the following two samples:

A.2.2.1 Take samples from the surfaces that is 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 is 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, but Enterobacteriaceae can be used as a health indicator. The content of Enterobacteriaceae shows the possibility of the existence of Salmonella, as well as the growing conditions of Salmonella and Cronobacter.

A.2.4 Sampling Locations and Number of Samples

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

The sampling locations should be a place 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 agglomerates on the vibrating screen. The sampling locations can be determined according to the 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 locations 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 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

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 the occurrence of long-term collection of Salmonella or Cronobacter.

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 Tools and Methods

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 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, genetic technology can be used to analyze information about the source of Cronobacter and 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 of Enterobacteriaceae and Cronobacter may lead to 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 action measures after the detection of Enterobacteriaceae 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 Enterobacteriaceae 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.