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National Dairy Standard - Good Manufacturing Practices for Powder

Report Categories:

FAIRS Subject Report

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Report Highlights:
On November 20, 2009, China notified the WTO of "National Food Safety Standard of the People's Republic of China for Good Manufacturing Practices for Powdered Milk Formula for Infants and Young Children" as SPS/N/CHN/143. The date for submission of final comments to the WTO is January 1, 2010. The proposed date of entry into force has not been specified.

Executive Summary:
On November 20, 2009, China notified the WTO of "National Food Safety Standard of the People's Republic of China for Good Manufacturing Practices for Powdered Milk Formula for Infants and Young Children" as SPS/N/CHN/143. The date for submission of final comments to the WTO is January 1, 2010. The proposed date of entry into force has not been specified.

Thanks go to the consortium of industry and 3rd country Embassies in Beijing for their assistance in

translating and reviewing this standard.

This report contains an UNOFFICIAL translation of National Standard on Good Manufacturing Practices for Powdered Milk Formula for Infants and Young Children.

General Information:

BEGIN TRANSLATION

ICS 67.040
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GB National Food Safety Standard
GB/T ××××--××××
Replacing GB/T 23790—2009

Good Manufacturing Practices for Powdered Milk Formula for Infants and Young Children

Issued on xx-xx-xxxx Implemented on xx-xx-xxxx

Issued by the Ministry of Health

of the People's Republic of China

Foreword

This national standard refers to the international standard CAC/RCP 66 – 2008 *Code of Hygienic Practice for Powdered Formulae for Infants and young children*.

This national standard will replace GB/T 23790-2009 *Good manufacturing practice for powdered formulae for Infants and young children*.

Compared with GB/T 23790-2009, the main charges made in this national standard are as follows:

——Recommended standard was modified to compulsory standard;

——Frame of standard provisions was modified;

——Relevant standard provisions were modified.

Annex A to this national standard was normative.

This national standard was proposed and is under the jurisdiction of the Ministry of Health of the People's Republic of China.

——GB/T 23790-2009.

1 Scope

This national standard specifies the conditions and requirements for address selection and factory environment, factory building and workshop, equipment, sanitation management, raw and packaging materials, food safety control during production process, product inspection, product storage and transportation, management of records and documents, product traceability and recall, training, organization and personnel, etc. that powdered formulae production enterprises for Infants and young children should meet.

This national standard is applicable to production enterprises of powdered formulae for Infants and young children (including powdered formulae for infants and powdered formulae for follow-up Infants and young children).

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this standard. For dated reference, subsequent amendments to (excluding corrigenda), or revisions of, any of these publications do not apply. However, parties to agreements based on this national standard are encouraged to investigate the possibility to applying the most recent editions of the standards indicated below. For undated references, the latest edition of the normative document referred to applies.

GB 5749	Sanitary Standard for Drinking Water
GB 12693	Good Manufacturing Practice for Dairy Product Factory
GB 13432	General Standard for the Labeling of Prepackaged Foods for Special Dietary Uses
GB/T 18204.1	Methods of Microbiological Examination For Air In Public Places — Determination Of Aerobic Bacterial Count

3 Terms and definitions

For the purposes of this national standard, the following terms and definitions apply.

3.1 Cleaning work area

Work area with high cleanliness requirement, such as storage, filling and inner packaging workshops of exposed semi-finished products ready for packaging.

3.2 Quasi-cleaning work area

Work area with lower cleanliness requirement compared with cleaning work area, such as starting material and pre-treatment workshops, etc..

3.3 Commonly work area

Work area with lower cleanliness requirement compared with quasi-cleaning work area, such as milk receiving workshop, raw material warehouse, packaging material warehouse, outer packaging workshop, finished product warehouse, etc..

3.4 Wet-mix process

The production process of processing and mixing the ingredients of powdered formulae for Infants and young children in liquid state. This process generally includes batching, heat treatment, concentration, drying procedures, etc..

3.5 Dry-mix process

The production process of processing and mixing the ingredients of powdered formulae for Infants and young children in dried state to produce final product.

3.6 Combined process

The production process of processing and mixing partial ingredients of powdered formulae for Infants and young children in liquid state, making them dried and then adding other parts of dry ingredients by adoption of dry-mix process to produce final product.

4 Address selection and factory environment

Shall meet the relevant specifications of GB 12693.

5 Factory building and workshop

5.1 Design and layout

5.1.1 Shall meet the relevant specifications of GB 12693.

5.1.2 Factory building and workshop shall be reasonably designed. Related facilities and equipment should be built and planned to avoid microorganism growth and contamination, espeically contamination caused by Salmonella and Enterobacter sakazakii (*Cronobacter* genus), At the same time, avoid or minimize the possibility of existance or reproduction of such bacteria at the hiding place. The design should take account of the following factors to avoid propagation of microorganisms:

a. In design, isolate damp area from dry area; Effectively control contamination caused by personnel, equipment and material flow. Prevent Salmonella and Enterobacter sakazakii from entering cleaning work area.

b. Design reasonable water drainage facility. Ground should be smooth, with a suitable slope to avoid water accumulation. In addition, avoid production of condensed water should be avoided in cleaning work area.

c. Do not improperly pile up processing material to avoid producing areas hard to clean.

d. Wet cleaning procedure should be designed reasonably. Production and spread of Salmonella and Enterobacter sakazakii caused by improper wet cleaning procedure should be avoided in dry area.

5.1.3 Internal design and layout of the production place for powdered formulae for Infants and young children shall be reasonable according to production process and sanitary cleaning requirements.

5.1.4 Operation in dry processing area without subsequent sterilization shall be carried out in cleaning work area, such as the operation from (or after) drying procedure to filling and sealed packaging.

5.1.5 Effective physical isolation shall be made for areas with different sanitary cleaning requirements (cleaning work area, quasi-cleaning work area, etc.). Cleaning work area should maintain a positive pressure differential to other areas to avoid cross contamination caused by incoming air not purified.

5.1.6 Reasonable access control should be implemented for cleaning work area and control measures should be taken to avoid or minimize pathogen contamination. When personnel, raw material, packaging material, waste, equipment, etc. enter cleaning work area, measures shall be taken to avoid cross contamination; such as setting change room for personnel to change work clothes, footware or shoe covers, setting special material passage and waste passage, etc.. For raw material or product that enters cleaning work area through pipeline transport, suitable air filtering system should be designed and installed.

5.1.7 Operation that will contact water, such as concentration, should be avoided in cleaning work area.

5.1.8 Production enterprises of powdered formulae for Infants and young children should determine clean levels of work areas according to requirements of production process and sanitation and quality. In principle it should be divided into commonly work area, quasi-cleaning work area and cleaning work area. cleaning work area should be installed with independent air purification system with filtering device and maintain a positive pressure differential that reach requirement specified in Table 1.

5.1.9 Clean level of each work area must satisfy the requirements for air purification in the processing of powdered formulae for infants and young children. Temperature, humidity and air cleanliness in cleaning work area should meet definite control requirements as required for production. Quality inspection department of the enterprise should detect air quality in cleaning area on a regular basis, which may be determined by using natural precipitation method as specified in GB/T 18204.1, where aerobic bacterial count in the air of each production work area shall be controlled within the value specified in Table 1:

Table 1

work area	Aerobic bacterial count per petri *dish* (cfu/dish)
Cleaning work area ≤	30
Quasi-cleaning work area ≤	50

5.1.10 Cleaning work area should be kept dry, where water supply facilities and systems should be minimized. If it is unavoidable, protective measures should be taken. In addition, it is forbidden to cross upper space of main working surfaces in order to avoid secondary contamination.

5.1.11 Factory building, workshop and warehouse should be provided with facilities that can prevent from insects and mice or other animals entering such area.

5.2 Area setting and isolation

Shall meet the relevant specifications of GB 12693.

5.3 Internal building structure

Shall meet the relevant specifications of GB 12693.

5.4 Facilities

5.5 water supply facility

Shall meet the relevant specifications of GB 12693.

5.6 Water drainage system

Shall meet the relevant specifications of GB 12693. In cleaning work area, suitable facilities or measures should be set or taken to keep it dry to avoid growth and spread of related microorganisms caused by residue of water produced.

5.7 Cleaning facility

5.4.3.1 Shall meet the relevant specifications of GB 12693.

5.4.3.2 The following measures should be taken for cleaning work area that should be kept dry:

a. Adopt dry cleaning procedure applicable to the place and equipment .

b. If dry cleaning measure cannot be taken, wet cleaning is applicable under controlled condition, whereas thoroughly dry state of equipment and environment should be restored in time to protect the area from contamination.

5.8 Personal sanitation facility

5.4.4.1 Shall meet the relevant specifications of GB 12693.

5.4.4.2 change room and hand-washing & disinfection room should be set near the entrance to processing workshop or at suitable place. Hand-washing & disinfection room should be equipped with. enough non-hand operated taps, disinfecting and automatic induction hand drying facilities.

5.4.4.3 Cleaning measures should be taken at the entrance to workshop to prevent shoes from contaminating workshop.

5.4.4.4 Secondary change room, should be set at the entrance to cleaning work area. Hands should be disinfected with hand disinfecting facility before entering cleaning work area.

5.9 Ventilation facility

Shall meet the relevant specifications of GB 12693.

5.10 Lighting facility

Shall meet the relevant specifications of GB 12693.

5.11 Storage facility

Shall meet the relevant specifications of GB 12693.

6 Equipment

6.1 Production equipment

6.1.1 General requirement

Shall meet the relevant specifications of GB 12693.

6.1.2 Material quality

Shall meet the relevant specifications of GB 12693.

6.1.3 Design

6.1.3.1 Production equipment shall meet the relevant specifications of GB 12693.

6.1.3.2 Production process of powdered formulae for Infants and young children includes dry-mix process, wet-mix process (including combined process). Related production equipment should be equipped according to process requirement.

6.1.3.3 Production equipment should be provided with clear status identifier, for which maintenance, care and qualification should be conducted on a regular basis. installation, maintenance and care of equipment shall not affect product quality. Equipment must be subject to qualification or validation after maintenance to ensure each item of performance can satisfy the process requirements. Equipment out of specification should be moved out of the production area, which should be provided with clear sign before being moved out.

6.1.3.4 Compressed air or other inert gas used for food, cleaning food contact surface or equipment should be filtered and purified to avoid causing indirect contamination.

6.2 Monitor equipment

Shall meet the relevant specifications of GB 12693.

6.3 Equipment maintenance and care

Shall meet the relevant specifications of GB 12693.

7 Health management

7.1 Health management system

Shall meet the relevant specifications of GB 12693.

7.2 Sanitation management for factory building and facility

Shall meet the relevant specifications of GB 12693.

7.3 Cleaning and disinfection

7.3.1 Shall meet the relevant specifications of GB 12693.

7.3.2 Wet cleaning should be avoided in cleaning work area that requires dry cleaning (such as dry mixing, filling packaging, etc.). Wet cleaning is only limited to equipment parts that can be moved to special room or available in the case that drying measure can be taken immediately after wet cleaning. To implement effective dry cleaning procedure for production and processing environment is the most effective method to avoid propagation of microorganisms.

7.4 Personnel health and sanitation management

7.4.1 Shall meet the relevant specifications of GB 12693.

7.4.2 Personnel working in cleaning work area should wear work clothes (or disposable work clothes) that meet the sanitation requirement of this area, and wear cap, gauze mask and work shoes. Personnel working in quasi-cleaning work area and commonly work area should wear work clothes that meet the sanitation requirement of the respective area, and wear cap and work shoes. Work clothes and shoes worn in cleaning work area and quasi-cleaning work area cannot be worn at the place other than designated area.

7.5 Pest control

Shall meet the relevant specifications of GB 12693.

7.6 Waste treatment

Shall meet the relevant specifications of GB 12693.

7.7 Management of toxic and harmful substances

Shall meet the relevant specifications of GB 12693.

7.8 Management of sewage and dirt

Shall meet the relevant specifications of GB 12693.

7.9 Management for work clothes

Shall meet the relevant specifications of GB 12693.

7.10 Monitor effectiveness

7.10.1 Effective supervision process should be formulated for health management to ensure the key processes (such as manual cleaning, cleaning in place (CIP) and equipment maintenance) meet the related specification and standard requirements. Especially the applicability of cleaning and disinfection scheme should be guaranteed, concentration of detergent and disinfectant should be suitable, CIP system should meet related temperature and flow rate requirement, and equipment should be washed reasonably when necessary.

7.10.2 Washing (or cleaning) and disinfection schedule should be formulated for all production workshops to ensure all areas can be cleaned. Equipment and appliance in important areas should be subject to special cleaning.

7.10.3 Enough cleaning personnel should be ensured and their responsibilities should be defined according to the requirement; All cleaning personnel should receive good training, fully understand the harm of contamination and significance of precaution. Cleaning and disinfection should be recorded.

7.10.4 Representative sample of finished product should be drawn batch by batch, including the first finished product and other samples of finished products that have been packaged every day. Inspection should be carried out according to the specifications of related national regulations and standards. Meanwhile, measures set forth in Annex A should be taken to ensure that reasonable and effective monitor is implemented.

8 Requirement for raw and packaging materials

8.1 General requirement

Shall meet the relevant specifications of GB 12693. Raw material used shall meet the requirements of the related national and industrial standards and related regulations. Infants and young children's safety should be guaranteed, and their requirement for nutrition should be satisfied. Substance that harms the nutrition or health of Infants and young children shall not be used.

8.2 Purchasing and acceptance of raw and packaging materials

8.2.1 Shall meet the relevant specifications of GB 12693.

8.2.2 Enterprise shall take measures for raw material that directly enter dry-mix process to ensure that raw material microorganism index meets the requirement of product standard. Ensure urease activity in soy bean material is negative; Processes and safety measures adopted by suppliers should be evaluated. When necessary, field inspection or process monitor should be carried out periodically.

8.3 Transportation and storage raw and packaging materials

8.3.1 Shall meet the relevant specifications of GB 12693.

8.3.2 food additives and nutrition enhancers should be in the charge of specially designated person, stored in a special warehouse or at a special area, and recorded on a special register (or required software for warehouse), where additive name, purchasing time, purchasing quantity, dosage, etc. should be indicated. In addition, attention should be paid to product expiration.

8.3.3 Food nutrition enhancers, such as vitamins, trace elements, etc. whose quality is likely to change should be inspected on a regular basis to ensure they can meet the requirements for raw material.

8.4 Keep purchasing, acceptance, storage and transportation records of raw and packaging materials .

9 Food safety control in production process

9.1 General requirements

9.1.1 Shall meet the relevant specifications of GB 12693.

9.1.2 Production enterprises of powdered formulae for Infants and young children should establish quality management system, take quality safety management measures and implement full-process control over powdered formulae for Infants and young children from raw material purchasing and acceptance to delivery of finished product to ensure product quality safety.

9.2 Key factors of food safety control

9.2.1 Microbial contamination control over

9.2.1.1 Shall meet the relevant specifications of GB 12693.

9.2.1.2 Microbiological test should cover analysis on samples drawn from raw and packaging materials, semi-finished and finished products from production line.

Verification and monitor procedure for contamination status of the powdered formulae for Infants and young children through environment test in clean work area should meet the requirements of Appendix A. Environment sample should be drawn from the area that is most likely to be contaminated.

9.2.1.3 When monitor, supervision or verification result for control measures shows any deviation, proper corrective measures should be taken. Finished product cannot be released unless the investigation result shows that it has met the related standards.

9.2.2 Chemical contamination control

Shall meet the relevant specifications of GB 12693.

9.2.3 Physical contamination control

Shall meet the relevant specifications of GB 12693.

9.2.4 Food additives

Food additives used in production and processing shall meet the relevant specifications of GB 12693.

9.2.5 Packaging material

Shall meet the relevant specifications of GB 12693.

9.2.6 Specific processing steps

Each production procedure of powdered formulae for Infants and young children shall meet the requirement of specific processing steps of related dry-mix or wet-mix process respectively, which shall also meet the following specifications:

9.2.6.1 heat treatment (wet-mix and combined mix process)

Heat treatment is a key step to ensure safety of powdered formulae for Infants and young children, and an important key control point. 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 related process should be established to check if there is deviation in temperature and time or not and proper corrective measures should be taken.

If the purchased soybean material is not subject to thermal inactivation of enzymes (inactivation is not complete), soybean-based powdered formulae for Infants and young children should be heat treated to reach the effect of killing pathogens and completely inactivating enzymes (urease is negative), and shall serve as a key control point for monitoring.

9.2.6.2 Intermediate storage

In wet-mix and combined process, related measures should be taken for intermediate storage of storage of liquid semi-finished product to prevent from growth of microorganism. Exposed raw material powder in dry-mix process or exposed powdered semi-finished product in wet-mix process should be kept at

the cleaning work area

9.2.6.3 Process steps from heat treatment to drying

All conveying pipe and equipment should be kept closed after heat treatment and before drying, and should be thoroughly cleaned and disinfected on a regular basis.

9.2.6.4 Cooling

In wet-mix and combined process, exposed powdered semi-finished product should be cooled in cleaning work after being dried.

9.2.6.5 Dry-mix

In dry-mix and combined process, the following key factors should be controlled in dry-mix:

a. Exposed powder procedure contacting air (such as pre-mix and sub-packaging, batching, feeding) should be conducted in cleaning work area. Temperature and relative humidity in cleaning work area shall adapt to production process of powdered formulae for Infants and young children. When there is no special requirement, temperature should be controlled below 27℃, and relative humidity should be controlled below 70%.
b. Materials should be accurately batched.
c. Key process parameters related to mixing homogeneity (such as mix time, pressure of compressed air, etc.) should be validated and confirmed. Mixing homogeneity should be confirmed.
d. Interior wall of the equipment contacting material should be smooth, flat, without dead angle, easy to clean, corrosion resistant. The inner surface layer should be made of material that will not react with the material and will not release particle or absorb material.
e. Compressed air required for material transport in positive pressure should be used after being de-oiled, filtered, dehydrated and sterilized.
f. Strict sanitation control requirements should be formulated for raw and packaging materials and personnel. Raw material should comply with necessary cleaning procedure and enter work area, through material passage. It should comply with the handling procedure of removing or disinfecting outer package. Working personnel should change work clothes once again and comply with hand cleaning and disinfection procedure, etc before entering cleaning work area. Ensure related personnel's hands are hygienic and they have worn work clothes, head covers, changed shoes or worn shoe covers.

9.2.6.6 Inner packaging procedure

The following key factors should be controlled:

a. Inner packaging procedure should be carried out in cleaning work area.
b. Only related working personnel are allowed to enter package room. Refer to

specification of Clause9.2.4.5 for requirements for raw and packaging materials and personnel.

c. Check to see if outer package of packaging material is complete or not before use to ensure that packaging material is not contaminated.

d. Production enterprise should adopt effective foreign matter control measures to prevent from and check foreign matters, such as screen, strong magnet, metal detector, etc. Process monitor or validity validation should be implemented for such measures.

e. Different categories of products produced on the same production should be effectively cleaned to ensure that product switch will not influence the next batch of product.

9.2.6.7 Production water

Production water, equipment cleaning water, etc. directly contacting food shall meet the related specification of GB 5749 Sanitary Standard for Drinking Water. Circulating water, ice, steam and other kind of water shall meet the relevant specifications of GB 12693.

9.2.6.8 Finished product

Ensure finished product of powdered formulae for Infants and young children meets the full-process control over food safety and good manufacturing practices of the enterprise.

9.2.7 Product information and label

9.2.7.1 Product label shall meet the specifications of GB13432 General Standard for the Labeling of Prepackaged Foods for Special Dietary Uses, national standard and other related national regulations for powdered formulae for Infants and young children. Product label should also be indicated with the main nutritional components and their contents. Correct usage and precautions should be indicated.

9.2.7.2 Product label should be indicated with information such as product reconstitution method, water for reconstitution and storage method, etc.. Directions should be given to prevent customers from catching food borne diseases caused by improper use of product during the course of reconstitution and handling and feeding of the product.

10 Product inspection

Shall meet the relevant specifications of GB 12693.

11 Product storage and transportation

Shall meet the relevant specifications of GB 12693.

12 Records and documents management

12.1 records and management

Shall meet the relevant specifications of GB 12693.

12.2 Documents management

Shall meet the relevant specifications of GB 12693.

13 Product traceability and recall

Shall meet the relevant specifications of GB 12693.

14 Training

Shall meet the relevant specifications of GB 12693.

15 Management organization and personnel

Shall meet the relevant specifications of GB 12693.