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National Standard of the People's Republic of China

GB 23790—2010

**National Food Safety Standard
Good Manufacturing Practice for Powdered
Formulae for Infants and Young Children**

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Foreword

This Standard replaces GB/T 23790-2009 *Good Manufacturing Practice for Infant formula Factory*.

This Standard refers to international standard CAC/RCP 66-2008 *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children*.

The main changes in this Standard over GB/T 23790-2009 are as follows:

- changing the name of this Standard into *Good Manufacturing Practice for Powdered Formulae for Infants and Young Children*.
- changing voluntary standard to mandatory standard;
- modifying provision framework of this Standard;
- adding relevant requirements for raw material purchase, acceptance, transport and storage;
- modifying food safety control measures for manufacturing process, adding specific treatment procedures for safety control, and formulating control requirements for important procedures such as heat treatment, intermediate storage, cooling, dry mixing and inner packaging; and referring to provisions of GB 12693-2010 for critical control measures for microbial, chemical and physical contamination;
- adding requirements for safety control of raw material soybean;
- adding monitoring and evaluation method for effectiveness of food safety control measures; and
- adding Annex A and specifying the requirements for monitoring main contamination sources in the environment of cleaning work area – salmonella, enterobacter sakazakii and other enterobacteriaceae.

Annex A of this Standard is normative.

The previous edition(s) replaced by this Standard is (are) as follows:

- GB/T 23790-2009.

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National Food Safety Standard

Good Manufacturing Practice for Powdered Formulae for Infants and Young Children

1 Scope

This Standard is applicable to manufacturers of powdered formulae for infants and young children (including powdered formulae for infants, powdered formulae for older infants and young children) with milk or soybean and its processed products as main materials.

2 Normative references

Documents referenced in this Standard are essential for application of this Standard. For dated references, only the dated edition is applicable to this Standard. For undated references, the latest edition (including all amendments) is applicable to this Standard.

3 Terms and Definitions

3.1 Cleaning work area

Work areas with high cleanliness requirement, such as workshops for storage, filling and inner packing of bare semi-products to be packed.

3.2 Quasi-cleaning work area

Work areas with cleanliness requirement lower than that of cleaning work area, such as raw material preprocessing workshop.

3.3 Commonly work area

Work areas with cleanliness requirement lower than that of quasi-cleaning work area, such as milk collecting workshop, raw material warehouse, packing material warehouse, outer packing workshop and finished products warehouse.

3.4 Wet-mix process

Production process processing and mixing ingredients of powdered formulae for infants and young children in liquid state, usually including blending, heat treatment, concentration, drying and other procedures.

3.5 Dry-mix process

Production process processing and mixing ingredients of powdered formulae for infants and young children in dry state to make finished products.

3.6 Combined process

Production process processing and mixing some ingredients of powdered formulae for infants and young children in liquid state, and adding the rest dry ingredients by the dry-mix process to make finished products after drying.

4 Site selection and factory environment

Relevant requirements of GB 12693 shall be met. Factories shall be away from livestock farms, and animals shall not be kept in the factories.

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5.1 Design and layout

5.1.1 Relevant requirements of GB 12693 shall be met.

5.1.2 Plant and workshop shall be reasonable designed, and relevant facilities and equipment suitable for production shall be constructed and planned to avoid microbial generation and contamination especially contamination caused by salmonella and enterobacter sakazakii (*Cronobacter*) and avoid or reduce existence or reproduction of these bacteria in concealed places. The following factors shall be taken into consideration in design to avoid the microbial generation:

5.1.2.1 In design, the wet area shall be isolated and separated from dry area; contamination caused by employees, equipment and material movement shall be controlled effectively to prevent salmonella and enterobacter sakazakii from entering the cleaning work area.

5.1.2.2 Reasonable drainage facilities shall be designed; ground shall be flat and have proper slope to avoid water accumulation; and condensation water shall be avoided in cleaning work area.

5.1.2.3 The processing materials shall be stored properly so as to avoid the generation of the place unfavorable for cleaning.

5.1.2.4 The wet cleaning process shall be designed properly to avoid the generation and transmission of salmonella and enterobacter sakazakii due to improper wet cleaning process in dry area.

5.1.2.5 Clearance among various pipes, cables and holes through building floors, ceilings and walls shall be enclosed and sealed well.

5.1.3 The interior design and layout of production place of the powdered formulae for infants and young children shall be arranged properly according to production process and hygiene requirements.

5.1.4 The operations in dry processing area without subsequent sterilization shall be made in cleaning work area, such as the operation from drying (or post-drying) process to filling and packaging.

5.1.5 Work areas shall be graded by cleanliness according to production process, hygiene and quality requirements. As a general rule, there are commonly work area, quasi-cleaning work area and cleaning work area. A separate air purification system with filter unit shall be installed in cleaning work area and shall remain under positive pressure.

5.1.6 Effective physical isolation shall be provided among work areas of different cleanliness levels. The positive pressure from cleaning work area to other areas shall be kept to prevent unpurified air entering cleaning work area to cause cross contamination.

5.1.7 Access to cleaning work area shall be reasonably restricted to avoid or reduce pathogenic bacterial contamination. Measures for preventing cross contamination shall be taken for personnel, raw materials, packing materials, waste, equipment, etc. entering and leaving the cleaning work area, such as establishment of personnel dressing room for changing work clothes, footwear or shoe covers, special material corridor, waste corridor, etc. For the raw materials or products entering the cleaning work area through pipes, proper air filtration system shall be designed and installed.

5.1.8 The purification level of each work area shall meet the requirements of processing the powdered formulae for infants and young children for air purification. The air cleanliness of cleaning work area and quasi-cleaning work area shall conform to the requirements of

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Table 1 Requirements for air cleanliness control of cleaning and quasi-cleaning work areas

Area	Total bacterial count (cfu/dish)	Test method
Cleaning work area	≤30	Determination according to natural precipitation method in GB/T 18204.1
Quasi-cleaning work area	≤50	

- 5.1.9** The cleaning work area shall be kept dry, and the water supply facilities and systems shall be minimized, otherwise protective measures shall be taken, and the upper space of main production work surface shall not be traversed to avoid the secondary contamination.
- 5.1.10** Plants, workshops and warehouses shall be provided with facilities preventing entrance of animals such as insects and rats.
- 5.2 Interior architectural structure**
Relevant requirements of GB 12693 shall be met.
- 5.3 Facilities**
- 5.3.1 Water supply facilities**
Relevant requirements of GB 12693 shall be met.
- 5.3.2 Drainage system**
Relevant requirements of GB 12693 shall be met. Within the cleaning work area, appropriate facilities shall be provided or appropriate measures shall be taken to keep dry so as to avoid the growth and spread of relevant microbes caused by production of water residue.
- 5.3.3 Cleaning facilities**
- 5.3.3.1** Relevant requirements of GB 12693 shall be met.
- 5.3.3.2** For cleaning work area requiring to keep dry, the following measures shall be taken:
- Dry cleaning process applicable to the plate and equipment shall be used; or
 - If the dry cleaning means are unavailable, wet cleaning may be used under controlled condition, but the equipment and environment shall be restored to dry completely in time to protect the area from contamination.
- 5.3.4 Personal hygiene facilities**
- 5.3.4.1** Relevant requirements of GB 12693 shall be met.
- 5.3.4.2** The dressing room and hand-washing disinfection room shall be arranged near the entrance to the processing workshop or at an appropriate place. Adequate non-manual faucets, disinfecting facilities and automation inductive hand drying facilities shall be provided in the hand-washing disinfection room.
- 5.3.4.3** Cleaning means shall be provided at the entrances of the workshops to avoid the contamination of footwear to workshops.
- 5.3.4.4** A second dressing room shall be provided at the entrance of the cleaning work area, and the hand disinfection facilities shall be provided before entry of the cleaning work area.
- 5.3.5 Ventilation facilities**
Relevant requirements of GB 12693 shall be met.

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5.3.7 Warehousing facilities

Relevant requirements of GB 12693 shall be met.

6 Equipment**6.1 Production equipment****6.1.1 General requirements**

Relevant requirements of GB 12693 shall be met.

6.1.2 Materials

Relevant requirements of GB 12693 shall be met.

6.1.3 Design**6.1.3.1 The production equipment shall conform to the relevant requirements of GB 12693.****6.1.3.2 The production of the powdered formulae for infants and young children is classified into the dry-mix process and the wet-mix process (including the combined process), and the corresponding production equipment shall be equipped according to the process demand.****6.1.3.3 The production equipment shall be marked with obvious running status and being repaired, maintained and verified regularly. The installation, repair and maintenance of the equipment shall not affect the quality of products. The repaired equipment shall be verified or confirmed to ensure that all performances meet the process requirements. Non-conforming equipment shall be removed from the production area, and shall be marked with obvious sign before removal.****6.1.3.4 Compressed air or other inert gases for food and cleaning food contact surfaces or equipment shall be subject to filtration and purification treatment to prevent any indirect contamination.****6.2 Monitoring equipment**

Relevant requirements of GB 12693 shall be met.

6.3 Maintenance and repair of equipment

Relevant requirements of GB 12693 shall be met.

7 Hygiene management**7.1 Hygiene management system**

Relevant requirements of GB 12693 shall be met.

7.2 Hygiene management for plant and facilities

Relevant requirements of GB 12693 shall be met.

7.3 Cleaning and disinfection**7.3.1 Relevant requirements of GB 12693 shall be met.****7.3.2 For the cleaning work area involving dry process (such as dry mix, filling and packaging), dry cleaning process for the production equipment and processing environment is the most effective measure to avoid the microbial reproduction, and the wet cleaning shall be avoided as much as possible. The wet cleaning shall be only available for the equipment components that can be handled to a special room or the circumstance that dry measures can be taken immediately after wet cleaning.**

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relevant provisions and standard requirements, especially to ensure the applicability of cleaning and infecting plan, appropriate concentration of cleaning agents and disinfectants, and to ensure that the CIP system conforms to the relevant temperature and time requirements. The equipment shall be washed properly when necessary.

7.3.4 Cleaning and disinfection schedule shall be formulated for all production workshops to ensure that all areas are cleaned, and special cleaning shall be made for important area, equipment and instrument.

7.3.5 The number of the cleaners shall be guaranteed and the responsibilities of each person shall be clarified as required; all the cleaners shall be well trained, and understand the hazard of contamination and importance of preventing contamination; and record shall be made for cleaning and disinfection.

7.4 Personal health and hygiene requirement

7.4.1 Relevant requirements of GB 12693 shall be met.

7.4.2 The employees at the cleaning work area shall wear work clothes (or disposable work clothes) conforming to hygiene requirements of the area, and wear hats, masks and footwear. The employees at the quasi-cleaning work area and commonly work area shall wear the work clothes conforming to hygiene requirements of the corresponding area, and hats and footwear. The work clothes and footwear used in the quasi-cleaning work area and commonly work area can not be worn outside the specified areas.

7.5 Insect control

Relevant requirements of GB 12693 shall be met.

7.6 Waste disposal

Relevant requirements of GB 12693 shall be met.

7.7 Management of toxic and hazardous substances

Relevant requirements of GB 12693 shall be met.

7.8 Sewage and dirt management

Relevant requirements of GB 12693 shall be met.

7.9 Work clothes management

Relevant requirements of GB 12693 shall be met.

8 Requirements for raw materials and packing materials

8.1 General requirements

Relevant requirements of GB 12693 shall be met. Raw materials to be used shall conform to the requirements of national standards and (or) related regulations, shall ensure the safety of infants and young children, and satisfy nutritional requirements, and substances harmful to nutrition and health of infants and young children and non-food substances shall not be used or added.

8.2 Purchase and acceptance requirements for raw materials and packing materials

8.2.1 Relevant requirements of GB 12693 shall be met.

8.2.2 For the raw materials entering the dry-mix process directly, enterprises shall take measures to ensure that the microbial indexes of the raw materials conforms to the requirements of product standard, and ensure that the urease activity of soybean is

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8.3 Transport and storage requirements for raw materials and packing materials**8.3.1** Relevant requirements of GB 12693 shall be met.**8.3.2** Food additives and food nutritional fortification substances shall be managed by special persons, and stored in special warehouse or area, and special register (or warehouse management software) shall be used to record the names, purchasing dates, purchasing volumes and use amount of the additives and nutritional fortification substances, and their terms of validity shall be kept in mind.**8.3.3** Vitamins, microelements and other nutritional fortification substances susceptible to quality change during storage shall be subject to raw material qualification, and shall be inspected when necessary to ensure that they meet the raw material requirements.**8.4 The purchase, acceptance, storage and transport records of raw materials and packing materials shall be kept.****9 Food safety control in production****9.1 Control of microbial contamination****9.1.1** Relevant requirements of GB 12693 shall be met.**9.1.2** When there is any deviation in the monitoring results of control measures, appropriate corrective measures shall be taken.**9.2 Control of chemical contamination**

Relevant requirements of GB 12693 shall be met.

9.3 Control of physical contamination

Relevant requirements of GB 12693 shall be met.

9.4 Food additives and nutritional fortification substances

Relevant requirements of GB 12693 shall be met.

9.5 Packing materials

Relevant requirements of GB 12693 shall be met.

9.6 Specific processing procedures

All processing procedures in production process of the powdered formulae for infants and young children shall conform to the requirements of the specific processing procedures of dry-mix process or wet-mix process, and shall conform to the following requirements:

9.6.1 Heat treatment (wet-mix process and combined process)

The heat treatment procedure shall be considered as a critical control point for ensuring the safety of powdered formulae for infants and young children. For temperature and time of the heat treatment, the impact of product attributes and other factors (e.g. fat content, total solid content) on thermal resistance of targeted microbes shall be taken into account. So relevant processes shall be formulated to check whether the temperature and time are deviated, and appropriate corrective measures shall be taken.

If the soybean purchased is not heated for enzyme inactivation (or experiences incomplete enzyme inactivation), such soybean-based products shall achieve the effect of killing pathogenic bacteria and complete enzyme inactivation simultaneously by heat treatment (urease is negative), and be monitored as the critical control point.

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9.6.2 Intermediate storage

During the wet-mix process and combined process, corresponding measures shall be taken for the intermediate storage of liquid semi-finished products to prevent the microbial growth. The bare raw material powder in the dry-mix production or the bare powdered semi-finished products in the wet-mix production shall be kept in the cleaning work area.

9.6.3 Process procedure from heat treatment to drying

From heat treatment to drying, all transport pipes and equipment shall be kept enclosed and be thoroughly cleaned and disinfected regularly.

9.6.4 Cooling

During the wet-mix process and the combined process production, the dried bare semi-finished powder shall be cooled in the cleaning work area.

9.6.5 Dry mixing

During the dry-mix process and the combined process, the following key factors shall be controlled in dry mixing:

9.6.5.1 The bare powder process (e.g. premixing, filling, batching and feeding) in contact with air environment shall be made in the cleaning work area. The temperature and relative humidity in the cleaning work area shall be compatible with the production process of the powdered formulae for infants and young children. If there is no special requirement, the temperature shall be not higher than 25 °C, and the relative humidity shall be below 65%.

9.6.5.2 Ingredients shall be weighed accurately.

9.6.5.3 The key process parameters (e.g. mixing time) related to mixing uniformity shall be verified; the mixing uniformity shall be confirmed.

9.6.5.4 The inner wall of equipment in contact with materials shall be smooth, flat, free of dead space, easy to clean and corrosion resistant, and its inner surface layer shall be made of materials which will not react with the materials, release particles or absorb materials.

9.6.5.5 Compressed air required by transporting materials at positive pressure can be used only after degreasing, dehydration, cleaning, filtering and sterilization treatment.

9.6.5.6 For raw materials, packing materials and personnel, strict hygienic control requirements shall be formulated. The raw materials shall enter the work area through the material channel after necessary cleaning procedures and shall subject to the procedures of removing outer package or experiencing outer package disinfection. Operating personnel shall enter the cleaning work area after the procedures of secondary dressing and hand cleaning and disinfection to ensure hand hygiene of the related personnel, and they shall wear work clothes, hoods, change shoes or wear shoe covers.

9.6.6 Inner packing procedure

The following key factors shall be controlled:

9.6.6.1 The inner packing procedure shall be carried out in the cleaning work area.

9.6.6.2 Only the related personnel shall be allowed to enter the packing room, and please refer to 9.6.5.6 for the requirements for raw materials, packing materials and personnel.

9.6.6.3 Before use, the outer package of the packing material shall be checked for intactness to ensure that the packing materials are uncontaminated.

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foreign matters, and process monitoring or effectiveness verification shall be performed for these measures.

- 9.6.6.5** When products of various types are produced in the same production line, the production line shall be effectively cleaned and site clearance records shall be kept to ensure that products switching will not affect products of the next batch.

9.6.7 Production water control

The production water and equipment cleaning water in direct contact with food shall conform to the relevant requirements of GB 5749. Circulating water, ice, steam and water for other purpose shall conform to the relevant requirements of GB 12693.

9.7 Product information and labels

- 9.7.1** Product labels shall conform to GB 13432, national standards for corresponding products and other relevant national regulations.

- 9.7.2** The labels shall indicate reconstitution method, reconstitution water, storage method of the products and other information, and shall guide customers to prevent the practice that may cause foodborne diseases due to improper use of the products when preparing and handling the products and feeding.

10 Inspection

- 10.1** Relevant requirements of GB 12693 shall be met.

- 10.2** Representative samples of finished products shall be taken batch by batch, including the first finished product after packing every day and other sampled finished products, and inspected according to provisions of relevant national regulations and standards.

11 Storage and transport of products

Relevant requirements of GB 12693 shall be met.

12 Product tracing and recall

Relevant requirements of GB 12693 shall be met.

13 Training

Relevant requirements of GB 12693 shall be met.

14 Management institution and personnel

Relevant requirements of GB 12693 shall be met.

15 Record and document management

15.1 Record management

Relevant requirements of GB 12693 shall be met.

15.2 Document management

Relevant requirements of GB 12693 shall be met.

16 Monitoring and evaluation of effectiveness of food safety control measures

The monitoring and evaluation measures in Annex A shall be used to ensure the effectiveness of food safety control measures

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Annex A
(Normative)
Environmental Monitoring Guide for Salmonella, Enterobacter Sakazakii and Other Enterobacteriaceae in Cleaning Work Area of Powdered Formulae for Infants and Young Children

- A.1** For a few enterobacteriaceae (EB for short) may exist in the production environment with good hygiene condition, including enterobacter sakazakii (*Cronobacter*), the pasteurized products may be contaminated by the environment, causing trace amount of enterobacteriaceae in the finished products. Therefore, the enterobacteriaceae in the production environment shall be monitored to confirm effectiveness of hygiene control procedure, and the manufacturers shall take corrective measures in time when there is any deviation. The basic data of the hygiene conditions is obtained by continuous monitoring and trend change shall be tracked. Practices of some manufacturers indicate that decreasing the amount of enterobacteriaceae in environment can reduce the amount of enterobacteriaceae (including enterobacter sakazakii and salmonella) in the finished products.

In order to prevent contamination and limitation of microbes in finished products for sampling inspection, environmental monitoring plan shall be formulated. The monitoring plan may act as a food safety management tool to evaluate the hygiene condition in the cleaning work area (dry area) and as a basic procedure of HACCP.

When formulating the monitoring plan, the following ecological characters of salmonella, enterobacter sakazakii and other enterobacteriaceae shall be considered:

- A.1.1** Although salmonella is seldom found in dry environment, a monitoring plan shall be formulated to prevent entry of salmonella, evaluate the effectiveness of the hygiene control measures in the production environment, and guide the related personnel to prevent further spread in case of salmonella detection.
- A.1.2** Enterobacter sakazakii is more often to be found than salmonella in the dry environment. Enterobacter sakazakii are easily detected if proper sampling and test methods are used. A monitoring plan shall be formulated to evaluate whether the amount of enterobacter sakazakii increase, and effective measures shall be taken to prevent growth.
- A.1.3** Enterobacteriaceae is widely distributed, are a kind of common coliform in dry environment, and easily detected. Enterobacteriaceae may act as indicator bacteria for production process and environmental hygiene condition.
- A.2** Factors to be considered while designing sampling plan
- A.2.1** Product varieties and process

The requirements and scope of the sampling plan shall be determined according to product characters, customer ages and hygiene conditions. For all kinds of products in this Standard, salmonella is specified as a pathogenic bacterium; while for some products, enterobacter sakazakii are specified as a kind of pathogenic bacteria.

Monitoring shall focus on the area where microbes can conceal and generate easily, e.g. the cleaning work area in dry environment. Special attention shall be paid to the boundary between this area and its neighbor area with lower hygiene level and the place that is close to production line and equipment is contaminated easily, for example, the opening in enclosed equipment for occasional inspection. The known or possible contaminated

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The monitoring plan shall contain the following two samples:

A.2.2.1 Samples shall be taken from the surfaces which do not contact food, e.g. ground, pipes and platform outside the equipment and around the production line. Under these conditions, degree of contamination risk and contaminant content will depend on the location and design of the production line and equipment.

A.2.2.2 Samples shall be taken from the surface in direct contact with food, such as the equipment that may contaminate products directly from powder spray tower to package, and microbes generate easily for the clots at tail of the screen absorb water. If there are indicator bacteria, enterobacter sakazakii or salmonella on food contact surface, the product contamination risk is high.

A.2.3 Target microbes

Salmonella and enterobacter sakazakii are the main target microbes, and enterobacteriaceae can act as the hygiene indicator. The enterobacteriaceae content shows the possibility of the existence of salmonella, and the growth conditions of salmonella and enterobacter sakazakii.

A.2.4 Sampling points and sample size

The sample size changes with the complexity of the process and the production line.

The sampling points shall be the places where microbes may hide or enter to cause contamination. The sampling points can be determined according to related documentations, and also can be determined according to experience and professional knowledge or historical data collected by factory contamination survey. The sampling points shall be evaluated regularly, and necessary sampling points shall be added in the monitoring plan according to special conditions, such as important maintenance and construction activities or worsening of the hygiene condition.

The sampling plan shall be comprehensive and representative, and scientific and reasonable sampling shall be performed at the production shifts of different types and different periods of these shifts. In order to verify the effectiveness of cleaning measures, sampling shall be made before startup for production.

A.2.5 Sampling frequency

The sampling frequency shall be decided according to factors in A.2.1, and be determined according to the data about existence of microbes in all current areas covered by the monitoring plan. If such data is unavailable, sufficient data shall be collected to determine reasonable sampling frequency, including collecting the occurrence of salmonella or enterobacter sakazakii for a long time.

The frequency of implementing the monitoring plan shall be adjusted according to the detection results and degree of contamination risk. When the quantity of pathogenic bacteria or indicator bacteria detected in finished product increases, environmental sampling and survey sampling shall be enhanced to determine the contamination sources. When the risk of contamination increases (e.g. after maintenance, construction or wet cleaning), the sampling frequency shall be increased properly.

A.2.6 Sampling tools and methods

The sampling tools and methods shall be chosen according to surface type and sampling location, for example, scraping the residue on the surface or powder in vacuum cleaner as samples directly, for bigger surface, wiping and sampling by sponge (or cotton swab)

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The analysis methods shall be capable of detecting the target microbes effectively, have acceptable sensitivity and related records. On the premise of ensuring the sensitivity, several samples may be mixed for detection. If positive result is detected, location of the positive sample shall be further determined. If necessary, gene technology can be used to analyze enterobacter sakazakii sources and the related information of contamination route of powdered formulae for infants and children.

A.2.8 Data management

The monitoring plan shall contain data record and evaluation system, e.g. trend analysis. The data must be subject to continuous evaluation so as to modify and adjust the monitoring plan properly. Effective management shall be performed on the data of enterobacteriae and enterobacter sakazakii, and the neglected mild or intermittent contamination may be found.

A.2.9 Corrective measures of positive results

The monitoring plan aims to find whether the target microbe exists in environment. Before formulating the monitoring plan, acceptance standard and corresponding measures shall be prepared. The monitoring plan shall specify specific measures and clarify the corresponding reasons. The relevant measures include being actionless (no risk of contamination), enhancing cleaning, tracing contamination sources (adding environmental test), evaluating hygiene measures, detaining and testing products.

The manufacturers shall formulate the measures after detecting enterobacteriae and enterobacter sakazakii so as to response accurately in case of exceeding standard. The hygiene procedures and control measures shall be evaluated. When salmonella is detected, corrective actions shall be taken immediately, the trend of enterobacter sakazakii and the change in quantity of enterobacteriae shall be evaluated, and the action to be taken shall depend on the possibility that the products are contaminated by salmonella and enterobacter sakazakii.