



**National Food Safety standard of the People's Republic of China**

GB 23790—2010

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**National food safety standard  
Good manufacturing practice for powdered formulae for  
infants and young children**

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## Foreword

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

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

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

- The name of the standard was modified to *Good manufacturing practice for powdered formulae for infants and young children*
- Recommended standard was modified to compulsory standard;
- Frame of standard provisions was modified;
- The relevant requirements on the raw material purchasing, acceptance and storage were supplemented;
- Food safety control measures of the production process was modified, special processing steps of safety control were supplemented; the control requirements of key processes as heating treatment, intermediate storage, cooling, dry mixing and internal packaging were formulated; and key control measures on microbial, chemical and physical pollution referred to the provisions of GB 12693-2010;
- Requirements on the safety control of soybean raw materials were supplemented;
- The monitoring and evaluation method of food safety control measures were supplemented;
- Annex A was supplemented, which specified the requirements on the major source of pollution - Salmonella, E. Sakazakii and other Enterobacter on the clean work areas.

Annex A to this national standard was normative.

This Standard supersedes the following standard:

- GB/T 23790-2009.



# National food safety standard

## Good Manufacturing Practice for Powdered Formulae for Infants and young children

### 1. Scope

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) with the main raw materials of milks or soybeans and its processing products.

### 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.

### 3. Terms and definitions

#### 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; Keep away from livestock farms. Keeping animals in the factory areas is prohibited.

#### 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, especially contamination caused by *Salmonella* and *Enterobacter sakazakii* (*Cronobacter* genus). At the same time, avoid or minimize the possibility of existence or reproduction of such bacteria at the hiding place. The design should take account of the following factors to avoid propagation of microorganisms:

5.1.2.1 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.

5.1.2.2 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.

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

5.1.2.4 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.

5.1.2.5 Do a good job of the enclosure and sealing of various types of pipes, cables and perforation gaps passing through building floor, ceiling and walls.

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 The production areas should be divided according to the production process and sanitation, and quality requirements. In principle, it is divided into common work area, cleaning work area, quasi-cleaning work area. Cleaning work area should be provided with independent air purification system with filtration devices and maintain a positive pressure differential.

- 5.1.6 Effective physical separation should be established between different cleaning grade of work areas. The clean work area should main a positive pressure differential to prevent non-purified air to access to the clean work area and cause cross-contamination.
- 5.1.7 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, footwear 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.
- 5.1.8 Clean level of each work area must satisfy the requirements for air purification in the processing of powdered formulae for Infants and young children. The air cleanliness in cleaning work area and quasi-cleaning work area should meet the requirements set ou in Table 1, and regular inspection should be carried out.

Table 1 Requirements on the control of air cleanliness in cleaning work area and quasi-cleaning work area

Work area		Aerobic bacterial count per petri dish (cfu/dish)	Test method
Cleaning work area	≤	30	Determine in accordance with the natural sedimentation method in GB/T 18204.1
Quasi-cleaning work area	≤	50	

- 5.1.9 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.
- 5.1.10 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 Internal building structure
- Shall meet the relevant specifications of GB 12693.
- 5.3 Facilities
- 5.3.1 Water supply facility
- Shall meet the relevant specifications of GB 12693.
- 5.3.2 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.
- 5.3.3 Cleaning facility

5.3.3.1 Shall meet the relevant specifications of GB 12693.

5.3.3.2 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.

#### 5.3.4 Personal health facilities

5.3.4.1 Shall meet the relevant specifications of GB 12693.

5.3.4.2 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.

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

5.3.4.4 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.

#### 5.3.5 Ventilation facility

Shall meet the relevant specifications of GB 12693.

#### 5.3.6 Lighting facility

Shall meet the relevant specifications of GB 12693.

#### 5.3.7 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.

7.3.3 Effective monitoring process 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 applicability of cleaning and disinfection programs, the appropriate concentration of cleaning agents and disinfectants, and the CIP system meets the relevant temperature and time requirements, and equipments are cleaned rationally when necessary.

7.3.4 All workshops should develop washing (or cleaning) and disinfecting periodic table, to

ensure that all areas are cleaned and the important areas, equipments and tools are specially cleaned.

- 7.3.5 Ensure the quantity of the cleaning staff member, and if necessary, define individual responsibilities; all personnel responsible for cleaning should be subject to good training, be aware of the hazardness of contamination and the importance of pollution prevention; do a good job of cleaning and disinfection.

#### 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.

### **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 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 and non-edible substances 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 validated and when necessary, 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 Control of microbial contamination

9.1.1 Shall meet the relevant specifications of GB 12693.

9.1.2 When the monitoring results on the control measures indicate any deviations, appropriate corrective measures should be taken.

### 9.2 Control of chemical pollution

Shall meet the relevant specifications of GB 12693.

### 9.3 Control of physical pollution

Shall meet the relevant specifications of GB 12693.

### 9.4 Food additives and food nutrition enhancer

Shall meet the relevant specifications of GB 12693.

### 9.5 Packaging materials

Shall meet the relevant specifications of GB 12693.

### 9.6 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:

#### 9.6.1 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.

The time, temperature and enzyme inactivation time and other key process parameters should be recorded in the production process.

#### 9.6.2 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.

#### 9.6.3 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.

#### 9.6.4 Cooling

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

#### 9.6.5 Dry-mix

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

9.6.5.1 Exposed powder procedure contacting air (such as pre-mix and subpackaging, 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 25°C, and relative humidity should be controlled below 65%.

9.6.5.2 Materials should be accurately batched.

9.6.5.3 Key process parameters related to mixing homogeneity (such as mix time, etc.) Should be validated and confirmed. Mixing homogeneity should be confirmed.

9.6.5.4 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.

9.6.5.5 Compressed air required for material transport in positive pressure should be

used after being deoiled, filtered, dehydrated and sterilized.

9.6.5.6 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.

#### 9.6.6 Inner packaging procedure

The following key factors should be controlled:

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

9.6.6.2 Only related working personnel are allowed to enter package room. Refer to specification of Clause 9.6.5.6 for requirements for raw and packaging materials and personnel.

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

9.6.6.4 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.

9.6.6.5 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.

#### 9.6.7 Control on 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.

#### 9.7 Product information and label

9.7.1 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.

9.7.2 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 foodborne diseases caused by improper use of product during the course of reconstitution and handling and feeding of the product.

### 10. Product inspection

10.1 Shall meet the relevant specifications of GB 12693.

10.2 Representative samples of finished products should be selected batch by batch, including the first finished product and other sampling finished products after daily packaging. Inspection should be carried out in accordance with the relevant state laws, regulations and standards.

### **11. Product storage and transportation**

Shall meet the relevant specifications of GB 12693.

### **12. Product traceability and recall**

Shall meet the relevant specifications of GB 12693.

### **13. Training**

Shall meet the relevant specifications of GB 12693.

### **14. Management organization and personnel**

Shall meet the relevant specifications of GB 12693.

### **15. Records and document management**

#### 15.1 Records Management

Shall meet the relevant specifications of GB 12693.

#### 15.2 Document Management

Shall meet the relevant specifications of GB 12693.

### **16. Monitoring and evaluation of effectiveness of food safety control measures**

The monitoring and evaluation measures in Annex A should be adopted to ensure the effectiveness of food safety control measures.

## Annex A

### (Normative)

#### Environment Monitor Guide for Salmonella

##### **Enterobacter sakazakii and other Enterobacteriaceae bacteria in Cleaning Work Area of Powdered Formulae For Infants and young children**

A.1 As these still exists small quantity of Enterobacteriaceae (EB) in production environment with good sanitary conditions, including Enterobacter sakazakii (Cronobacter genus), pasteurized product may be contaminated by environment, causing existence of a trace of Enterobacteriaceae in final product. Therefore Enterobacteriaceae in production environment should be monitored to confirm if sanitation control procedure is effective or not. Production enterprises should take corrective measures in time. Acquire basic data of sanitation status by way of continuous monitor and follow up the change in trend. The related factory practices show that reduction of the quantity of Enterobacteriaceae (including Enterobacter sakazakii and Salmonella) in environment may decrease that in final product.

To prevent from occurrence of contamination incidents, avoid limitation of microbiological test on randomly selected samples of final product, Environment monitor programme should be formulated. Monitor programme may serve as a food safety management tool to implement evaluation on sanitation status of cleaning work area (dry area), and also serve as a basic program of HACCP.

Monitor programme should be formulated based on the following ecological features of Salmonella, Enterobacter sakazakii and other Enterobacteriaceae:

A.1.1 It seldom discovers Salmonella in dry environment, whereas monitor programme is still required to prevent from its invasion, evaluate the effectiveness of sanitation control measures in production environment and give directions for related personnel to prevent from further spread when Salmonella is detected.

A.1.2 Compared with Salmonella, it is easier to discover Enterobacter sakazakii in dry environment. If suitable sampling and testing method is adopted, Enterobacter sakazakii can be more easily detected. Monitor programme should be formulated to evaluate if Enterobacter sakazakii increases or not, and effective measures should be taken to prevent from its growth.

A.1.3 Enterobacteriaceae is widely spread as it is a common colony in dry environment, and can be easily detected. Enterobacteriaceae may serve as the indicator bacteria of sanitation status in production process.

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

A.2.1 Product category and process

Requirement and scope of sampling scheme should be determined according product characteristics, customers' age and health status. In this national standard, Salmonella is defined as pathogenic bacteria in various categories of products, and Enterobacter sakazakii is defined as pathogenic bacteria in partial products.

Emphasis of monitor should be placed on areas where it is easy for microorganisms to

hide and grow, such as cleaning work area in dry environment. Extra attention should be paid to the boundary of such areas and their adjacent areas with lower clean level, places close to production line and equipment that are likely to be contaminated, such as opening for occasional inspection on closed equipment. Priority should be given to the areas where contamination has existed or may exist.

#### A.2.2 Sample type

Monitor programme should cover the following two types of samples:

A.2.2.1 Sample drawn from surface never contacting food, such as outside of equipment and ground of around production line, pipe and platform. In these cases, contamination risk degree and contaminant content depends on location of production line and equipment and design.

A.2.2.2 Sample drawn from surface directly contacting food, such as powder spray tower and other equipment that may directly contaminate product before packaging, for example, microorganisms are easy to grow in agglomerated powder formulae at screen tail due to absorption of water content. If indicator microorganism *Enterobacter sakazakii* or *Salmonella* exists on food-contacting surface, it indicates a high risk of product contamination.

#### A.2.3 Target microorganisms

*Salmonella* and *Enterobacter sakazakii* are the main target microorganisms, whereas Enterobacteria can serve as sanitation indicator. EB content shows possible existence of *Salmonella* and condition for *Salmonella* and *Enterobacter sakazakii* growth.

#### A.2.4 Sampling points and sample size

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

Sampling points should be the places that may be contaminated by hidden or invaded microorganisms. Sampling points may be determined according to relevant literatures, or experience and professional knowledge or historical data collected in factory contamination investigation. Sampling points should be evaluated on a regular basis. Necessary sampling points should be added in monitor programme in special cases, such as overhaul, construction activity or when sanitation condition get worse.

Sampling scheme should be all-around and representative, and samples should be drawn scientifically and reasonably by taking account of different types of production shifts and different periods of time in these shifts. To validate the effect of cleaning measures, sample should be drawn before starting production.

#### A.2.5 Sampling frequency

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

Implementation frequency of environment monitor programme should be adjusted



according to test results and serious degree of contamination risks. When pathogenic bacteria are detected or quantity of indicator microorganism increases in final product, environment sampling and investigation should be strengthened to determine the contamination source. When contamination risk increases (such as after maintenance, construction or wet cleaning), sampling frequency should also increase.

#### A.2.6 Sampling tool and method

Sampling tool and method should be selected according to surface type and sampling point. For example, directly scrape surface residues or dust in cleaner as sample. Swab sample from relatively great surfaces with sponge (or swab).

#### A.2.7 Analysis method

Analysis method should be capable of effective detection of target microorganisms, with an acceptable sensitivity and related records. On the premise of ensuring sensitivity, many samples may be mixed for detection. If positive result occurs, further detection is required to determine the position of positive sample. If required, gene technology may be applied to analyze information related to source of *Enterobacter sakazakii* and contamination path of powdered formulae for Infants and young children.

#### A.2.8 Data management

Monitor programme should cover data records and evaluation system, such as trend analysis. Data must be subject to continuous evaluation in order to modify and adjust monitor programme accordingly. Implementation of effective management for Enterobacteriaceae and *Enterobacter sakazakii* may help discover mild or intermittent contamination that may be ignored.

#### A.2.9 Corrective measure for positive results

The purpose of monitor programme is to discover the existing target microorganisms in environment. Before working out the monitor programme, acceptance criteria and countermeasures should be formulated. Monitor programme should specify the specific actions and explain the related reasons. Related measures include: taking no action (as there is no contamination risk), strengthening cleaning, tracking contamination source (increasing environmental tests), evaluating sanitary measures, detaining and testing products.

Production enterprises should formulate actions after Enterobacteriaceae and *Enterobacter sakazakii* are detected so that out-of-specification cases can be dealt with accurately. Sanitation procedure and control measures should be evaluated. Corrective actions should be taken immediately after *Salmonella* is detected. In addition, *Enterobacter sakazakii* trend and change in Enterobacteriaceae quantity should be evaluated; Which kind of action should be taken depends on possibility of product contamination by *Salmonella* and *Enterobacter sakazakii*.