



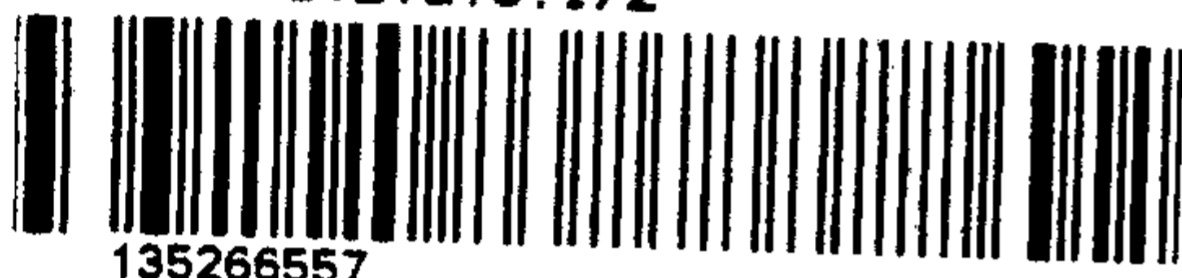
Ministero della Salute

DIPARTIMENTO DELLA SANITA' PUBBLICA VETERINARIA, DELLA SICUREZZA
ALIMENTARE E DEGLI ORGANI COLLEGIALI PER LA TUTELA DELLA SALUTE
DIREZIONE GENERALE PER L'IGIENE E LA SICUREZZA DEGLI ALIMENTI E DELLA
NUTRIZIONE
UFFICIO IX ex DGSAN

Ministero della Salute
DGSAN

0006828-P-27/02/2014

I.2.a.c.1/2



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Regioni e
Province Autonome di Trento e Bolzano
Servizi Veterinari
LORO SEDI

Associazioni di categoria
Loro sedi

E p.c. D.S.V.E.T.O.C.
Ufficio III

Oggetto: Cina - Registrazione degli stabilimenti che producono latte e derivati del latte e prodotti "infant formula"

L'Ambasciata italiana a Pechino ha fatto pervenire a questo Ministero la nota riguardante la richiesta da parte delle Autorità cinesi di disporre ufficialmente di una lista di stabilimenti ritenuti idonei per l'esportazione in Cina di:

- a) latte e prodotti a base di latte;
- b) prodotti "infant formula".

Le procedure di registrazione per le due fattispecie sono differenti; pertanto qualora uno stabilimento produca entrambi i prodotti dovrà compilare le due modulistiche.

L'obbligo di registrazione riguarda sia gli impianti già registrati nel sito dell'AQSIQ sia quelli nuovi che intendono avviare l'attività di esportazione verso la Repubblica Popolare cinese.

Al fine della registrazione gli O.S.A. interessati alla esportazione di prodotti di cui alla lettera a) dovranno fare richiesta alla propria Autorità sanitaria competente che compilerà la dichiarazione di conformità **all'allegato 1** e la specifica dei prodotti elencati che si intende esportare **all'allegato 2**.

Gli OSA invece interessati alla esportazione di prodotti di cui alla lettera b) dovranno fare richiesta alla propria Autorità sanitaria competente e compilare in lingua inglese anche il questionario di cui **all'allegato 3**.

La documentazione dovrà essere trasmessa ai Servizi Veterinari regionali che provvederanno all'invio per posta certificata a questo Ministero al seguente indirizzo export.alimenti@sanita.it.

Il formulario (allegato 3) per la registrazione degli stabilimenti che producono prodotti "infant formula" richiede che l'impianto sia riconosciuto per tale produzione. Il prodotto deve in ogni caso rispondere alla legislazione europea.

Relativamente alla compilazione del modulo (allegato 3) per i prodotti "infant formula" si evidenziano i seguenti aspetti:

Parte 1, lettera A

- ➡ punto 1: per numero di registrazione si intende il marchio di identificazione;
- ➡ punto 3: per autorità registrante si intende l'Autorità sanitaria competente per lo stabilimento.
- ➡ punto 5: per data della costruzione dello stabilimento deve intendersi la data dell'ultima ristrutturazione;
- ➡ punto 8: si intendono i layout dello stabilimento;
- ➡ punto 9: per marchio registrato deve intendersi il nome commerciale riportato in etichetta. In ogni caso per tipo di prodotto, sono ammessi anche i prodotti di cui alle direttive 2006/141 e 1999/21 e 2009/39.

Considerato che le liste devono pervenire alle Autorità cinesi entro il 1° maggio, le domande dovranno essere inviate a questo Ministero entro il 4 aprile 2014.

Si coglie l'occasione per dare alcune indicazioni in materia di etichettatura fornite dalla nostra Ambasciata:

a) dal 1.04.2014 tutti i prodotti alimentari destinati ad essere esportati in Cina dovranno riportare le indicazioni in lingua cinese già sulla confezione all'origine e non farla apporre dall'importatore;

b) sulla confezione è richiesta l'indicazione del distributore cinese e non dell'importatore che deve essere registrato sul sito di AQSIQ così come un eventuale cambio dell'importatore. Il distributore ed i dati relativi ai suoi contatti dovranno invece essere stampati già sulla confezione; nessuna correzione è permessa. Ne consegue, quindi, che il cambio del distributore implica la ristampa della confezione.

Al fine di fornire un riferimento normativo, si trasmette l'**allegato 4** GB 12693-2010 sulle GMP cinesi per i prodotti lattiero caseari.

Si rappresenta che gli stabilimenti che producono prodotti di cui alla citata lettera b) potranno essere autorizzati all'esportazione solo dopo una ispezione diretta (data da definire) da parte di esperti cinesi.

Nel chiedere a Codesti Assessorati di voler cortesemente informare di quanto sopra i Servizi Veterinari territorialmente competenti si ringrazia per la collaborazione.

IL DIRETTORE GENERALE
(Dr. Silvio Benello)

Official declaration of conformity

To the kind attention of the Certification and Accreditation Administration of the People's Republic of China (CNCA)

The Local Veterinary Unit of..... requires to update the list of the establishments of ITALY, Region....., which are interested to export registered milk products in the People's Republic of China, and in particular:

- a) New establishment (Name, address and approval number):.....
.....
- b) Establishment already registered, interested to amend its data:.....
.....
- c) Cancellation of establishment:.....
.....

I, undersigned official veterinarian, hereby certify that the establishment are newly registered in conformity with the hygienic requirements of the People's Republic of China and Italy.

Signature and stamp of the official veterinarian

Done at:.....

On.....

Paese 国家/ Regione 地区 :

Lista stabilimenti che producono prodotti lattiero – caseari richiedenti la registrazione (escludi quelli che producono latte in polvere e liquido per bambini) 申请在华注册的乳品(婴幼儿配方乳品除外)生产企业名单							
Nr di registrazione 注册编号	Nome dello stabilimento 企业名称	Luogo di registrazione 注册地址	Citta' / contea 市/县	Provincia/ Regione 洲/省/区	Tipo di stabilimento 企业类型	Prodotto 产品	Note 备注

Data 日期

Timbro dell' autorità 官方印章

Tipo di stabilimento : PP stabilimento per la lavorazione
 CS magazzino refrigerato
 Dry Store magazzino non refrigerato

Tipologia di prodotti registrati /注册产品品种

Latte pastorizzato /巴氏杀菌乳
 Latte sterilizzato/灭菌乳
 Latte modulato/调制乳
 Altri tipi di latte sterilizzati/其它消毒乳
 Latte fermentato/发酵乳
 Latte fermentato aromatizzato/发酵风味乳
 Latte in polvere/乳粉
 Latte in polvere intero/ 全脂乳粉
 Latte in polvere parzialmente scremato/部分脱脂乳粉
 Latte in polvere dolcificato/全脂加糖乳粉
 Latte in polvere scremato/脱脂乳粉

Latte in polvere aromatizzato /调味乳粉
 Latte artificiale in polvere / 配方乳粉
 Latte artificiale in polvere fortificato/ 营养强化配方乳粉
 Altro latte artificiale in polvere/其他乳粉
 Burro/黄油
 Panna/稀奶油
 Altri grassi caseari/其他奶油
 Latte condensato/炼乳
 Latte condensato dolcificato/加糖炼乳
 Latte evaporato/无糖炼乳
 Altri tipi di latte condensato/其他炼乳

Formaggio/干酪
 Formaggio duro/硬质干酪
 Altri tipi di formaggio/其他奶酪
 Siero in polvere demineralizzato/ 脱盐乳清粉
 Siero in polvere /乳清粉
 Proteine di siero concentrato/乳清浓缩蛋白粉
 Altri tipi di siero in polvere/其他乳清粉
 Altro latte e prodotti derivati/其他乳与乳制品

Note 备注

prodotti lattiero-caseari bovini/ 牛奶
 prodotti lattiero-caseari ovini o caprini/羊奶
 prodotti lattiero-caseari di bovini selvatici, bufalini e yak/野牛,水牛及牦牛等



Imported Milk-based Infant and Follow on Formula (Formula Milk Powder and Liquid)

Overseas Production Enterprise Registration Application Form

NOTE: This application on foreign dairy products producing, processing and storage is required by CNCA for evaluation and registration to export dairy products to China. All information must be submitted in Chinese or English. Application data content should be true and accurate to avoid misleading and delays. Please provide any additional information to support your application.

Part I General Information About the Enterprise

A General Information

1. Production enterprise

Registered name (actual production organization): _____

Registered address (actual production address): _____

Registration number (if applicable): _____

2. Contact person:

Telephone:

Fax:

E-mail:

3. Registration (approval) authority:

4. If the actual address of the producer differs from the address on the business licence, please provide the name, address, telephone number, fax number, email and other contact details of the production enterprise which is liable for the products exported to China, specifying the relationship between the producer which is liable for products exported to China and the actual



production enterprise.

5 Date of plant establishment:

6.Total area:

7.Total building area:

8. Please provide layout of workshops, division of clean area, people flow and logistic as attachment.

9 Name of products to be exported to China:

Serial No.	Product type ^①	Applicable age bracket ^②	Packaging form ^③	Registered trademark ^④

①Product type: Complete it according to "infant formula milk powder", "infant formula liquid milk";

②Applicable age bracket: for example, 0-6 months etc;

③Packaging form: for example, paper box with inner package, can with inner package, can without inner package etc (please provide details about inner and outer packaging forms)

④Registered trademark: please provide registered trademark approved by competent authorities

10. Please provide the actual production quantity of final products of infant and follow on formula in the past 2 years (ton/year).



B. Production Information

1. Please choose the production process from the list below and provide a clear processing flow chart in the form of attachment:

Wet-mix process

Dry-mix process

Combined process

For definitions of wet-mix, dry-mix and combined processes, please refer to the *Hygienic Operation Specification for Infant Formula Milk Powder* (Codex Alimentarius Commission, CAC/RCP66-2008).

2. Production capacity and equipment

(1) Please list the main production equipments, quantity, designed production capacity;

(2) Please provide the information on production capacity per shift (ton), number of shifts per day, annual average number of working days;

3. Hygiene and quality management system

If the Hazard Analysis and Critical Control Point (HACCP) system has been established and implemented, please provide hazard analysis worksheet and HACCP plan form. If certified by an accredited third-party certification organization and awarded with HACCP certificates, please provide the certificate and documentary evidences concerning the qualification of the third-party organization.

If the Food Safety Management System (ISO22000 or other equivalent hygiene and quality management system) has been established and implemented, please provide HACCP plans and its preconditions. If certified by an accredited third-party certification organization and awarded with relevant certificates, please provide the certificate and documentary evidences concerning the qualification of the third-party certification organization.

If none is implemented, please provide hazard source analysis and the corresponding prevention and control measures.



4. Please specify whether there are isolation and washing (or cleaning) measures between the production of products with different batch numbers, formulas and varieties;

Yes, please provide supporting evidence in the form of attachment;

No.

5. Please provide environmental monitoring plan for *salmonella*, *enterobactersakazakii* and other enteric bacilli, and air purity testing plan for cleaning work area as well as the latest two test reports as attachment.

6. Are there any automatic valve arrays in enterprise's processing workshop? (if applicable)

No.;

Yes, please provide the following information.

When there is CIP cleaning during the production, please provide CIP cleaning information concerning major production equipments:

Item	Manufacture equipment	Chemical name of the cleaner	Temperature, concentration, time, flux	Cleaning effect validation way

When equipments and parts are manually cleaned during the production, please provide the following information:

Item	Manufacture	Chemical name of the cleaner	Temperature, concentration, time, flux	Cleaning effect validation way

7. Please provide the name of the disinfectant, cleaner and others used in the production and operation area used by the production enterprise in the form of attachment.

8 Water/ice/steam supply (if applicable)

(1) Water source

Water for public use

Water source self-owned by enterprise: whether water from self-owned water sources is



disinfected; if any, please specify the mode of treatment and limiting value for monitoring.

Ozone treatment

Chlorination

Others

(2) Please provide water supply and drainage drawings, indicating water flow direction.

(3) Please provide, in the form of attachment, the plan of monitoring water for production, ice/steam (if applicable) which directly contact food, including bacteriological examination items, method, frequency and the latest two test reports.



C. Raw Material Information

1. Please specify the raw materials for infant formula dairy products used by enterprise:

(1) Raw milk

① Please specify the Standards for acceptance check of incoming raw milk (including indicators, maximum level, acceptance check requirements etc);

② type of milk source;

Milk source owned by enterprise;

Milk source owned by parent company of enterprise and managed according to relevant regulations of the country (territory) where it is located;

Milk source from dairy farms owned by enterprise through cooperatives

Milk source which is qualified through evaluation by enterprise or accredited organization, managed according to relevant regulations of the country (territory) where it is located and signs milk supply contract covering three years or more with enterprise.

other milk source

③ Please provide information on the annual raw milk output from milk source (ton): _____ ,
annual supply (ton): _____

(2) Dairy products (whole milk (powder), skimmed milk (powder), whey (powder) etc);

① Standards for acceptance check of incoming raw material (including indicators, maximum level, acceptance check requirements etc);

② Source of raw material:

Domestic purchase;

if not domestic purchase, please provide the country of origin.

2. Please briefly describe the enterprise's system for examination and approval of raw material



中华人民共和国国家认证认可监督管理局
Certification and Accreditation Administration of the People's Republic of China

ALLEGATO 3)

suppliers.



D. Product Traceability and Recall

1. Are there any logos, symbols or number and other items for traceability printed on product package?:

Yes; please explain the meaning of the logo, symbol or number for traceability, the position on the package, and how consumers should use such logo, mark or number etc;

No.

2. Has the enterprise established a product recall system? If yes, please provide a brief introduction to the product recall system in the form of attachment.

E. Product Testing

1. Laboratory for finished products release testing:

Official testing organization:

Laboratory name: _____

Third-party testing organization:

Laboratory name: _____

Laboratory owned by enterprise

Please provide documentary evidence concerning laboratory testing capacity or its qualification information in the form of attachment.

2. Please provide, in the form of attachment, the disposal procedures of non-conforming raw materials, semi-finished products and finished products of the enterprise.



F. Enterprise Location and Plant Environment

1. Please describe the location of the enterprise. Is it located within industrial, agricultural or residential area? Is it far away from pollution including smell, smoke and dust from livestock farm, refinery, municipal refuse, chemical plant and sewage treatment plants (please attach the enterprise location plan in the form of attachment to clearly show the surrounding environment of the plant area)?

2. Please provide pest and mouse control chart in the form of attachment.



G Enterprise Statement

1. The enterprise here declares that the enterprise and nutritional ingredients and additives for infant formula dairy products to be exported to China by the enterprise comply with relevant Chinese laws, regulations, food safety standards.

2. The above information and additional materials submitted are authentic and accurate.

Name and position of legal representative

Signature of legal representative and company seal and date

H. Confirmation by Competent Authority

It is hereby certified that through examination and confirmation, the above materials provided by the enterprise are authentic and accurate.

Name and position of the responsible person

Signature of the responsible person and seal of competent department (date)

Part II Overview of Enterprise's Export to China

A. Please describe the relationship among the producer, exporter, importer, the trademark holder that exports the products to China and the responsible party that exports the products to China.

B. Import information

Regione del Veneto-AO O Giunta Regionale n. prot. 98595 data 06/03/2014



1 Importer information

Name: _____

Address: _____

Telephone: _____

Fax: _____

E-mail: _____

Contact person: _____

2. Please list the trademarks of products to be exported to China in the form of attachment, clarifying the trademarks holder that exports the products to China, the country in which the trademarks are registered and the approval authority, and provide relevant supporting evidences.

3. Please list all the ingredients (formula) information according to the amount added to the products to be exported to China in the form of attachment.

4. Are there any logos, symbols or numbers for product recall printed on the packages of the products exported to China?

Yes, please explain the meaning of the logos, symbols or numbers for product recall, the position on the package and how consumers should use the logos, symbols and numbers, etc.

No.

5 For infant and follow on formula products exported to China, has the enterprise established or authorised a third party to establish a complaints platform in Chinese and an inquiry system of product information?

self-owned

authorised a third party

Please briefly introduce how to introduce the established complaints platform and the inquiry



system of product information to the consumers. Please give an example on the proceeding procedure when consumers use the complaints platform and the inquiry system of product information in Chinese.

6 Please provide the licence of independent legal entity, business licence, licence of legal representatives or identification of the authorised person as well as contact details of the importer or legal representative of the enterprise in China which is liable for recall in China of products exported to China according to Chinese laws and regulations.

B Export information

1 Exporter Information

Name: _____

Address: _____

Telephone: _____

Fax: _____

E-mail: _____

Contact person: _____

2. Product information

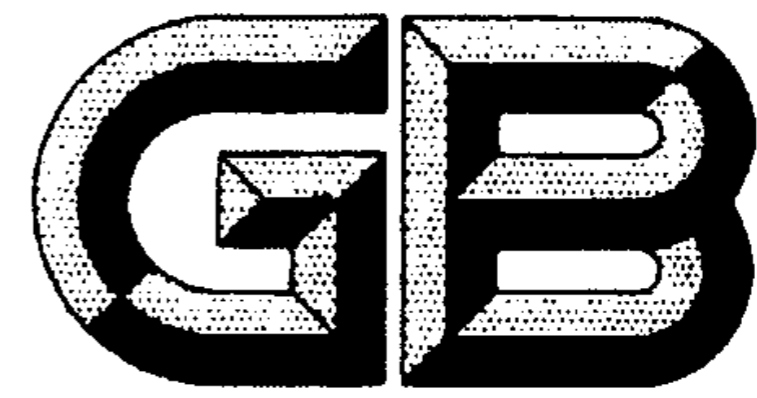
Please describe the history of products exported to China in the past 2 years in the form below.

Item	Product type ^①	Applicable age bracket ^②	Registered trademark	Quantity (ton)	Date of exporting for the first time (if applicable)

^①Product type: Complete it according to "infant formula milk powder", "infant formula liquid milk";

^② Applicable age bracket: for example, 0-6 months etc;

Regione del Veneto - A.O. Giunta Regionale n. prot. 99595 data 06/03/20



National Standards of the People's Republic of China

GB 12693—2010

National Food Safety Standard
Good manufacturing practice for milk products

Issued on 2010-03-26

Implementation from 2010-12-01

Published by Ministry of Health of People's Republic of China

Preface

The Standard is in substitution of GB 12693—2003 *Good Manufacturing Practice of Milk Product Factory* and GB/T 21692—2008 *Hygienic Practice for Dry Milk Powder*.

The Standard corresponds to Codex Alimentarius Commission (CAC) CAC/RCP1-1969, Rev.4-2003 *Recommended International Code of Practice General Principles for Food Hygiene* and CAC/RCP57-2004 *Code of Hygienic Practice for Milk and Milk Products*, the consistence of the Standard with CAC/RCP1-1969, Rev.4-2003 and CAC/RCP 57-2004 is non-equivalent. This standard as well as makes reference to EU Regulations (EC) No 852/2004 *Regulation on the Hygiene of Foodstuffs* and (EC) No 853/2004 *Laying down specific hygiene rules for food of animal origin*.

As compared to GB12693-2003 and GB/T 21692-2008, the standard has made the following amendments:

- Change the standard name to Good Manufacturing Practice for Milk Products;
- Adjust the application scope and emphasize the application to all kinds of milk product companies;
- Modify the framework of the standard;
- Stressing on the contamination prevention in the whole production process of incoming of raw materials, food safety control during production process, product transportation and storage;
- Adjust “Production Equipment”, setting out requirements for layout, material and design of production equipment in view of preventing microbial, chemical and physical contamination;
- Cancel the hardware requirement in construction of laboratories;
- Add requirements related to the purchasing, acceptance, transportation and storage of raw materials;
- Emphasize the food safety control in production, and formulate the major measures for control of microbial, chemical and physical contamination;
- Add packaging materials and its use instructions;
- Add control specification, monitor and record requirements of critical control points;
- Add particular requirements for traceability and recall;
- Add requirements for record and document management.

The appendix A of this standard is a referential appendix.

Publication status of previous versions substituted by the Standard is as follows:

- GB 12693-1990, GB12693-2003;
- GB/T 21692-2008.

National Food Safety Standard

Good manufacturing practice for milk products

1 Scope

The Standard applies to the production enterprises those manufacture various kinds of milk products using cow milk (or goat milk) and their processed products as the main raw materials.

2 Cited Normative Documents

The provisions of the following documents become the provisions of the Standard upon citation hereto. Where the cited documents are dated, none of their subsequent amendments (exclusive of corrections) or revisions shall be applicable to the Standard. However, the parties concluding any agreement in accordance with the Standard are encouraged to study if to use the latest versions of such documents. Where the cited documents are not dated, their latest versions shall be applicable to the Standard.

3 Terms and Definition

3.1 Cleaning Work Area

Work area with high requirement for cleanness, such as storage area for exposed semi-finished products, filling room and inner packing area, etc.

3.2 Quasi-cleaning Work Area

Work area with requirement for cleanness next to that of cleaning work area, such as pretreatment workshops of raw materials, etc.

3.3 Commonly Work Area

Work area with requirement for cleanness next to the quasi-cleaning work area, such as milk collection unit, raw material warehouse, packaging material warehouse, outer packing workshop and finished-product warehouse, etc.

4 Location and Plant Environments

Refer to related requirements in GB14881.

5 Plant and Workshop

5.1 Design and Layout

5.1.1 Any construction, expansion and reconstruction project shall be designed and executed according to the relevant national regulations.

5.1.2 Plant and workshop shall be laid out to prevent any cross contaminations in milk product manufacturing process and avoid any contact with toxic and unclean substances.

5.1.3 Cleaning Work Area, Quasi-cleaning Work Area and Commonly Work Area in the workshop shall be adopted some suitable control measures to prevent any cross contaminations.

5.2 Internal Building Structure

5.2.1 Roof

5.2.1.1 Interior roofs and the top angles in processing, packing and storage areas should be easily cleaned to minimize the build up of dirt and condensation, the grown up of the mold and the shedding of particles. Where the roof of cleaning work area, quasi-cleaning work area and other arenas of foodstuff exposure (except for milk collection unit) is of the structure that can easily be dirty, it shall install the smooth and easy-to-clean ceilings; in case of the reinforced concrete structure, the interior roof should be smooth and seamless.

5.2.1.2 The interior flat roof or ceiling in the workshop should be made of impervious materials in white or light-color and with odorless and non-toxic effect in intended use; where the paint coating and spraying is required, it should use the mould-proof, non-shedding and easily cleaned paint.

5.2.1.3 Pipelines of steam, water and electricity shall not be arranged right above the food exposure; otherwise, facilities shall be installed to prevent dust and condensed water from falling down.

5.2.2 Walls

5.2.2.1 Walls should be constructed with non-toxic, odorless, smooth, water-proof and easy-to-clean light-color anti-corrosion materials.

5.2.2.2 The wall corners and pillar corners in the cleaning work area and quasi-cleaning work area should be in sound condition, easy to clean and disinfect.

5.2.3 Doors and windows

5.2.3.1 Smooth and anti-absorption materials shall be used, which should be easy to clean and disinfect

5.2.3.2 For the production workshop and storage areas, doors and windows shall be tightly installed and the dirt prevent, animal and insect-proof screens shall be arranged, which can be easy to clean.

5.2.3.3 The exits of the cleaning work area and quasi-cleaning work area should be installed with doors that can be automatically closed (such as with auto inductor or door closer) and/or air curtain.

5.2.4 Flooring

5.2.4.1 The floor should be made with non-toxic, odorless and impervious materials and shall be even and non-slippery, seamless and easy for cleaning and sterilizing.

5.2.4.2 The floor in the areas with drainage or waste water flowing to the floor in operation, frequently wet work environment or cleaning by washing with water should be also anti-acid and anti-alkali, and should have certain drainage slope and drainage system.

5.3 Facilities

5.3.1 Water supply facilities

5.3.1.1 Able to ensure the processing water quality, pressure and volume can achieve the production requirements.

5.3.1.2 For water supply equipment and apparatus, it should get drinking water sanitation and safety permission documents from Health Administration Ministry provincial level and above.

5.3.1.3 The inlet and outlet of water supply facilities should be equipped with safety and hygiene devices to prevent any animals and other substances entering and contaminating the foodstuffs.

5.3.1.4 The standby water supply shall comply with the provisions of GB17051.

5.4.1.5 To use the standby water sources, it should be compliance with the related hygienic requirements of central drinking water supply services from National Health Administration Ministry.

5.3.1.6 The piping system for non-drinking water not in contact with foodstuffs (such as cooling water, sewage or waste water, etc) should be clearly divided from the piping system for foodstuff processing water, and such water shall be delivered with separate pipelines without any backflow or intersection.

5.3.1.7 The quality of processing water shall comply with the provisions of GB5749.

5.3.2 Drainage system

5.3.2.1 It is necessary to allocate the proper drainage system, and avoid, in designing and constructing, products or production water from being contaminated.

5.3.2.2 The drainage system should have a slope and remain unobstructed and convenient for washing; the juncture of sides and bottom of the drainage ditch should have certain radian.

5.3.2.3 At the inlet of the drainage system, a floor drain with water stop should be installed to prevent any solid waste from flowing in and foul smell from coming out.

5.3.2.4 No other processing water pipelines shall be arranged inside and below the drainage system.

5.3.2.5 The drainage outlet shall be equipped with a device to prevent the invasion of any animals.

5.3.2.6 The flow direction of indoor drainage should be from the area with higher requirement of cleanness to the area with lower requirement of cleanness, and should be designed to prevent the backflow of waste water.

5.3.2.7 Waste water shall be discharged into the waste water treatment system or disposed in other proper ways.

5.3.3 Cleaning facilities

Proper facilities should be allocated for foodstuffs, apparatus and equipment cleaning and for storage of refuse and waste materials.

5.3.4 Personal hygienic facilities

5.3.4.1 Such personal hygienic facilities shall comply with the provisions of GB14881.

5.3.4.2 The sterilizing facilities shall be installed before entering the cleaning work area, second dressing room shall be arranged when necessary.

5.3.5 Ventilation facilities

5.3.5.1 Measures of natural ventilation or artificial ventilation should be made available to reduce the atmospheric contamination and control odor so as to secure the food safety and product characteristics. For production of milk power, the ambient temperature should be also controlled in the cleaning work area and so is the atmospheric humidity when it is necessary.

5.3.5.2 The cleaning work area shall be installed with air conditioning facilities to prevent condensation of steam and keep the interior air fresh; the commonly work area shall be installed with ventilation facilities to promptly exhaust humid and dirty air. In case of air conditioning, ventilation and exhausting or fan application inside the plant, the air flow direction should be from the area of higher cleanness to the area of lower cleanness to prevent contamination of any foodstuff, production equipment and inner packaging materials.

5.3.5.3 In the area with odor and gas (steam as well as toxic and harmful gas) or dust that may contaminate foodstuffs, proper elimination, collection and control devices shall be allocated.

5.3.5.4 The air inlet should be at least 2m above the floor, far away from the contamination source and air outlet and provided with air filters. Air outlets should be equipped with the corrosion-resistant screen covers that can be easily cleaned to prevent the invasion of animals. The ventilating and exhausting devices should be easily removed for cleaning, maintenance or replacement.

5.3.5.5 The compressed air or other gas used for foodstuffs, for food contact face or equipment cleaning shall be filtered and purified to prevent any indirect contamination.

5.3.6 Lighting facilities

5.3.6.1 Plant should have adequate natural lighting or artificial lighting inside. The lighting coefficient for the workshop shall not be lower than Standard IV; the mixed illumination shall not be lower than 540 lx for the work area of quality monitoring and control, not less than 220 lx for the work area of processing, and not less than 110 lx for other areas, except for the areas sensitive to light. The light source shall not cause any change in the color of foodstuffs.

5.3.6.2 The lighting facilities shall not be installed right above the foodstuff exposure; otherwise, safety lighting facilities shall be used to prevent to prevent any break and contamination of foodstuff.

5.3.7 Storing facilities

5.3.7.1 Enterprises shall have storing facilities which can match the types and quantity of milk products produced and operated.

5.3.7.2 Separate storage areas should be arranged according to different natures of raw materials, semi-finished products, finished products and packaging materials and, when necessary, cooling (cold) stores should be arranged. To store goods of different nature in one warehouse, it is necessary to apply proper isolation (e.g., by classification, rack and division) with distinct symbols.

5.3.7.3 Warehouses shall be built with non-toxic and solid materials, the floor shall be level and even for ventilation and should be provided with devices to prevent the invasion of animals (such as rat guard or ditch set up at the entrance of the warehouse).

5.3.7.4 Warehouses should be arranged with adequate stack board (for placing goods). Keep the stored goods appropriately away from the walls and floor so as to air circulation and goods handling.

5.3.7.5 Cooling (cold) stores should be equipped with the thermostat, temperature measuring device or temperature auto recording meter that can accurately indicate the temperature inside the warehouse and carry out the real-time control of temperature.

6 Equipment

6.1 Production equipment

6.1.1 General requirements

6.1.1.1 Adequate production and operation equipments should be arranged in compliance with the types and quantity of milk products produced and operated, of which the capacity can cooperate with each other.

6.1.1.2 All the production equipments shall be orderly arranged as per technical procedures to avoid any cross contamination.

6.1.1.3 For the special equipments used in production (such as pressure vessel and pressure pipeline, etc), it is necessary to formulate the relevant operation instructions.

6.1.2 Material quality

6.1.2.1 All the equipments and instruments in direct or indirect contact with raw materials, semi-finished products and finished products shall be made with safe, non-toxic, smell-free or odorless, non-absorptive and corrosion-resistant materials that can bear the repeated cleaning and sterilizing.

6.1.2.2 The material of contact surface with products shall comply with the related product standards, with smooth surfaces, easy for cleaning and sterilizing, water-proof and non-shedding.

6.1.3 Design

6.1.3.1 All the machinery and equipments shall be designed and constructed for the convenience of cleaning and sterilizing and the easy for checking. They should have such construction as to avoid, in use, entrance of any lubricant, metal slag, sewage or other substance that may cause contamination into foodstuff and shall comply with the relevant requirements.

6.1.3.2 The contact surface with foodstuff shall be smooth and even, without any sag or split to reduce the accumulation of foodstuff debris, dirt and organic matters.

6.1.3.3 The storage, transportation and processing system (including the gravity, pneumatic, enclosure and automation system) should be designed and manufactured to the convenience to keep it in a good hygienic state. Materials storage equipments shall be able to seal.

6.1.3.4 A designated area for storing the spare parts of equipment shall be arranged in order to get required spare parts immediately during equipment maintenance; the storage area of equipment spare parts shall be kept clean and dry.

6.2 Monitoring Equipment

6.2.1 Such monitoring equipments for measuring, controlling and recording as pressure gauge and thermostat, etc., should be calibrated, maintained periodically to ensure accuracy and effectiveness.

6.2.2 In using a computer system and the network technology thereof for collection of monitoring data at the critical control points and for management of different records, the relevant functions of the computer system and the network technology thereof may be referred to the provisions of Addendum A to the Standard (Referential Appendix).

6.3 Service and Maintenance of Equipment

6.3.1 It is necessary to establish and strictly execute the equipment service and maintenance procedures.

6.3.2 It is necessary to establish the daily maintenance and service schedule for equipment and carry out regular overhaul and keep proper records.

6.3.3 Before each production, it is necessary to check if the equipment is in a normal state to avoid any impact on the hygienic quality of products; in case of any fault, it is necessary to promptly eliminate it and record the faulting time, reason and batches of products that may be affected.

7 Hygiene Management

7.1 Hygiene Management System

7.1.1 Enterprise shall formulate the hygiene management system and examination standards and implement the post responsibility system.

7.1.2 Enterprise shall formulate the hygiene inspection schedule, record and file the execution of such schedule.

7.2 Hygiene Management for Plant and Facilities

7.2.1 All facilities inside the plant shall be kept clean and promptly maintained and replaced; in case of any damage to the plant roof, ceiling and walls, repair shall be immediately carried, while the floor shall not be allowed to have any damage or water logging.

7.2.2 Equipment and tools and instruments for processing, packing, storing and transporting, production pipelines and contact surface with foodstuffs shall be regularly cleaned and sterilized. In cleaning and sterilizing, make sure to prevent any contamination to foodstuffs, contact surface with foodstuff and inner packaging materials.

7.2.3 The cleaned and sterilized movable equipment and instruments shall be kept in a place that can prevent their contact surface with foodstuffs from being contaminated again and keep them in an applicable state.

7.3 Cleaning and Sterilizing

7.3.1 It is necessary to formulate the effective plan and procedure for cleaning and sterilizing to ensure the clean and hygienic state of foodstuff processing areas, equipment and facilities, to prevent any contamination of foodstuffs.

7.3.2 Enterprises may choose the cleaning and sterilizing methods according to the features of products and process.

7.3.3 Equipment and instruments used for cleaning and sterilizing shall be kept properly in a special place.

7.3.4 It is necessary to record the cleaning and sterilizing procedures, such as the type of detergent and sterilizer, time, density, object, temperature, etc.

7.4 Human Health and Hygiene Requirements

7.4.1 Human health

7.4.1.1 Enterprises shall establish and execute the employees' health management system.

7.4.1.2 Milk processing and operation personnel shall annually undertake the health check and obtain the

health certificate before being put into work.

7.4.1.3 Persons suffering from such infectious disease of digestive tract as dysentery, typhoid, viral hepatitis type A and type E, persons suffering such diseases impacting the food safety as active pulmonary tuberculosis, suppurative or effusive skin diseases and persons with skin injuries shall be transferred to other positions not impacting the food safety.

7.4.2 Personal hygiene

7.4.2.1 Milk product processing personnel shall maintain excellent personal hygiene.

7.4.2.2 Before entering the production workshop, it is a must to wear or put on the clean work uniform, cap and shoes or boots. The work uniform should cover the overcoat; hair should not come from the cap and mask should be put on when necessary. It is not allowed to wear the work uniform, shoes and boots to enter the toilet or leave the production and processing areas.

7.4.2.3 Before being posted, for instance after going to the toilet, contacting any goods that may contaminate the foodstuffs or undertaking any other activities not related to production, it is necessary to wash hands and apply sterilization. The hands shall be kept clean in the process of operating.

7.4.2.4 Persons in direct contact with milk product shall not use any nail oil and perfume and shall not wear watch and jewelries.

7.4.2.6 At work station, smoking, taking food or other activities that may impact the hygiene of dairy products shall not be allowed.

7.4.2.7 Personal clothes shall be kept in the lockers in the locker room and other personal belongings shall not be allowed for carrying in the production workshop.

7.4.3 Visitors

To enter the foodstuff production, processing and operating areas, visitor shall comply with the hygienic requirements for the operating personnel on the spot.

7.5 Pest Control

7.5.1 Formulate measures for pest control. Keep the buildings intact and environment clean to prevent the invasion and breeding of pests.

7.5.2 At the entrance of production workshop and storage areas, pest-capture lights shall be set up and screens or other facilities shall be installed at the place connected with outside such as windows to prevent or eliminate the harmful pests.

7.5.3 Regularly monitor and check if the plant environment and production areas have any sign of pests; in case of observing any pest, trace and find out the source to avoid occurrence again.

7.5.4 Physical, chemical or biological preparation may be used for treatment, but their eliminating method shall not impact the safety and characteristics of foodstuffs and contaminate the contact surface with foodstuffs and packaging materials (e.g., avoid using insecticide).

7.6 Disposal of Refuses

7.6.1 Formulate rules for placing and eliminating refuses.

7.6.2 The vessels containing the refuses, processing by-products and non-edible or dangerous substances shall have special labels and rational construction, and, when it is necessary, shall be sealed to prevent any contamination to the foodstuffs.

7.6.3 It is necessary to set up the temporary dumping facilities a proper location for classified dumping as per characteristics of refuses, while the corruptive refuses should be regularly eliminated.

7.6.4 The dumping place of refuses shall not produce any bad smell or harmful, toxic gas. It is necessary to prevent the breeding of pest and prevent any contamination to the foodstuffs, contact surface with foodstuff, water source and ground.

7.7 Management of Toxic and Harmful Substances

Management of toxic and harmful substances shall be subject to the relevant provisions of GB 14881.

7.8 Management of Sewage and Filth

7.8.1 Sewage discharge shall be compliant with the requirements of GB 8978 and those are non-compliance with the standard shall be purified for qualification before being discharged.

7.8.2 Management of filth shall be subject to the relevant provisions of GB 14881.

7.9 Management of Work Uniforms

Management of work uniforms shall be subject to the relevant provisions of GB 14881.

8 Requirements for Raw Materials and Packing Materials

8.1 General Requirements

8.1.1 Production enterprises of milk products shall establish the management system related to the purchasing, acceptance check, transportation and storage of raw materials and packaging materials so as to ensure the raw materials and packaging materials used are in compliance with the requirements of the legislations and regulations. It is not allowed to use the substances which may be harmful to human health and safety.

8.1.2 Raw milk collection centers constructed by production enterprises of milk products shall comply with the relevant national and local regulations.

8.2 Requirements for Purchasing, Acceptance check of Raw Materials and Packaging Materials

8.2.1 Production enterprises of milk products shall establish the supplier management system, specifying the supplier selection, audit and evaluation procedures.

8.2.2 Production enterprises of milk products shall establish the incoming inspection system for raw materials and packaging materials.

8.2.2.1 Production enterprises using raw milk to produce milk products, shall test the raw milk batch by batch according to food safety standard, record truly the quality inspection status, suppliers' names and contact modes, delivery date, etc, and check the raw milk transporting vehicles receipts. It is not allowed to purchase raw milks from any unit and individual without the license of raw milk acquisition.

8.2.2.2 In inspecting and accepting other raw materials and packaging materials, it is necessary to check the

qualification certification documents (enterprise's self-analysis report or third party testing report) for the batch of raw materials and packaging materials; in case of failing to provide such effective qualification certification documents, incoming materials shall be inspected according to the relevant food safety standards or the enterprise's inspection and acceptance standard and shall be only accepted and used upon qualification. It should record truly the relevant information of raw materials and packaging materials.

8.2.3 Rejected raw materials and packaging materials shall be labeled and separately stored. The supplier shall be notified for further action.

8.2.4 In case food safety issues of raw materials or packaging materials were found, milk product Production enterprise shall report to food safety supervision authority locally.

8.3 Transportation and Storage of Raw Materials and Packaging Materials

8.3.1 Production enterprises of milk products shall transport and store raw materials and packaging materials according to the requirements to quality and safety.

8.3.2 Transportation and storage of raw milk

8.3.2.1 The vessels for transporting and storing fresh milk shall comply with the relevant national food safety standard.

8.3.2.2 Raw milk shall be, within 2 hours after milking, cooled down to 0°C~4°C and transported in normal temperature lorry. The lorry shall maintain completed certificate and record.

8.3.2.3 The raw milk shall be promptly processed when delivery to the factory. In case that raw milk cannot be processed timely, it shall be stored in cooling storage and be monitored and recorded the temperature and relevant data.

8.3.3 Transportation and storage of other raw and packaging materials

8.3.3.1 It shall avoid any direct sunlight, rain, rapid temperature and humidity change and sharp strike during transporting and storing raw and packaging materials. Loading and shipping with toxic and harmful goods is prohibited.

8.3.3.2 In the process of transporting and storing, it shall avoid any contamination and damage of raw and packaging materials minimize the quality degradation; the raw and packaging materials with humidity and temperature requirement or other special requirements shall be transported and stored according to the specified conditions.

8.3.3.3 During the storage, different raw and packaging materials shall be divided storage according to their respective features, for which the identification should be set up to indicate the relevant information and quality status.

8.3.3.4 Regularly check the stocked raw materials and packaging materials; as for the raw materials and packing materials that have been stored for a longer period and may have observe any change in quality, regularly sampling to check the quality; timely dispose the deteriorated or expired raw materials and packaging materials.

8.3.4 The qualified raw materials and packaging materials should follow the principle of "First In First Out" or "First Expired First Out" for rational arrangement of use.

8.4 Maintain the Records on Purchasing, Acceptance check, Storage, Transportation of Raw Materials and Packaging Materials.

9. Food Safety Control in Production

9.1 Microbial Contamination Control

9.1.1 Temperature and time

9.1.1.1 The method for eliminating or constraining growth and spread of microorganisms, such as heat treatments, freezing or cold storage according to the features of products shall be specified and the effective monitor and control shall be implemented.

9.1.1.2 The control measures and corrective actions for temperature and time shall be established, the regular verification shall be carried out.

9.1.1.3 For the process with strict control of temperature and time, it shall establish real-time monitoring measures and maintain the monitoring records.

9.1.2 Humidity

9.1.2.1 Atmospheric humidity in the wet control area shall be controlled according to features of product and processes in order to reduce the growth of harmful microbes; set up critical criteria for air humidity and implement effectively.

9.1.2.2 Establish the real-time control and monitoring measures for atmospheric humidity, conduct regularly verification and keep records.

9.1.3 Atmospheric cleanness in production area

9.1.3.1 Production workshop shall be kept with clean air to prevent the contamination to foodstuffs.

9.1.3.2 Determine as per natural settlement method specified in GB/T 18204.1, the total plate count (TPC) in the air of the clean work area shall be controlled within 30cfu/dish.

9.1.4 Prevention against microbial contamination

9.1.4.1 The necessary control measures for the whole process from raw and packaging materials incoming to finished products dispatching shall be taken to prevent any microbial contaminations.

9.1.4.2 Operating, using and maintaining the equipment, vessel and instrument, which are used for conveying, loading or storing raw materials, semi-finished products and finished products, shall avoid any contamination to the foodstuffs during processing or storing.

9.1.4.3 The water of ice lumps and steam which are direct contact with foodstuffs shall be used in compliance with the requirements of GB 5749.

9.1.4.4 Recycle water and circulating water in the evaporation or drying processes can be used, but it must be ensured such water will not cause hazard to the food safety and characteristics. Water treatment shall be conducted when necessary and effectively monitored.

9.2 Control of Chemical Contamination

9.2.1 The management system shall be established to prevent chemical contamination, potential

contamination sources and channels shall be analyzed and control measures shall be set up.

9.2.2 Qualified detergent, sterilizer, insecticide and lubricant should be selected and used as pre use instruction; should be registered the use and kept the records well to avoid any hazards of contaminating the foodstuffs.

9.2.3 Chemical substances shall be stored separate from foodstuffs, labeled clearly and managed by designated personnel.

9.3 Control of Physical Contamination

9.3.1 Equipment maintenance, hygiene management, on-line management, outsources management and manufacturing process supervision shall be taken to ensure that products will not be contaminated by the foreign bodies (such as glass or metal fragments, dust, etc).

9.3.2 Effective measures (such as sieve, trap, magnet, electronic metal detector, etc) shall be taken to prevent metals or other foreign bodies from being mixed into the products.

9.3.3 Welding, cutting and grinding shall not be allowed during production to avoid smelly odor and foreign bodies.

9.4 Food Additives and Nutrition Fortifications

9.4.1 Food additives and nutrition fortifications shall be used reasonable according to the provisions of the food safety standard on types, application and dosage.

9.4.2 Weigh the food additives accurately when use and maintain proper records.

9.5 Packaging Materials

9.5.1 Packaging materials should be clean, non-toxic and compliant with the national relevant regulations.

9.5.2 Packaging materials or gas for packing must be non-toxic, and shall not affect the food safety and characteristics of products under the specific storing and using conditions.

9.5.3 The inner packaging materials should be able to adequately protect foodstuffs from contamination and against damages in the normal storage, transportation and sale condition.

9.5.4 The recycle packaging materials such as glass bottles and stainless vessels should be washed clean and sterilized before being used.

9.5.5 It is necessary to check the labels of the packaging materials to be used before packing to avoid misuses, and keep corresponding records including the product name, quantity, operator and date.

9.6 Product label should comply with GB7718, relevant national standards and other related regulations.

10 Testing of Products

10.1 Enterprises are allowed to conduct independently tests for raw materials and finished goods or entrust a third party qualified testing organization for foodstuff testing. Independently testing enterprises should have corresponding test capabilities.

10.2 Each batch of products should be tested according to relevant standards and samples should be kept.

10.3 Testing laboratory quality management shall be strengthened to ensure the accuracies and integrities of the test results.

10.4 Testing records and reports shall be kept completely.

11 Product Storage and Transportation

11.1 Choose the storage and transportation mode according to the products categories and characteristics and ensure compliance with storage condition claimed on the product label.

11.2 It shall avoid any direct sunlight, rain, rapid temperature and humidity change and sharp strike during transporting and storing products. Loading and shipping with toxic and harmful goods is prohibited.

11.3 The vessels, tools and equipments, which are used for storing, transporting and loading, shall be clean, safe and in a good condition to prevent the products from contamination.

11.4 Periodically check the products in warehouses shall be checked periodically, temperature and/or humidity shall be recorded when necessary; a prompt action shall be taken once incompliance.

11.5 Product tested shall be indicated quality status.

11.6 Products storage and transportation records and the dispatched products deliver note shall be kept so as to recall products in case of any problem observed.

12 Product Traceability and Recall

12.1 Enterprises shall establish the product traceability system to ensure effectively tracing the product at the whole process from raw materials purchasing to product sales.

12.2 Enterprises shall establish the product recall system. Once a batch or category of products contained or might contain some hazards which will harm consumers' health is observed, it is necessary to actuate the product recall procedure as per national relevant regulation, promptly notify the relevant department and properly record.

12.3 Harmless treatments and destructions shall be conducted to the recall products; report to the relevant department about product recall and disposal status.

12.4 It is necessary to establish the customer complaint handling system. Enterprises' relevant management department shall record, find the reason and properly handle the written or oral points and complaints from consumers.

13 Training

13.1 A training system shall be established and the food safety knowledge training shall be conducted to all the employees.

13.2 Enterprises should set the annual training program according to different position needs and training the staffs correspondingly; certificates shall be required for the specific position.

13.3 It is necessary to regularly examine and revise the training program, evaluate the training effect and carry out routine inspection so as to ensure the effective implementation of the program.

13.4 Training should be recorded.

14 Management Organization and Personnel

14.1 Enterprises shall establish and improve their respective food safety management system and adopt relevant management measures to control the quality and food safety for the whole milk production processes including raw materials incoming to finished products delivering, to ensure the products are in compliance with related legislation, regulation and standards' requirements.

14.2 A food safety management organization shall be built to conduct the food safety management.

14.3 The personnel in charge of food safety organization should be the executive of the enterprise or the responsible person authorized by enterprise executive.

14.4 All the functions in the organization shall set the clear management responsibilities and ensure the responsibilities which related to quality and safety are carried out. All functions shall allocate with tasks effectively to prevent overlapping, duplicate or absent responsibilities. Set up management procedures and make clear the management person and the role for internal and external plant surroundings, maintenance and management for plant facilities and equipments, quality management for production process, health management and quality traceability.

14.5 All the functions in the food safety organization shall be allocated with fulltime or part-time food safety management personnel to train the food safety legislations and regulations and supervise and record the execution status.

15 Management of Records and Documents

15.1 Records and Management

15.1.1 Relevant record management system shall be established to record the purchasing of raw and packaging materials, production, storage, testing and sales in milk product manufacturing process so as to increase the reliability and effectiveness of the food safety management system.

15.1.1.1 Raw materials, food additives and food-related products shall be truly recorded the names, specifications, quantities, supplier's names and addresses, as well as incoming date, etc.

15.1.1.2 Manufacturing process (including manufacturing parameters, environment monitoring data, etc.), products storage status, testing batch number, testing date, inspectors, test results shall be truly recorded.

15.1.1.3 Delivered products' names, specifications, quantities, production date, production batch numbers, delivery places, receiver's name and address as well as delivery date shall be truly recorded.

15.1.1.4 Recalled products' names, batch numbers, specifications, quantities, recall reasons and subsequent corrective action plan shall be truly recorded.

15.1.2 All the records shall be checked and signed or stamped by the executor and relevant supervisor; the original text shall not be blurred out and illegible in case of any modification in the record. The modifier shall sign or stamp on the modified text after the modification.

15.1.3 All the production and quality management records shall be reviewed by the relevant department to confirm if all the disposals are compliance with the procedures; immediate actions shall be taken in case of anything abnormal observed.

15.1.4 All the relevant records specified hereto shall be kept not less than two years.

15.2 Document Management

15.2.1 Document management system and complete quality management files shall be set up; documents shall be filed and kept as per classification. Documents to be distributed and used shall be the approved current version. The withdrawal or invalid documents shall not appear in the work area except for filing and reference.

15.2.2 Enterprises are encouraged to use advanced technologies (such as computer information system) for documents and records management.

Appendix A

(Referential appendix)

Requirements for Computer System Application of Milk Product Factories and Formulae for Infants and Young Children Factories

The computer system of milk product factories and formulae for infants and young children factories shall comply with Food Safety Law and relevant regulations and standards, shall set the complete information chain attributed to tracking, tracing and positioning the food safety issues in the whole process from raw material incoming to finished products delivering, shall report and send the related data as administration requirements. Such computer system shall comply with (but not limited to) to the following requirements:

A.1 The system shall have the data collection and record keep capabilities related to food safety including the process of raw material purchasing, inspection, storage and use, manufacturing process critical control point monitoring, finished product release, storage, transportation and sales.

A.2 The system shall be able to evaluate and alert the food safety risk of raw materials and manufacturing processes of the enterprise.

A.3 The system and its database shall be established with a completed authority management system to ensure mandatory use of staff's username and password, and to protect the system and database from the loophole of unauthorized access.

A.4 Based on the privilege management mechanism, the system must be achieved the completed safety strategy and set up the relevant strategy groups for different positions to ensure that the users with specific roles have the corresponding authority. All the data contacted and generated by the system shall be saved in the corresponding database. It shall not store in form of document. Make sure all the data accesses shall be controlled by privilege management of the system and database.

A.5 Special security strategy shall be used for confidential information to ensure that only the information possessor will be authorized to read, write and delete. In case of any actual need for confidential information to be stored and transmitted outside the system and database security control range, it is necessary to ensure:

A.5.1 Encrypted storage shall be applied to the confidential information to prevent unauthorized readers from reading such information.

A.5.2 Check code shall be generated before transmission of the confidential information, which shall be transmitted separately with information (after being encrypted) and the check code shall be used to verify that the information has not be tampered at the receiving end.

A.6 In the event that the system needs to collect the data generated by the automation detector, the system shall provide safe and reliable data interface to ensure the accuracy and high applicability at the interface and guarantee that the data generated thereof can be timely and accurately collected by the system.

A.7 It is necessary to achieve perfect and adequate management functions of system and database logs, including:

A.7.1 The system log records each user's log-in of the system and database (user, time, address of the log-in, etc).

A.7.2 The operating log records each revision of data (including the revising user, revising time, revised content, original content, etc).

A.7.3 The system log and operating log shall have the saving strategy; no users (except for the system administrator) shall not delete or change within the set time limit, to ensure the tracing capacity of certain time-effect.

A.8 Formulate the detailed rules for use and management of the system, which shall include at least the following content:

A.8.1 Real-time recording rules for the original data, intermediate data, generated data and data processing ensure the representation of the whole work process.

A.8.2 Detailed backup management rules ensure the quickly action can be taken to recover the damaged system and corresponding database after any fault or disaster.

A.8.3 The computer room should be equipped with UPS to be connected with the system to ensure that, in case of power cut, UPS will supply electricity instead and notify the working system for data saving and logging (UPS shall have adequate power for the emergency saving of the system).

A.8.4 Perfect data saving and reading management rules: it is prohibited to save the confidential data in the sharing equipment; the internal data sharing of departments shall be also subject to the authority management system for authorized access.

A.8.5 Complementary system maintenance rules, including the regular saving and arrangement and system detecting to ensure the long-term and stable operation of the system;

A.8.6 Security management rules: it is necessary to regularly change the passwords for different users of the system, limit the log-in location of some users and timely delete any account that is no longer required.

A.8.7 Specify the users who log in from the extranet shall not open and use the user/password memory function provided by the operating system of the external computer to prevent any information from being embezzled.

A.9 When the real-time monitoring data at the critical control point conflicts with the standard value, the system can record the deviation date, batch and particular method of correction, operator name, etc.

A.10 The data and relevant records in the system can be copied for the administration to inspection and analyze.