Annex 7 (a)

SPECIFIC EXPORT REQUIREMENTS FOR EXPORT OF MILK AND DAIRY PRODUCTS TO PEOPLE'S REPUBLIC OF CHINA

BACKGROUND

Export establishments intend to export milk and dairy products to China shall comply with all China requirements on milk and dairy products. The export establishment and the category of the products to be exported shall be approved and listed by the General Administration of Customs China (GACC) prior to export.

APPLICATION PROCESS

The application shall be submitted to FSQD (HQ) according to the application form as stated in Annex 7 (b).

VERIFICATION AND LISTING PROCEDURE

Verification and listing procedure shall be carried out as laid down in this protocol as stated in Annex 7(c).

SPECIFIC REQUIREMENTS

1. Export establishments shall implement Hazard Analysis Critical Control Point (HACCP) as a food safety assurance programme.
2. The raw milk must be obtained from sources within the supply chain and verified by Competent Authorities i.e. FSQD and DVS
3. The export establishment shall only process and export milk and dairy products to China once the export establishment is included in the List of Milk and Dairy Products Establishments Registered to P.R. China as published on the GACC website http://jckspj.customs.gov.cn/spj/zwgk75/2706880/2811812/jkrpjwscqyzcmd3/index.html
4. Trader shall obtained milk and dairy products from the GACC approved establishments as listed on the GACC website

http://jckspj.customs.gov.cn/spj/zwgk75/2706880/2811812/jkrpjwscqyzcmd3/index.html

5. The listed export establishments shall participate in Monitoring Export Programme.
6. Export facilities shall implement other requirements imposed by other relevant agency, where necessary

ADDITIONAL INFORMATION

Export facilities shall ensure compliance to China requirements as laid down in the China National Standard such as

i. GB 2760-2014 Standard for Food Additive Use

ii. GB 2761-2017 Maximum Limits for Mycotoxin in Food

iii. GB 2762-2017 Maximum Limit for Contaminant in Food

iv. GB 2763-2019 Maximum Residue Limits for Pesticides in Food

v. GB 4789.26-2013 Food Microbiological Examination Commercial Sterilization Examination

vi. GB 5420-2010 Cheese

vii. GB 5749-2006 Sanitary Standard for Drinking Water

viii. GB 7718-2011 General Principles of Labelling for Pre-packaged Food

ix. GB 10765-2010 Infant Formula

x. GB 10767-2010 Older Infants and Young Children Formula

xi. GB 10769-2010 Cereal-based Complementary Foods for Infants and Young Children

xii. GB 10770-2010 Canned Complementary Foods for Infants and Young Children

xiii. GB 11674-2010 Whey Powder and Whey Protein Powder

xiv. GB 12693-2010 Good Manufacturing Practice for Milk Products

xv. GB 13102-2010 Evaporated Milk, Sweetened Condensed Milk and Formulated Condensed Milk

xvi. GB 13432-2013 Food Labelling of Pre-packaged Foods For Special Dietary Supplies

xvii. GB 14880-2012 Standard for Food Enrichment Use

xviii. GB 14881-2013 General Hygiene Code for Food Production

xix. GB 14882-1994 Limited Concentration Standard of Radioactive Substances in Food

xx. GB 19301-2010 Raw Milk

xxi. GB 19302-2010 Fermented Milk

xxii. GB 19644-2010 Milk Powder

xxiii. GB 19645-2010 Pasteurized Milk

xxiv. GB 19646-2010 Cream, Butter and Anhydrous Milkfat

xxv. GB 23790-2010 Good Manufacturing Practice for Powdered Formulae for Infants and Young Children

xxvi. GB 25190-2010 Sterilized Milk

xxvii. GB 25191-2010 Modified Milk

xxviii. GB 25192-2010 Process(ed) Cheese

xxix. GB/T 27341-2009 HACCP System General Requirements for Food Processing Plants

xxx. GB 28050-2011 General Rules for Nutrition Labelling of Pre-packaged Foods

xxxi. GB 29921-2013 Maximum Limits for Pathogenic Microorganism in Food

xxxii. NY/T 939-2016 Identification of Reconstituted Milk in Pasteurized and UHT Milk

Note : China National Standard are subject to change from time to time

Annex 7 (b) (i)

Form CND/E/1-2014

Ministry of Health

APPLICATION FORM FOR LISTING OF PROCESSING ESTABLISHMENT FOR EXPORT OF MILK AND DAIRY PRODUCTS TO CHINA

1.0 Type of Application(1): ❑ New ❑ Re-apply
❑ Others, please specify .....

2.0 Product (1): ❑ Infant formula and follow up formula powder
❑ Others, please specify.....

3.0 Particulars of Applicant

3.1 Name of Applicant: .....

3.2 NRIC Number: .....

3.3 Name and Address of Company: .....

.....

.....

3.4 Tel. No.: .....3.5 Fax No.: .....3.6 H/P No. .....

3.7 E-mail address: .....

3.8 Company Registration Number (ROC): .....
(Please attach copy of the certificate)

3.9 Correspondence Address (if different from para 3.3): .....

.....

.....

3.10 Supporting Documents (please attach e.g. license, any certification etc.):.....

---

(1) Tick (✓) where appropriate

4.0 Information on Sources of Raw Milk:

No	Name of processing establishment	Address of processing establishment	Country of processing establishment	Name of Raw Milk	Type or raw milk (√ where applicable)		Import Approval No. by DVS
					Powder	Liquid	

I hereby, based on my knowledge and the information gathered to this date, certify that the above statements are all correct without prejudice.

Signature: _____

Name: _____

Date: _____

Company stamp :_____

Please return complete application form to:

Senior Director
Food Safety and Quality Division
Ministry of Health
Level 4, Menara Prisma
No. 26, Jalan Persiaran Perdana, Presint 3
62675 Putrajaya.
(Attn: Export Branch)
Tel. No:03-88850797
Fax No:03-88850798

***TOTAL AMOUNT OF DAIRY PRODUCT EXPORTED TO CHINA**

Please classify the total amount of dairy goods exported to China in the last 2 years (if applicable).

Product Category	**Total amount of dairy product exported to China (10^4 tons)**	
	Year of ××	**Year of ××**
Milk powder (excluding milk-based infant and follow up formula powder)		
milk-based infant and follow up formula powder		
Pasteurized milk		
Sterilized milk		
Modified milk		
Other disinfection milk		
Fermented milk		
Flavoured fermented milk		
Whole milk powder		
Partly skimmed milk powder		
Sweetened milk powder		
Skimmed milk powder		
Flavoured milk powder		
Formula milk powder		
Fortified formula milk powder		
Other milk powder		
Butter		
Cream		
Other milk fat		
Condensed milk		
Sweetened condensed milk		
Evaporated milk		
Other condensed milk		
Cheese		
Hard cheese		
Other cheese		
Demineralized whey powder		
Whey powder		
Whey protein concentrate		
Other whey powder		
Other milk and milk product		

* Extract from Annex 1- CNCA's Questionnaire of Overseas Manufacturer Registration Management for Exported Dairy Products

Annex 7 (b) (ii)

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 type①	Applicable age bracket②	Packaging form③	Registered trademark④

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*, *Enterobacter sakazakii* 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

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

②type 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

③Please 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.);

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

②Source 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 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, and 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.

A. Import information

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 type①	Applicable age bracket②	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.;

Annex 7 (b) (iii)

Name List Of Dairy Product (Except Infant Formula Products) Processing Establishments Applied To Register In China						
Name of Processing Establishment	**Address of Processing Establishment**	**City/ County**	**State/ Province/ Region**	****Type of Establishments***	****Product**	*****Remark**

****Type of Establishments:***
PP-production processing; CS-cold storage; Dry Store

*****Product varieties to be registered:***

Pasteurized milk	*Butter*
Sterilized milk	*Cream*
Modified milk	*Other milk fat*
Other disinfection milk	*Condensed milk*
Fermented milk	*Sweetened condensed milk*
Flavoured fermented milk	*Evaporated milk*
Milk powder	*Other condensed milk*
Whole milk powder	*Cheese*
Partly skimmed milk powder	*Hard cheese*
Sweetened milk powder	*Other cheese*
Skimmed milk powder	*Demineralised whey powder*
Flavoured milk powder	*Whey powder*
Formula milk powder	*Whey protein concentrate*
Fortified formula milk powder	*Other whey powder*
Other milk powder	*Other milk and milk product*

******Remarks:***
Bovine dairy
Goat or Sheep
Bovine

Annex 7 b (iv)

Application Form for Registration of Foreign Production Enterprises of Imported Liquid Milk

1.This application form is applicable to the new registration of production enterprise, addition of product category, and the expansion and renovation of production facilities that export liquid milk (including pasteurized milk, sterilized milk, modified milk, fermented milk, flavored fermented milk and other treated milk, but excluding infant formula liquid milk) to China.

2. The foreign production enterprises of pasteurized milk, sterilized milk, modified milk, fermented milk, flavored fermented milk and other treated milk shall carry out reference check in accordance with the requirements in the "Registration Conditions of Foreign Production Enterprises of Imported Liquid Milk and Key Points of Reference Check", and provide supporting material to prove that the enterprises can meet the standards of Chinese laws and regulations.
3. Please fill in and submit in Chinese or English. The contents shall be complete and accurate in order to avoid delays in application.

□New Registration □Addition of Product Category □Renovation and Expansion

Part I Business Profile

1. Enterprise name

2. Processing Establishment address

3. Registration number

4. Name/position of contact person

5. Telephone/E-mail of Contact person

6. Name of production/export qualification approval agency of the enterprise

7. Date of Plant establishment

8. List the products of the enterprise applying for registration

9. List the date when the enterprise has been registered in China and the approved products for export(if applicable)

10. Briefly describe the expansion and renovation of production facilities (if applicable)

11. List the production capacity of relevant products of the enterprise (please list them separately according to the products applying for registration)

Each shift: ___tons, daily shift: ___shift, annual production time: ___ days .
Annual processing capacity: ___ tonne

12. Raw materials

12.1 Raw milk (if applicable)

12.1.1 Type of supplier

□Buying from dairy farmers □Owned dairy farm □ Cooperative Nature

12.1.2 Raw milk type

□Cow Milk □Sheep Milk □Other

12.2 Dairy products [whole milk (powder), skim milk (powder), whey (powder), etc.] (if applicable). Specify the dairy products used.

13. Water for production and processing

Source of water

□Public water □ Self-owned water source of the enterprise

Whether the self-owned water source is disinfected or not, if so, please indicate the treatment method.

□Ozone treatment □ Chlorination treatment □other_____

14. List the current importing countries and the type of products exported to (if applicable)

15. Whether the foreign enterprise of pasteurized milk, sterilized milk, modified milk, other treated milk and fermented milk have done the self-inspection according to the "Registration Conditions of Foreign Production Enterprises of Imported Liquid Milk and Key Points of Reference Check" and confirmed that they can meet the corresponding requirements. (Yes/No)

Part II Enterprise Statement

1. The enterprise declares that the dairy products exported to China and their production process comply to the relevant provisions of Chinese laws, regulations and standards.
2. The above information and the additional materials submitted are true and correct.

Name and position of legal representative

_____

Signature of legal representative, company seal and date

_____

Part III Confirmation by Competent Authority

After verification and confirmation, it is certified that the above-mentioned materials provided by the enterprise are true and correct, and that the sanitary conditions of the enterprise could meet relevant provisions of Chinese laws, regulations and standards.

Name and position of person in charge

_____

Signature by the person in charge and seal by the competent authority (date)

_____

Annex 7 (b) (v)

Registration Conditions of Foreign Production Enterprises of Imported Liquid Milk and Key Points of Reference Check

Enterprise name and registration number:

Processing establishment Address:

Instruction of filling the form: 1. According to the Provisions on the Administration of Registration of Foreign Production Enterprises of Imported Food (promulgated as Order No. 145 of the former General Administration of Quality Supervision, Inspection and Quarantine, and amended according to Order No. 243 of the General Administration of Customs of the People's Republic of China), the sanitary conditions of foreign dairy enterprises applying for registration in China shall comply with the relevant provisions of Chinese laws, regulations, standards and norms. This form is specially formulated for foreign production enterprises exporting liquid milk (including pasteurized milk, sterilized milk, modified milk, fermented milk, flavored fermented milk, and other treated milk, but excluding infant formula liquid milk) to China to fill in and submit evidentiary materials according to the main conditions and basis listed, and carry out reference check for the purpose of evaluation and application for registration.

2. The applicants shall submit relevant documents and materials in Chinese or English truly and completely. The annexes of supporting materials submitted shall be numbered. The number and content of such annexes shall correspond accurately to the number and content in the column of "Filling Requirements and Evidentiary Materials", and the list of contents of the annexes shall be submitted at the same time.

Items	Conditions and Basis	**Filling Requirements and Evidentiary Materials**	Audit Key Points	Compliance Judgement	Remarks
1. Enterprise Profile					
1.1 Enterprise name, address, registration number, production/export qualification approval authority	1. Clause 6 and 7 of the Provisions on the Administration of Registration of Foreign Production Enterprises of Imported Food	1.1 Fill in the enterprise name, address, registration number, production/export qualification approval authority in the Application Form for Registration of Foreign Production Enterprises of Imported Liquid Milk.	1. The information provided by the applicants shall be consistent with the information of the list of companies submitted by the competent authorities of the applicant country.	□ Compliant □ Incompliant	
1.2 Products applying for registration	1. National Food Safety Standard Pasteurized Milk (GB 19645) 2. National Food Safety Standard Fermented Milk (GB 19302) 3. National Food Safety Standard Sterilized Milk (GB 25190) 4. National Food Safety StandardModified Milk (GB 5420)	1.2.1 List the standards of the products applying for registration which are complying with in part 1.8 of the Application Form for Registration of Foreign Production Enterprises of Imported Liquid Milk 1.2.2 If the products applying for registration is raw dairy product, indicate “raw dairy product” in part 1.8 of the	1. The products applying for registration shall comply with the definition of relevant standards.	□ Compliant □ Incompliant	

		Application Form for Registration of Foreign Production Enterprises of Imported Liquid Milk.			
2. Enterprise Location and Workshop Layout					
2.1 Enterprise selection and surrounding of the plant	1. Part 3 of the National Food Safety Standard General Hygienic Code for Food Production (GB14881).	2.1.1 Provide the layout plan of the plant area, indicating the names of different operation areas. 2.1.2 Provide pictures of the surrounding area where the plant is located. The pictures shall indicate the surrounding area information (urban, suburban, industrial, agricultural and residential areas).	1. Plant layout meets the needs of production and processing. 2. There is no pollution source around the plant.	□ Compliant □ Incompliant	
2.2 Workshop Design and Layout	1. Clause 5.12 and 5.13 of the National Food Safety Standard Good Manufacturing Practice for Milk Products (GB12693).	2.2 Provide workshop layout plan. The plant layout shall indicate the worker flow, raw material and finished goods flow, the functions of different processing areas and areas with the different cleanliness level.	1. Workshop layout shall be reasonable to meet the production and processing requirements and avoid cross contamination.	□ Compliant □ Incompliant	

3. Facilities and Equipment					
3.1 Production and processing equipment	Clause 6.1 of the National Food Safety Standard Good Manufacturing Practice for Milk Products (GB12693).	3.1 Provide a list of main equipment and facilities, and their processing capabilities.	1. Enterprise shall be equipped production equipment which matches its production capacity.	□ Compliant □ Incompliant	
3.2 Storage facilities	Clause 8.3.2.3 and Part 11 of the National Food Safety Standard Good Manufacturing Practice for Milk Products (GB12693).	3.2.1 Provide the photos of the raw milk storage facilities, storage capacity and temperature control requirements. (When applicable) 3.2.2 If there is a cold storage, please describe the temperature control requirements and monitoring methods. (When applicable)	1. Storage facilities could meet the product storage temperature requirements.	□ Compliant □ Incompliant	
4. Water/steam/ice supply					
4.1 Production water/steam/ice (if	1. Clause 5.3.1 of the National Food Safety Standard Good Manufacturing Practice for	4.1.1 Provide the photos of the self-provided water sources or secondary water	1. The production water monitoring plan shall cover all water outlets in the plant.	□ Compliant □ Incompliant	

applicable)	Milk Products (GB12693).	supply facilities, and explain whether there are any food defense measures such as assigning specific person in charge, locking and so on. (If applicable) 4.1.2 Provide the monitoring plans for production water and ice/steam (when applicable) which is direct contact with food, including bacteriological examination parameters, methods, frequency, records, test results and the latest 2 test reports. 4.1.3 Provide the boiler additives used in the production of steam which is direct contact with food, and explain whether they meet	2. Whether the parameters and methods meet the requirement of "Standard For Drinking Water" (GB5749). 3. The hygiene control procedures for secondary water supply facilities shall be designated and implemented with appropriate food defense measures. 4. The boiler additives used to produce steam which is direct contact with food shall meet the requirements of food production and processing.		

		the requirements of food production and processing.			
5. Raw Materials, Processing Aids and Packaging Materials					
5.1 Raw milk	1. National Food Safety Standard Raw Milk (GB 19301). 2. Clause 8.2.2.1 of the National Food Safety Standard Good Manufacturing Practice for Milk Products (GB12693). 3. Clause 6.2 of the Provisions on the Administration of Registration of Foreign Enterprises Producing Imported Food.	5.1 Provide the acceptance criteria for raw milk, including acceptance parameters and standard. (If applicable)	1. Raw milk meets the requirements of the National Food Safety Standard Raw Milk (GB 19301-2010) and respective country. 2. Milk comes from non-epizootic areas.	□ Compliant □ Incompliant □ Not applicable	
5.2 Dairy products [whole milk (powder), skim milk (powder), whey (powder),	1. National Food Safety Standard Milk Powder (GB 19644). 2. National Food Safety Standard Whey Powder and Whey Protein Powder (GB 11674).	5.2.1 Provide the list of dairy raw materials used. 5.2.1 Provide the acceptance criteria for	1. The dairy raw materials used in dairy products shall comply with the national food safety standards of China.	□ Compliant □ Incompliant □ Not applicable	

etc.]		dairy raw material, including parameters and standard.			
5.3 Other raw materials	1. Fermentation agents: Article 4.1.3 of the National Food Safety Standard Fermented Milk (GB 19302) List of Strains Used for Food (W. B. J. D. F. [2010] No. 65) 2. Food additives Article 9.4.1 of the National Food Safety Standard Good Manufacturing Practice for Milk Products (GB12693). 3. The use of food	5.3.1 Provide the list of other raw materials used. The name and function category of food additives shall be listed according to Appendix D of the National Food Safety Standard for the Use of Food Additives (GB2760). (If applicable). Shall specify the name of specific strains contained in the fermentation agents. (If applicable)	1. Fermentation agents: Are they within the scope of strains approved by China's health administration? 2. Additives: The usage scope and dosage of food additives and nutritional fortifiers. 3. When fruit jam products are used, the use of additives in fruit jam raw materials shall also meet the requirements of the	□ Compliant □ Incompliant □ Not applicable	

	additives and nutrient fortifiers shall comply with the provisions of the National Food Safety Standard for the Use of Food Additives (GB 2760) and the National Food Safety Standard for the Use of Food Nutrition Fortifiers (GB 14880).		National Food Safety Standard for the Use of Food Additives (GB 2760).		
5.4 Packaging Materials	1. Clause 9.5 of the National Food Safety Standard Good Manufacturing Practice for Milk Products (GB12693)	5.4 Provide the supporting materials indicating that the internal and external packaging materials are suitable for dairy product packaging.	1. The packaging materials do not affect food safety and product characteristics under specific storage and use conditions.	□ Compliant □ Incompliant	
5.5 Raw material supplier audit	1. Clause 8.2.1 of the National Food Safety Standard Good Manufacturing Practice for	5.5 Provide the procedures of raw material supplier audit.	1. Enterprises shall establish the supplier audit procedures, and stipulate the procedures for supplier selection, audit and evaluation.	□ Compliant □ Incompliant	

	Milk Products (GB12693).				
6. Production and Processing Control					
6.1 HACCP system	1. Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Production Enterprise (GB/T 27341)	6.1.1 Provide the process flow charts, hazard analysis worksheets and HACCP plan summary of all products intended to be exported to China. 6.1.2 Enterprise with HACCP, ISO22000 and other certification shall provide the corresponding certificate (if applicable).	1. The HACCP program shall analyze and effectively control biological, physical and chemical hazards. 2. The process flow shall be reasonable and shall prevent cross contamination. 3. The setting of CCP shall be scientific and feasible, and the corrective action and verification shall be appropriate. 4. Does the HACCP system cover all products applying for registration?	□ Compliant □ Incompliant □ Not applicable	
6.2 Production and processing technology	1. National Food Safety Standard Pasteurized Milk (GB 19645) National Food Safety Standard Fermented Milk (GB 19302)	6.2.1 Provide the process flow chart, list the main process parameters such as temperature/time of the heat treatment, etc. and describe the process.	1. Whether the production process of the enterprises comply with the product definition. 2. Whether the	□ Compliant □ Incompliant	

	National Food Safety Standard Sterilized Milk (GB 25190) National Food Safety StandardModified Milk (GB 25191) 2. Pasteurized milk: Pasteurization conditions in "Identification of Restored Milk in NY/T 939-2016 Pasteurized Milk and UHT Sterilized Milk" of the Ministry of Agriculture are as follows: Pasteurization treatment mode is kept for a long time at low temperature (62-65 ℃, 30 min) or for a short time at high temperature (72-76 ℃, 15 s; or 80-85℃, 10 S-15 s).	6.2.2 Enterprises with heat treatment process shall provide heat treatment temperature/ time curve (if applicable). 6.2.3 When using extended shelf life (ESL) process, enterprises shall explain the main process parameters and describe the processes. The description or supporting documents showing the ESL process could meet the requirements of relevant China standards shall be provided.	pasteurization temperature/ time curve of pasteurized milk is consistent with the pasteurization temperature/time declared by the enterprises. 3. Whether the heat treatment temperature of sterilized milk meets the requirements of China national standards.		
6.3 Packaging	1. National Food Safety Standard - Standard for the Nutrition Labeling of Prepackaged Foods (GB 7718) 2. National Food Safety Standard Nutrition	6.3.1 Provide the label sample of the products to be exported to China. 6.3.2 Provide the procedures of sealing inspection, which shall	1. The product label shall conform to the National Food Safety Standard - Standard for Nutrition Labeling of Prepackaged Foods (GB 7718).	□ Compliant □ Incompliant □ Not applicable	

	Label Standard of Prepackaged Foods (GB 28050)	include at least inspection points, operators, inspection methods and inspection frequency (applicable for sterilized milk, modified milk and other treated milk).	2. For tetra pack products, the sealing test parameters shall include at least the parameters listed in the Tetra Pack Integrity Check Manual.		
6.4 Product Shelf Life	1.Clause 2.5 of the National Food Safety Standard - Standard for Nutrition Labeling of Prepackaged Foods(GB 7718-2011)	6.4.1 Fill in the following information: Product storage method ___. Shelf life __. 2. Provide the basis or data which have been used to determine the shelf life of the product.	1. Whether the shelf life indicated on the actual label is consistent with the basis which is used to determine the shelf life. 2. Whether the shelf life testing conditions correspond to the actual storage and transportation condition.	□ Compliant □ Incompliant □ Not applicable	
7. Cleaning and Sanitization					
7.1 Cleaning and sanitization procedures of production line.	1. Clause 7.3 of the National Food Safety Standard Good Manufacturing Practice for Milk Products (GB12693-2010).	7.1 Provide the cleaning and sanitization procedures covering the entire production line. 7.1.1 When CIP (Clean in Place) is used, the cleaning and sanitization procedures	1. Is acid cleaning or other removal method of denatured proteins and salts used on heated surfaces of pipes and equipment? 2. Verification of	□ Compliant □ Incompliant □ Not applicable	

		provided shall include the following: CIP plan and frequency; type of sanitizer, action time, concentration, target and temperature used in CIP; verification of cleaning and sanitization effectiveness; and measures to prevent CIP from contaminating the products. (If applicable) 7.1.2 Provide cleaning and sanitization procedures, frequency and effectiveness verification if dry cleaning is used. (If applicable)	detergent residues (e.g. conductivity test, pH value, etc.) 3. Verification of cleaning effectiveness (e.g. microbial detection, ATP test, etc.).		
8. Self-inspection and Self-monitoring					
8.1 Real-time inspection and control of products	8.1 Clauses 9.1.1.1, 9.1.1.2 and 9.1.1.3 of the National Food Safety Standard Good Manufacturing Practice for Milk Products (GB12693-2010).	8.1.1 Provide the real-time inspection plan for products, including specifying inspection contents, parameters, frequency and verification according to the process.	1. Whether the real-time control measures effectively monitor and control the hazards which have been analyzed by enterprises.	□ Compliant □ Incompliant □ Not applicable	
8.2 Finished product inspection	8.2 Part 10 of the National Food Safety Standard Good	1. Provide the testing plan, testing standards and the	1. The inspection standards and sampling	□ Compliant □ Incompliant	

	Manufacturing Practice for Milk Products (GB12693-2010).	latest two batches of testing reports concerning the release of final products to be exported to China.	plans for finished products shall comply with the corresponding national food safety standards of China. For example, the limit requirements in product standards such as GB 19645-2010 National Food Safety Standard Pasteurized Milk, GB 19302-2010 National Food Safety Standard Fermented Milk, GB 25190-2010 National Food Safety Standard Sterilized Milk, GB 25191-2010 National Food Safety Standard Modified Milk, GB 5420-2010 National Food Safety Standard Cheese, GB 25192-2010 National Food Safety Standard Processed Cheese, GB 19646-2010 National Food Safety Standard Cream, Butter and Anhydrous Cream, GB	□ Not applicable	

			19644-2010 National Food Safety Standard Milk Powder, GB 13102-2010 National Food Safety Standard Condensed Milk, GB 11674-2010 National Food Safety Standard Whey Powder and Whey Protein Powder, etc.		
8.3 Aseptic verification scheme for production line and its implementation (if applicable)	1. Clause 4.6 of the National Food Safety Standard Sterilized Milk (GB 25190). 2. Clause 4.6.1 of the National Food Safety StandardModified Milk (GB25191). 3. National Food Safety Standard Food Microbiology Examination Commercial Sterility (GB 4789.26)	1. Provide sterility verification program of the production line for sterilized products.	1. A commercial aseptic test report shall be provided in accordance with the method specified in GB 4789.26.	□ Compliant □ Incompliant □ Not applicable	
9. Chemicals and Pest Control					
9.1 Chemical control	1. Clause 9.2 of the National Food Safety Standard Good Manufacturing Practice for	9.1 Briefly describe chemical use and storage requirements.	1. Chemicals shall be stored in specific areas, strictly managed and clearly identified.	□ Compliant □ Incompliant	

	Milk Products (GB12693-2010).		2. Prevent contamination of products by the chemicals used.		
9.2 Pest control	1. Clause 7.5 of the National Food Safety Standard Good Manufacturing Practice for Milk Products (GB12693-2010).	9.2 Provide the pest control methods and layout plan, and provide third-party qualification if undertaken by a third party.	1. Pests and rodents shall be prevented from affecting the safety and hygiene of production.	□ Compliant □ Incompliant	
10. Product Traceability					
10.1 Product traceability	1. Part 12 of the National Food Safety Standard Good Manufacturing Practice for Milk Products (GB12693-2010).	10.1 Briefly describe the product traceability procedure. Taking the batch number of a batch of finished product as an example, explain how to trace to the corresponding raw materials from the finished products.	1. Traceability procedures shall be established to achieve the two-way traceability of raw materials, processing and finished products.	□ Compliant □ Incompliant	
11. Personnel Management and Training					
11.1 Personnel Health and Hygiene Management	1. Clause 7.4 of the National Food Safety StandardGood Manufacturing Practice for Milk Products (GB12693-2010).	11.1 Provide requirements of the employees pre-employment health management and employee physical examination	1. Before employment, physical examination shall be done and prove to be suitable working in food processing	□ Compliant □ Incompliant	

			enterprise. 2. Employees shall be physical examined regularly and the records shall be kept.		
11.2 Personnel training	1. Part 13 of the National Food Safety Standard Good Manufacturing Practice for Milk Products (GB12693-2010).	11.2 Provide employee annual training plan, content, assessment and records	1. The training content shall cover the memorandum of inspection and quarantine of milk products exported to China, agreements and protocols, China laws and regulations and standards, etc.	□ Compliant □ Incompliant	
12. Statement					
12.1 Enterprise statement	1. Articles 6 and 7 of the Provisions on the Administration of Registration of Foreign Enterprises Producing Imported Food		1. Shall have the signature of the legal person and the stamp of the company.	□ Compliant □ Incompliant	
12.2 Official statement	1. Articles 6 and 7 of the Provisions on the Administration of Registration of Foreign		1. Shall have the competent authority personnel signature and the competent	□ Compliant □ Incompliant	

	Enterprises Producing Imported Food		authority stamp		

Annex 7 (c) (i)

Reg MDP-China Checklist – Rev 0/14

CHECKLIST FOR REGISTRATION OF PROCESSING ESTABLISHMENT OF MILK AND DAIRY PRODUCTS EXPORT TO CHINA (MILK PRODUCTS)
FOOD SAFETY AND QUALITY DIVISION
MINISTRY OF HEALTH MALAYSIA

ESTABLISHMENT NAME AND ADDRESS:	DATE INSPECTED: PRODUCT(S):
NAME AND TITLE OF RESPONSIBLE PLANT OFFICIAL:	TEL. NO.: FAX NO.:
References consulted: GB 12693—2010	Total time of verification:

INSTRUCTIONS:

Answer the following questions by checking the appropriate box.

NC= *No Conformity* ***PC=*** *Partial Conformity* ***C****= Conformity*

1.0 PLANT AND WORKSHOP

		NC	PC	C	COMMENTS
1.1	**Design and Layout**				
1.1.1	Any construction, expansion and reconstruction project shall be designed and executed according to the relevant national regulations.				
1.1.2	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.				
1.1.3	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.				
1.2	**Internal Building Structure**				
1.2.1	**Roof**				
1.2.1.1	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.				
1.2.1.2	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.				
1.2.1.3	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.				
1.2.2	**Walls**				
1.2.2.1	Walls should be constructed with non-toxic, odorless, smooth, water-proof and easy-to-clean light-color anti-corrosion materials.				
1.2.2.2	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.				
1.2.3	**Doors and windows**				

1.2.3.1	Smooth and anti-absorption materials shall be used, which should be easy to clean and disinfect				
1.2.3.2	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				
1.2.3.3	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.				
1.2.4	**Flooring**				
1.2.4.1	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.				
1.2.4.2	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.				
1.3	**Facilities**				
1.3.1	**Water supply facilities**				
1.3.1.1	Able to ensure the processing water quality, pressure and volume can achieve the production requirements.				
1.3.1.2	For water supply equipment and apparatus, it should get drinking water sanitation and safety permission documents from Health Administration Ministry provincial level and above.				
1.3.1.3	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				
1.3.1.4	The standby water supply shall comply with the provisions of GB17051.				
1.3.1.5	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.				
1.3.1.6	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.				
1.3.1.7	The quality of processing water shall comply with the provisions of GB5749.				
1.3.2	**Drainage system**				
1.3.2.1	It is necessary to allocate the proper drainage system, and avoid, in designing and constructing, products or production water from being contaminated.				
1.3.2.2	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.				
1.3.2.3	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.				
1.3.2.4	No other processing water pipelines shall be arranged inside and below the drainage system.				
1.3.2.5	The drainage outlet shall be equipped with a device to prevent the invasion of any animals.				
1.3.2.6	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.				
1.3.2.7	Waste water shall be discharged into the waste water treatment system or disposed in other proper ways.				
1.3.3	**Cleaning facilities**				

1.3.3.1	Proper facilities should be allocated for foodstuffs, apparatus and equipment cleaning and for storage of refuse and waste materials.				
1.3.4	**Personal hygienic facilities**				
1.3.4.1	Such personal hygienic facilities shall comply with the provisions of GB14881.				
1.3.4.2	The sterilizing facilities shall be installed before entering the cleaning work area, second dressing room shall be arranged when necessary.				
1.3.5	**Ventilation facilities**				
1.3.5.1	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 powder, the ambient temperature should be also controlled in the cleaning work area and so is the atmospheric humidity when it is necessary.				
1.3.5.2	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.				
1.3.5.3	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.				
1.3.5.4	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.				
1.3.5.5	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.				
1.3.6	**Lighting facilities**				
1.3.6.1	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.				
1.3.6.2	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.				
1.3.7	**Storing facilities**				
1.3.7.1	Enterprises shall have storing facilities which can match the types and quantity of milk products produced and operated.				
1.3.7.2	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.				
1.3.7.3	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).				
1.3.7.4	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.				

1.3.7.5	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.				
2.0 EQUIPMENT					
		NC	**PC**	**C**	**COMMENTS**
2.1	**Production equipment**				
2.1.2	**General requirements**				
2.1.2.1	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.				
2.1.2.2	All the production equipments shall be orderly arranged as per technical procedures to avoid any cross contamination.				
2.1.2.3	For the special equipments used in production (such as pressure vessel and pressure pipeline, etc.), it is necessary to formulate the relevant operation instructions.				
2.1.3	**Material quality**				
2.1.3.1	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.				
2.1.3.2	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.				
2.1.4	**Design**				
2.1.4.1	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.				
2.1.4.2	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.				
2.1.4.3	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.				
2.1.4.4	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.				
2.1.5	**Monitoring Equipment**				
2.1.5.1	Such monitoring equipments for measuring, controlling and recording as pressure gauge and thermostat, etc., should be calibrated, maintained periodically to ensure accuracy and effectiveness.				
2.1.5.2	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).				
2.1.6	**Service and Maintenance of Equipment**				
2.1.6.1	It is necessary to establish and strictly execute the equipment service and maintenance procedures.				
2.1.6.2	It is necessary to establish the daily maintenance and service schedule for equipment and carry out regular overhaul and keep proper records.				
2.1.6.3	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.				
3.0 HYGIENE MANAGEMENT					
		NC	**PC**	**C**	**COMMENTS**
3.1	**Hygiene Management System**				
3.1.1	Enterprise shall formulate the hygiene management system and examination standards and implement the post responsibility system.				
3.1.2	Enterprise shall formulate the hygiene inspection schedule, record and file the execution of such schedule.				
3.2	**Hygiene Management for Plant and Facilities**				
3.2.1	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.				
3.2.2	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.				
3.2.3	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.				
3.3	**Cleaning and Sterilizing**				
3.3.1	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.				
3.3.2	Enterprises may choose the cleaning and sterilizing methods according to the features of products and process.				
3.3.3	Equipment and instruments used for cleaning and sterilizing shall be kept properly in a special place.				
3.3.4	It is necessary to record the cleaning and sterilizing procedures, such as the type of detergent and sterilizer, time, density, object, temperature, etc.				
3.4	**Human Health and Hygiene Requirements**				
3.4.1	**Human health**				
3.4.1.1	Enterprises shall establish and execute the employees' health management system.				
3.4.1.2	Milk processing and operation personnel shall annually undertake the health check and obtain the health certificate before being put into work.				
3.4.1.3	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.				
3.4.2	**Personal hygiene**				
3.4.2.1	Milk product processing personnel shall maintain excellent personal hygiene.				
3.4.2.2	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.				
3.4.2.3	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.				
3.4.2.4	Persons in direct contact with milk product shall not use any nail oil and perfume and shall not wear watch and jewelleries.				

3.4.2.5	At work station, smoking, taking food or other activities that may impact the hygiene of dairy products shall not be allowed.				
3.4.2.6	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.				
3.4.3	**Visitors**				
3.4.3.1	To enter the foodstuff production, processing and operating areas, visitor shall comply with the hygienic requirements for the operating personnel on the spot.				
3.4.4	**Pest Control**				
3.4.4.1	Formulate measures for pest control. Keep the buildings intact and environment clean to prevent the invasion and breeding of pests.				
3.4.4.2	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.				
3.4.4.3	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.				
3.4.4.4	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).				
3.4.5	**Disposal of Refuses**				
3.4.5.1	Formulate rules for placing and eliminating refuses.				
3.4.5.2	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.				
3.4.5.3	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.				
3.4.5.4	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.				
3.4.6	**Management of Toxic and Harmful Substances**				
3.4.6.1	Management of toxic and harmful substances shall be subject to the relevant provisions of GB 14881.				
3.4.7	**Management of Sewage and Filth**				
3.4.7.1	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.				
3.4.7.2	Management of filth shall be subject to the relevant provisions of GB 14881.				
3.4.8	**Management of Work Uniforms**				
3.4.8.1	Management of work uniforms shall be subject to the relevant provisions of GB 14881.				
4.0 REQUIREMENTS FOR RAW MATERIALS AND PACKING MATERIALS					
		NC	**PC**	**C**	**COMMENTS**
4.1	**General Requirements**				
4.1.1	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.				

4.1.2	Raw milk collection centers constructed by production enterprises of milk products shall comply with the relevant national and local regulations.				
4.2	**Requirements for Purchasing, Acceptance check of Raw Materials and Packaging Materials**				
4.2.1	Production enterprises of milk products shall establish the supplier management system, specifying the supplier selection, audit and evaluation procedures.				
4.2.2	Production enterprises of milk products shall establish the incoming inspection system for raw materials and packaging materials.				
4.2.3	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.				
4.2.4	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.				
4.2.5	Rejected raw materials and packaging materials shall be labeled and separately stored. The supplier shall be notified for further action.				
4.2.6	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.				
4.3	**Transportation and Storage of Raw Materials and Packaging Materials**				
4.3.1	The vessels for transporting and storing fresh milk shall comply with the relevant national food safety standard.				
4.3.2	Raw milk shall be, within 2 hours after milking, cooled down to 0°C-4℃ and transported in normal temperature lorry. The lorry shall maintain completed certificate and record.				
4.3.3	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.				
4.4	**Transportation and storage of other raw and packaging materials**				
4.4.1	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.				
4.4.2	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.				
4.4.3	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.				
4.4.4	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.				
4.4.5	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.				

4.4.6	Maintain the Records on Purchasing, Acceptance check, Storage, Transportation of Raw Materials and Packaging Materials.				
5.0 FOOD SAFETY CONTROL IN PRODUCTION					
		NC	**PC**	**C**	**COMMENTS**
5.1	**Microbial Contamination Control**				
5.1.1	**Temperature and time**				
5.1.1.1	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.				
5.1.1.2	The control measures and corrective actions for temperature and time shall be established, the regular verification shall be carried out.				
5.1.1.3	For the process with strict control of temperature and time, it shall establish real-time monitoring measures and maintain the monitoring records.				
5.1.2	**Humidity**				
5.1.2.1	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.				
5.1.2.2	Establish the real-time control and monitoring measures for atmospheric humidity, conduct regularly verification and keep records.				
5.1.3	**Atmospheric cleanness in production area**				
5.1.3.1	Production workshop shall be kept with clean air to prevent the contamination to foodstuffs.				
5.1.3.2	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.				
5.1.4	**Prevention against microbial contamination**				
5.1.4.1	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.				
5.1.4.2	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.				
5.1.4.3	The water of ice lumps and steam which are direct contact with foodstuffs shall be used in compliance with the requirements of GB 5749.				
5.1.4.4	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.				
5.1.5	**Control of Chemical Contamination**				
5.1.5.1	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.				
5.1.5.2	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.				
5.1.5.4	Chemical substances shall be stored separate from foodstuffs, labeled clearly and managed by designated personnel.				
5.1.6	**Control of Physical Contamination**				
5.1.6.1	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.).				

5.1.6.2	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.				
5.1.6.3	Welding, cutting and grinding shall not be allowed during production to avoid smelly odor and foreign bodies.				
5.1.7	**Food Additives and Nutrition Fortifications**				
5.1.7.1	Food additives and nutrition fortifications shall be used reasonable according to the provisions of the food safety standard on types, application and dosage.				
5.1.7.2	Weigh the food additives accurately when use and maintain proper records.				
5.1.8	**Packaging Materials**				
5.1.8.1	Packaging materials should be clean, non-toxic and compliant with the national relevant regulations.				
5.1.8.2	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.				
5.1.8.3	The inner packaging materials should be able to adequately protect foodstuffs from contamination and against damages in the normal storage, transportation and sale condition.				
5.1.8.4	The recycle packaging materials such as glass bottles and stainless vessels should be washed clean and sterilized before being used.				
5.1.8.5	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.				
5.1.8.6	Product label should comply with GB7718, relevant national standards and other related regulations.				
6.0 TESTING OF PRODUCTS					
		NC	**PC**	**C**	**COMMENTS**
6.1	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.				
6.2	Each batch of products should be tested according to relevant standards and samples should be kept.				
6.3	Testing laboratory quality management shall be strengthened to ensure the accuracies and integrities of the test results.				
6.4	Testing records and reports shall be kept completely.				
7.0 PRODUCT STORAGE AND TRANSPORTATION					
		NC	**PC**	**C**	**COMMENTS**
7.1	Choose the storage and transportation mode according to the products categories and characteristics and ensure compliance with storage condition claimed on the product label.				
7.2	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.				
7.3	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.				
7.4	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.				
7.5	Product tested shall be indicated quality status.				
7.6	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.				

8.0 PRODUCT TRACEABILITY AND RECALL					
		NC	**PC**	**C**	**COMMENTS**
8.1	Enterprises shall establish the product traceability system to ensure effectively tracing the product at the whole process from raw materials purchasing to product sales.				
8.2	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.				
8.3	Harmless treatments and destructions shall be conducted to the recall products; report to the relevant department about product recall and disposal status.				
8.4	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.				
9.0 TRAINING					
		NC	**PC**	**C**	**COMMENTS**
9.1	A training system shall be established and the food safety knowledge training shall be conducted to all the employees.				
9.2	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.				
9.3	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.				
9.4	Training should be recorded.				
10.0 MANAGEMENT ORGANIZATION AND PERSONNEL					
		NC	**PC**	**C**	**COMMENTS**
10.1	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.				
10.2	A food safety management organization shall be built to conduct the food safety management.				
10.3	The personnel in charge of food safety organization should be the executive of the enterprise or the responsible person authorized by enterprise executive.				
10.4	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.				
10.5	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.				
10.0 MANAGEMENT OF RECORDS AND DOCUMENTS					
		NC	**PC**	**C**	**COMMENTS**
10.1	**Records and Management**				
10.1.1	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.				
10.1.2	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.				
10.1.3	Manufacturing process (including manufacturing parameters, environment monitoring data, etc.), products storage status, testing batch number, testing date, inspectors, test results shall be truly recorded.				
10.1.4	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.				
10.1.5	Recalled products' names, batch numbers, specifications, quantities, recall reasons and subsequent corrective action plan shall be truly recorded.				
10.1.6	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.				
10.1.7	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.				
10.1.8	All the relevant records specified hereto shall be kept not less than two years.				
10.2	**Document Management**				
10.2.1	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.				
10.2.2	Enterprises are encouraged to use advanced technologies (such as computer information system) for documents and records management.				
GENERAL COMMENTS					
EVALUATION OF COMPLIANCE					
VERIFIERS NAME AND SIGNATURE					

Annex 7 (c) (ii)

CHECKLIST FOR REGISTRATION OF PROCESSING ESTABLISHMENT OF MILK AND DAIRY PRODUCTS EXPORT TO CHINA (POWDERED FORMULAE FOR INFANTS AND YOUNG CHILDREN)
FOOD SAFETY AND QUALITY DIVISION
MINISTRY OF HEALTH MALAYSIA

ESTABLISHMENT NAME AND ADDRESS:	DATE INSPECTED: PRODUCT(S):
NAME AND TITLE OF RESPONSIBLE PLANT OFFICIAL:	TEL. NO.: FAX NO.:
References consulted: GB 23790—2010	Total time of verification:

INSTRUCTIONS:

Answer the following questions by checking the appropriate box.

NC= *No Conformity* ***PC=*** *Partial Conformity* ***C****= Conformity*

1.0 FACTORY BUILDING AND WORKSHOP

		NC	PC	C	COMMENTS
1.1	**Design and layout**				
1.1.1	Shall meet the relevant specifications of GB 12693.				
1.1.2	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:				
1.1.2.1	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.				
1.1.2.2	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.				
1.1.2.3	Do not improperly pile up processing material to avoid producing areas hard to clean.				
1.1.2.1	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.				
1.1.2.4	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.				
1.1.3	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.				
1.1.4	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.				

<table>
<tr><td>1.1.5</td><td>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.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>1.1.6</td><td>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.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>1.1.7</td><td>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, foot ware 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.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>1.1.8</td><td>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 in Table 1, and regular inspection should be carried out.
<table>
<tr><th>Work area</th><th>Aerobic bacterial count per petri dish (cfu/dish)</th><th>Test method</th></tr>
<tr><td>Cleaning work area ≤</td><td>30</td><td rowspan="2">Determine in accordance with the natural sedimentation method in GB/T 18204.1</td></tr>
<tr><td>Quasi-cleaning work area ≤</td><td>50</td></tr>
</table></td><td></td><td></td><td></td><td></td></tr>
<tr><td>1.1.9</td><td>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.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>1.1.10</td><td>Factory building, workshop and warehouse should be provided with facilities that can prevent from insects and mice or other animals entering such area.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>1.2</td><td colspan="5">Internal building structure</td></tr>
<tr><td>1.2.1</td><td>Shall meet the relevant specifications of GB 12693.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>1.3</td><td colspan="5">Facilities</td></tr>
<tr><td>1.3.1</td><td colspan="5">Water supply facility</td></tr>
<tr><td>1.3.1.1</td><td>Shall meet the relevant specifications of GB 12693.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>1.3.2</td><td colspan="5">Water drainage system</td></tr>
<tr><td>1.3.2.1</td><td>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.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>1.3.3</td><td colspan="5">Cleaning facility</td></tr>
<tr><td>1.3.3.1</td><td>Shall meet the relevant specifications of GB 12693.</td><td></td><td></td><td></td><td></td></tr>
</table>

1.3.3.2	The following measures should be taken for cleaning work area that should be kept dry:				
1.3.3.2.1	Adopt dry cleaning procedure applicable to the place and equipment.				
1.3.3.2.2	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.				
1.3.4	**Personal health facilities**				
1.3.4.1	Shall meet the relevant specifications of GB 12693.				
1.3.4.2	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.				
1.3.4.3	Cleaning measures should be taken at the entrance to workshop to prevent shoes from contaminating workshop.				
1.3.4.4	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.				
1.3.5	**Ventilation facility**				
1.3.5.1	Shall meet the relevant specifications of GB 12693.				
1.3.6	**Lighting facility**				
1.3.6.1	Shall meet the relevant specifications of GB 12693.				
1.3.7	**Storage facility**				
1.3.7.1	Shall meet the relevant specifications of GB 12693.				
2.0 EQUIPMENT					
		NC	**PC**	**C**	**COMMENTS**
2.1	**Production equipment**				
2.1.1	**General requirement**				
2.1.1.1	Shall meet the relevant specifications of GB 12693.				
2.1.2	**Material quality**				
2.1.2.1	Shall meet the relevant specifications of GB 12693.				
2.1.3	**Design**				
2.1.3.1	Production equipment shall meet the relevant specifications of GB 12693.				
2.1.3.2	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.				
2.1.3.3	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.				
2.1.3.4	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.				
2.2	**Monitoring equipment**				
2.2.1	Shall meet the relevant specifications of GB 12693.				

2.3	**Equipment maintenance and care**				
2.3.1	Shall meet the relevant specifications of GB 12693.				
3.0 HEALTH MANAGEMENT					
		NC	**PC**	**C**	**COMMENTS**
3.1	**Health management system**				
3.1.1	Shall meet the relevant specifications of GB 12693.				
3.2	**Sanitation management for factory building and facility**				
3.2.1	Shall meet the relevant specifications of GB 12693.				
3.3	**Cleaning and disinfection**				
3.3.1	Shall meet the relevant specifications of GB 12693.				
3.3.2	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.				
3.3.3	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.				
3.3.4	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.				
3.3.5	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.				
3.4	**Personnel health and sanitation management**				
3.4.1	Shall meet the relevant specifications of GB 12693.				
3.4.2	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.				
3.5	**Pest control**				
3.5.1	Shall meet the relevant specifications of GB 12693.				
3.6	**Waste treatment**				
3.6.1	Shall meet the relevant specifications of GB 12693.				
3.7	**Management of toxic and harmful substances**				
3.7.1	Shall meet the relevant specifications of GB 12693.				
3.8	**Management of sewage and dirt**				
3.8.1	Shall meet the relevant specifications of GB 12693.				
3.9	**Management for work clothes**				

3.9.1	Shall meet the relevant specifications of GB 12693.				
4.0 REQUIREMENT FOR RAW AND PACKAGING MATERIALS					
		NC	**PC**	**C**	**COMMENTS**
4.1	**General requirement**				
4.1.1	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.				
4.2	**Purchasing and acceptance of raw and packaging materials**				
4.2.1	Shall meet the relevant specifications of GB 12693.				
4.2.2	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.				
4.3	**Transportation and storage raw and packaging materials**				
4.3.1	Shall meet the relevant specifications of GB 12693.				
4.3.2	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.				
4.3.3	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.				
4.4	Keep purchasing, acceptance, storage and transportation records of raw and packaging materials.				
5.0 FOOD SAFETY CONTROL IN PRODUCTION PROCESS					
		NC	**PC**	**C**	**COMMENTS**
5.1	**Control of microbial contamination**				
5.1.1	Shall meet the relevant specifications of GB 12693.				
5.1.2	When the monitoring results on the control measures indicate any deviations, appropriate corrective measures should be taken.				
5.2	**Control of chemical pollution**				
5.2.1	Shall meet the relevant specifications of GB 12693.				
5.3	**Control of physical pollution**				
5.3.1	Shall meet the relevant specifications of GB 12693.				
5.4	**Food additives and food nutrition enhancer**				
5.4.1	Shall meet the relevant specifications of GB 12693.				
5.5	**Packaging materials**				
5.5.1	Shall meet the relevant specifications of GB 12693.				
5.6	**Specific processing steps**				
5.6.1	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:				
5.6.1.1	**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.				
5.6.1.2	**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.				
5.6.1.3	**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.				
5.6.1.4	**Cooling** In wet-mix and combined process, exposed powdered semi-finished product should be cooled in cleaning work after being dried.				
5.6.1.5	**Dry-mix** In dry-mix and combined process, the following key factors should be controlled in dry-mix:				
5.6.1.5.1	Exposed powder procedure contacting air (such as pre-mix and sub packaging, batching, feeding) should be conducted in cleaning work area. Temperature and relative humidity in cleaning work area shall adapt to production process of powdered formulae for Infants and young children. When there is no special requirement, temperature should be controlled below 25℃ and relative humidity should be controlled below 65%.				
5.6.1.5.2	Materials should be accurately batched.				
5.6.1.5.3	Key process parameters related to mixing homogeneity (such as mix time, etc.) Should be validated and confirmed. Mixing homogeneity should be confirmed.				
5.6.1.5.4	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.				
5.6.1.5.5	Compressed air required for material transport in positive pressure should be used after being deoiled, filtered, dehydrated and sterilized.				
5.6.1.5.6	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.				
5.6.1.6	**Inner packaging procedure** The following key factors should be controlled:				
5.6.1.6.1	Inner packaging procedure should be carried out in cleaning work area.				
5.6.1.6.2	Only related working personnel are allowed to enter package room. Refer to specification of Clause 5.6.1.5.6 for requirements for raw and packaging materials and personnel.				
5.6.1.6.3	Check to see if outer package of packaging material is complete or not before use to ensure that packaging material is not contaminated.				
5.6.1.6.4	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.				
5.6.1.6.5	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.				
5.6.1.7	**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.				
5.7	**Product information and label**				
5.7.1	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.				
5.7.2	Product label should be indicated with information such as product reconstitution method, water for reconstitution and storage method, etc.. Directions should be given to prevent customers from catching food borne diseases caused by improper use of product during the course of reconstitution and handling and feeding of the product.				
6.0 PRODUCT INSPECTION					
		NC	**PC**	**C**	**COMMENTS**
6.1	Shall meet the relevant specifications of GB 12693.				
6.2	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.				
7.0 PRODUCT STORAGE AND TRANSPORTATION					
		NC	**PC**	**C**	**COMMENTS**
7.1	Shall meet the relevant specifications of GB 12693.				
8.0 PRODUCT TRACEABILITY AND RECALL					
		NC	**PC**	**C**	**COMMENTS**
8.1	Shall meet the relevant specifications of GB 12693.				
9.0 TRAINING					
		NC	**PC**	**C**	**COMMENTS**
9.1	Shall meet the relevant specifications of GB 12693.				

10.0 MANAGEMENT ORGANIZATION AND PERSONNEL					
		NC	**PC**	**C**	**COMMENTS**
10.1	Shall meet the relevant specifications of GB 12693.				
11.0 RECORDS AND DOCUMENT MANAGEMENT					
		NC	**PC**	**C**	**COMMENTS**
11.1	**Records Management**				
11.1.1	Shall meet the relevant specifications of GB 12693.				
11.2	**Document Management**				
11.2.1	Shall meet the relevant specifications of GB 12693.				
12.0 MONITORING AND EVALUATION OF EFFECTIVENESS OF FOOD SAFETY CONTROL MEASURES					
		NC	**PC**	**C**	**COMMENTS**
12.1	The monitoring and evaluation measures in Annex A should be adopted to ensure the effectiveness of food safety control measures.				

GENERAL COMMENTS

EVALUATION OF COMPLIANCE

VERIFIERS NAME AND SIGNATURE

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 Enterobacteriaece (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 Enterobacteriaece in final product. Therefore Enterobacteriaece 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 Enterobacteriaece (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 Enterobacteriaece:

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 Enterobacteriaece is widely spread as it is a common colony in dry environment, and can be easily detected. Enterobacteriaece 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 Enterobacteriaece 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 Enterobacteriaece 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 i*s detected. In addition, *Enterobacter sakazakii* trend and change in Enterobacteriaece quantity should be evaluated; which kind of action should be taken depends on possibility of product contamination by *Salmonella* and *Enterobacter sakazakii*.