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

Overseas Production Enterprise Registration Application Form

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

Part I General Information About the Enterprise

A General Information

1. Production enterprise

Registered name (actual production organization): _____

Registered address (actual production address): _____

Registration number (if applicable): _____

2. Contact person:

Telephone:

Fax:

E-mail:

3. Registration (approval) authority:

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

5 Date of plant establishment:

6.Total area:

7.Total building area:

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

9 Name of products to be exported to China:

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

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

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

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

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

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

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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

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awarded with relevant certificates, please provide the certificate and documentary evidences concerning the qualification of the third-party certification organization.

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

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

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

No.

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

6. Is 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

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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 for monitoring water for production, ice/steam (if applicable) which directly contact food, including bacteriological examination items, method, frequency and the latest two test reports.

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C. Raw Material Information

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

(1) Raw milk

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

② type of Milk source;

Milk source owned by enterprise;

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

Milk source from dairy farms owned by enterprise through cooperatives

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

other milk source

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

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

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

② Source of raw material:

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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.

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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.

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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 for the plant area)?
2. Please provide pest and mouse control chart in the form of attachment.

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G Enterprise Statement

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

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

Name and position of legal representative

Signature of legal representative and company seal and date

H. Confirmation by Competent Authority

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

Name and position of the responsible person

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

Part II Overview of Enterprise's Export to China

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

B.Import information

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.

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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: _____

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Contact person: _____

2. Product information

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

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

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

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

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