Attachment 7-3-3

Application for Registration Renewal of Overseas Manufacturers of Infant Formula

**(Included formula milk powder and formula liquid milk)**

Description: This is an application for registration renewal required by GACC which must be provided by overseas manufacturers of exporting infant formula to China (formula milk powder and formula liquid milk). Please fill in this form with Chinese or English. Content of the application materials shall be true and accurate to avoid misleading and delaying. Please also provide any other information supporting this application.

1. Basic Information
2. Name of the manufactures:
3. Address of Production site\* (A new application for registration is required if the production site is relocated):
4. Registration number\* (Provide supporting documents. A new application for registration is required if registration number has changed):
5. Registration (approval) organization: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. Date of establishment:
7. Total area:
8. Total architectural area:
9. Please provide workshop layout, clean are division map and diagram for human flow and logistics flow in the form of attachments.
10. Date of renovation and expansion; description of renovation and expansion project (if applicable)
11. Export trade situation in the past 2 years (countries or regions that have been exported, corresponding types of export products)
12. Name of products that plan to export to China:

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| --- | --- | --- | --- | --- |
| Number | Type of product① | Applicable age group② | Package style③ | Trademark④ |
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|  |  |  |  |  |

Whether different brands of infant formula are produced with the same formula (yes/no).

①Type of product: Fill in according to “Infant formula milk powder”, “Infant formula liquid milk”;

②Applicable age group: For example, fill in the age of 0~6 months, etc.;

③Package style: For example, fill in the carton with inner packaging, the iron can with inner packaging, the iron can without inner packaging, etc. (the form of inner and outer packaging needs to be explained in details);

④Trademark: Please fill in the registered trademark approved by the competent authority.

1. The actual production volume of finished infant formula milk products in the last 2 years (\_\_\_\_ tons / year)
2. List the designed annual production and processing capacity of the enterprise (\_\_\_\_ tons/year)
3. Name, phone number and email address of legal representative\* (A new registration is required if the legal representative has changed)
4. Name, phone number and email address of contact person
5. Proof of business identity (For example, business license issued by the competent authority of the country where you are located, etc.)
6. Production Information
7. Please select the production process of the product, and please provide a clear process flow chart in the form of an attachment:

[ ] Wet-mix process;

[ ] Dry-mix process;

[ ] Combined process.

(Note: definition of wet-mix process, dry-mix process and combined process, please refer to *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children CAC/RCP66-2008*, which is issued by Codex Alimentarius Commission)

1. Production capacity and equipment
2. List main equipment, quantity and design production capacity that used for production;
3. Production capacity per shift (tons), number of shifts per day and number of working days per year.
4. Hygiene quality management system

[ ] Hazard Analysis and Critical Control Point (HACCP) system has been established and implemented, please provide hazard analysis worksheet and HACCP plan. If you have passed the certification of a qualified third-party agency and obtained the HACCP certification, please provide the certificate and the qualification of the third-party agency;

[ ] A food safety management system (ISO22000 or other equivalent hygienic quality management system) has been established and implemented, please provide the HACCP plan and its prerequisites. If you have passed the certification of a qualified third-party agency and obtained corresponding certification, please provide the certificate and the qualification of the third-party agency;

[ ] Not implemented, please provide hazard source analysis and corresponding preventive and control measures.

1. Please indicate whether there are segregation and washing (or cleaning) measures between production of different batches, formulations and varieties of products:

[ ] Yes, please provide proof in the form of attachments;

[ ] No.

1. Please provide environmental monitoring plan for salmonella, enterobacter sakazakii and other enterobacteriaceae, air cleanliness monitoring plan in the cleaning work area, as well as the latest 2 test reports in the form of attachments.
2. Is there an automatic valve array in processing workshop of the enterprise? (where applicable)

[ ] Does not exist;

[ ] Yes, please provide following information.

(Note: If automatic valve array exists, please select “Yes” and fill in following information; and please select “Does not exist” if there isn’t any. )

If there is CIP (Clean in place) cleaning in the production process of the enterprise, please provide CIP cleaning information of main production equipment:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Number | Name of the production equipment | Chemical name of cleaning agent | Temperature, concentration, time, flow | The way to check cleaning effect |
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If there are manual cleaning equipment and components in the production process of the enterprise, please provide following information:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Number | Name of the production equipment | Chemical name of cleaning agent | Temperature, concentration, time | The way to check cleaning effect |
|  |  |  |  |  |
|  |  |  |  |  |

1. Please list in the form of attachments the names of chemicals such as disinfectants and cleaning agents used in the production area used by the enterprise.
2. Supply of water/ice/steam (where applicable)
3. Water source

[ ] Public water supply;

[ ] Enterprise's self-own water source: Whether the water is disinfected by the enterprise's self-own water source, if so, please explain treatment method and monitoring limit.

[ ] Ozone treatment

[ ] Chlorination

[ ] Other

1. Please provide water supply and drainage diagrams to show the flow of water;
2. Please provide monitoring plan for production water and ice/steam in direct contact with food (if applicable) in the form of attachments, including items, methods, frequency of bacteriological inspections, and the last two test reports.
3. Please list batch release items and sampling plan of final product in the form of attachments.
4. Raw Material Information
5. The raw materials used in the production of infant formula milk are:
6. [ ] Raw milk

① Acceptance criteria for raw milk entering the factory (including indicators, limits, acceptance requirements, etc.);

②Type of milk source:

 [ ] The milk source from the enterprise’s self-own property rights;

 [ ]  The parent company of the enterprise group owns the milk source with property rights, and manages it according to relevant regulations of the country (region) where it is located;

 [ ]  Owning the enterprise's farm milk source through a cooperative;

 [ ]  The milk source that has passed evaluation of the enterprise or an institution with corresponding qualifications, and it is managed according to relevant regulations of the country (region) where it is located, and it has signed a milk source supply contract with the enterprise for three years or more;

 [ ] Other milk source

③ Milk source raw milk annual output (tons):\_\_\_ ; Annual supply (tons): \_\_\_\_

1. [ ] Dairy products (whole milk (powder), skim milk (powder), whey (powder), etc.

① Acceptance criteria for incoming raw materials (including indicators, limits, and acceptance requirements);

② Source of raw materials:

 [ ] Domestic purchase;

 [ ]  For non-domestic purchases, please provide source country;

 [ ]  Dairy products produced by self-owned company that belongs to the parent company of the enterprise group shall be managed in accordance with relevant regulations of the country (region) where it is located.

1. Please briefly describe the enterprise's audit system for raw material suppliers.
2. Information on nutritional fortifiers used in the production of infant formula by enterprises:
3. Acceptance criteria for nutritional fortifiers entering the factory (including indicators, limits, acceptance requirements, etc.);
4. Source of nutritional supplements:

[ ] Domestic purchase;

[ ]  For non-domestic purchases, please provide source country.

1. Information on food packaging materials that are in direct contact with food used in the production of infant formula:
2. Acceptance criteria for food packaging materials entering the factory that come into direct contact with food (including indicators, acceptance requirements, etc.)
3. Source of materials:

[ ] Domestic purchase;

[ ]  For non-domestic purchases, please provide source country.

1. Product Traceability and Recall
2. Whether there are logos, signs or numbers for traceability printed on the product packaging:

[ ] Yes, please explain the meaning of logo, sign or number used for traceability, where it is printed on the package, and how consumers use these logos, signs or numbers, etc.;

[ ] No.

1. Whether the company has established a product recall system or not. Please provide a brief introduction to the product recall system in the form of an attachment.
2. Product Testing
3. Laboratory for batch release of finished products:

[ ] Official testing agency

Name of the laboratory: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] Third-party testing agency

Name of the laboratory: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] Enterprise self-owned laboratory

Please provide the laboratory testing ability certificate or qualification information in the form of attachments.

1. Please provide disposition procedures for unqualified raw materials, semi-finished products and finished products of the enterprise in the form of attachments.
2. Enterprise Location and Factory Environment
3. Please describe the location of the enterprise, is it in an industrial, agricultural or residential area? Is it far away from odor, smoke and other pollution caused by livestock and poultry farms, refineries, municipal waste, chemical factories and sewage treatment plants? (Please provide a location map of the enterprise in the form of attachments in order to clearly reflect surrounding environment of the factory.)
4. Please provide a pest control map in the form of attachment.
5. Declaration of the Enterprise

It is declared that above information and submitted materials are true and correct, and that the self-examination is qualified in accordance with the “table of Registration Conditions for Overseas Manufactures of Imported Foods and the Key Points for Comparison and Inspection”, and the enterprise can meet requirements with relevant Chinese laws and regulations and national food safety standards.

Name and position of legal representative:

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Signature of legal representative and stamp of the enterprise Date:

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1. Acknowledgment by the Competent Authority

After review and confirmation, this is to certify that above information and submitted materials of the enterprise are true and correct. Enterprise applying for registration can meet with requirements of the “table of Registration Conditions for Overseas Manufactures of Imported Foods and the Key Points for Comparison and Inspection”, and meet requirements with relevant Chinese laws and regulations and national food safety standards.

Name and position of the person in charge:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the person in charge and stamp of the competent authority Date:

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