Attachment 4-3-3

Registration conditions and key points for comparison and inspection of overseas manufacturers of imported dairy products

**(without pasteurized milk and infant formula)**

Registration number:

Company Name:

company address:

Form filling date:

Instructions for filling out the form:

1. According to the " Regulations of the People's Republic of China on the Administration of Registration of Overseas Production Enterprises of Imported Food" (Order No. 248 of the General Administration of Customs), the sanitary conditions of overseas dairy production enterprises that apply for registration in China shall comply with the relevant provisions of Chinese laws, regulations and standards , in line with the requirements of the Protocol on Inspection and Quarantine of Dairy Products Exported to China. This form is for the overseas competent authorities of imported dairy products (excluding pasteurized milk and infant formula) to conduct official inspections on dairy production enterprises based on the listed main conditions and bases, with reference to the review points ; Conditions and basis, fill in and submit supporting materials, and conduct self-examination according to the review points, which can be used for self-assessment before the enterprise applies for registration.

2. Overseas competent authorities and overseas dairy production enterprises should truthfully make compliance judgments based on the actual situation of the comparison inspection.

3. The submitted materials should be filled in in Chinese or English, the content is true and complete, the attachments should be numbered, and the number and content of the attachments should accurately correspond to the item number and content in the column of "Filling Requirements and Certification Materials". At the same time, submit the list of attachments of the certification materials.

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| project | Conditions and basis | **Fill in the requirements and supporting materials** | Review points | Compliance determination | Remark |
| **1. Basic information of the company** |
| 1.1 Enterprise name, address, registration number, production/export qualification approval agency | 1. Articles 9 and 10 of " Regulations of the People's Republic of China on the Administration of Registration of Overseas Manufacturers of Imported Foods" (Order No. 248 of the General Administration of Customs) . | Application for Registration of Overseas Manufacturers of Imported Dairy Products" (excluding pasteurized milk and infant formula)Chinese enterprise name, address, registration number, production/export qualification approval agency name. | 1. The information filled in by the applicant enterprise should be consistent with the information on the list of enterprises submitted by the competent authority of the applicant country. | □Compliant□ does not meet |  |
| 1.2 Apply for product registration | 1. "National Food Safety Standard Fermented Milk" (GB 19302-2010 ) .2. "National Food Safety Standard Sterilized Milk" (GB 25190-2010 ) .3. "National Food Safety Standard Modulated Milk" (GB 5 191-2010 ).4. " National Food Safety Standard Condensed Milk " ( GB 13102-2010 ) .5. " National Food Safety Standard Milk Powder "》 ( GB 19644-2010 ) .6. " National Food Safety Standard for Whey Powder and Whey Protein Powder " ( GB 11674-2010 ) .7. " National Food Safety Standard for Cream, Cream and Anhydrous Cream " ( GB 19646-2010 ) .8. Food Safety National Standard Cheese ( GB 5420-2010 ) .9. " National Food Safety Standard Processed Cheese " ( GB 25192-2010 ) . | 1.2 In the " Application for Registration of Overseas Manufacturers of Imported Dairy Products" (excluding pasteurized milk and infant formula) . 1.3 lists the standards that the product applying for registration meets. | 1. The product applying for registration shall conform to the definition of relevant standards. | □Compliant□ does not meet |  |
| **2. Enterprise location and workshop layout \* (no need to fill in the application form, it will be used for self-inspection and provided if necessary)** |
| 2.1 Enterprise location and factory environment | 1. "National Food Safety Standard Food Production General Hygiene Code" (GB14881-2013) 3. | Plant floor plan, indicating the names of different operating areas.A picture of the environment in the area where the factory is located, and the surrounding environment information (urban, suburban, industrial, agricultural and residential areas) should be indicated in the picture . | 1. The layout of the factory area meets the needs of production and processing.2. There is no pollution source around the factory. | □Compliant□ does not meet | For self-examination use, if necessary. |
| 2.2 Workshop Design and Layout | 1. 5.12 and 5.13 in "National Food Safety Standard Dairy Good Manufacturing Practice" (GB12693-2010). | Workshop floor plan. The figure shows the flow of people, the direction of logistics, the functions of different processing areas, and the range of areas with different degrees of cleanliness. | 1. The layout of the workshop should be reasonable, meet the production and processing requirements, and avoid cross-contamination. | □Compliant□ does not meet | For self-examination use, if necessary. |
| **3. Facilities \* (no need to fill in the application form, for self-inspection use, provided if necessary)** |
| 3.1 Production and processing equipment | 6.1 in "National Food Safety Standard for Good Manufacturing Practice for Dairy Products" (GB12693-2010). | List of main equipment and facilities , and design processing capacity. | 1. Enterprises should be equipped with production equipment suitable for production capacity . | □Compliant□ does not meet | For self-examination use, if necessary. |
| 3.2 Storage facilities | 8.3.2.3, 11 in "National Food Safety Standard for Good Manufacturing Practice for Dairy Products" (GB12693-2010). | Photos of raw milk storage equipment, storage capacity and temperature control requirements. (where applicable)If there is a cold storage , please describe the temperature control requirements and monitoring methods . (where applicable) | 1. Warehousing facilities can meet product storage temperature requirements . | □Compliant□ does not meet | For self-examination use, if necessary. |
| **4. Water/steam/ice supply \* (no need to fill in the application form, it will be used for self-checking and provided if necessary)** |
| 4.1 Process water/steam/ice (if applicable) | 1. 5.3.1 in "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB12693-2010). | Photos of self-provided water sources or secondary water supply facilities, and indicate whether there is a special person responsible for food protection measures such as locking. (if applicable)Monitoring plan for water used in production and processing and ice/steam (if applicable) in direct contact with food, including items, methods, frequency, records, test results and the last two test reports of bacteriological inspection.Boiler additives used in the production of steam in direct contact with food, and indicate whether they meet the requirements of food production and processing. | 1. The production water monitoring plan should cover all water outlets in the factory.2. Whether the project and method meet the requirements of "Drinking Water Standard" (GB5749-20 06 ).3. The secondary water supply facilities shall formulate and implement sanitation control procedures and have appropriate food protection measures.4. Boiler additives used in the production of steam directly in contact with food shall meet the requirements of food production and processing. | □Compliant□ does not meet | For self-examination use, if necessary. |
| **5. Raw materials and packaging materials \* (no need to fill in the application form, they will be used for self-inspection and provided if necessary)** |
| 5.1 Raw milk | 1. "National Food Safety Standard Raw Milk" (GB 19301-2010).2. 8.2.2.1 in "National Food Safety Standard Dairy Good Manufacturing Practice" (GB12693-2010).3. Article 5 of " Regulations on the Administration of Registration of Overseas Production Enterprises of Imported Food " . | Raw milk acceptance criteria, including acceptance items and indicators. (if applicable) | 1. Raw milk complies with "National Food Safety Standard Raw Milk" (GB 19301-2010) and national requirements.2. The milk source comes from the epidemic-free area. | □Compliant□ does not meet□Not applicable | For self-examination use, if necessary. |
| 5.2 Dairy products <whole milk (powder), skim milk (powder), whey (powder), etc.> | 1. "National Food Safety Standard Milk Powder" (GB 19644-2010).2. "National Food Safety Standard for Whey Powder and Whey Protein Powder" (GB 11674-2010). | List of dairy ingredients used.Acceptance criteria for dairy products, including acceptance items and indicators. | 1. The raw materials of dairy products used should meet the national food safety standards of China. | □Compliant□ does not meet□Not applicable | For self-examination use, if necessary. |
| 5.3 Other raw materials | 1. Starter:"National Food Safety Standard for Fermented Milk" (GB 19302-2010) 4.1.3"List of strains that can be used in food" (Supervision issued by the Health Office [2010] No. 65).2. Food additivesArticle 9.4.1 of "National Food Safety Standard Dairy Good Manufacturing Practice" (GB12693-2010).3. The use of food additives and nutritional fortifiers shall comply with the "National Food Safety Standard for the Use of Food Additives" (GB 2760-2014 ) and the "National Food Safety Standard for the Use of Food Nutrition Fortifiers" (GB 14880-2012 ) Regulation. | List of other ingredients used. | 1. Starter: whether it is within the range of strains approved by the Chinese health administrative department.2. Additives: the scope and dosage of food additives and nutritional fortifiers.3. If the products used are jam products, the use of additives in the jam raw materials should also meet the limit requirements of the "National Food Safety Standard for the Use of Food Additives" (GB 2760-201 4 ). | □Compliant□ does not meet□Not applicable | For self-examination use, if necessary. |
| 5.4 Packaging Materials | 1. 9.5 in "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB 12693-2010). | Evidence that the inner and outer packaging materials are suitable for dairy packaging. | 1. Packaging materials do not affect the safety and product characteristics of food under specific storage and use conditions. | □Compliant□ does not meet | For self-examination use, if necessary. |
| 5.5 Raw material supplier audit | 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB 12693-2010) 8.2.1. | Audit procedures for raw material suppliers. | 1. Enterprises should establish supplier audit procedures and stipulate procedures for supplier selection, audit and evaluation. | □Compliant□ does not meet | For self-examination use, if necessary. |
| **6. Production and processing control \* (no need to fill in the application form, it will be used for self-inspection and provided if necessary)** |
| 6.1 HACCP system | 1. "General Requirements for Hazard Distribution and Critical Control Points (HACCP) System Food Production Enterprises" (GB/T 27341-20 09 ). | The production and processing process flow chart, hazard analysis worksheet and HACCP plan of all products to be exported to China.If you have obtained HACCP, ISO22000 certification, etc., please provide the corresponding certification certificate (if applicable). | 1. The HACCP plan shall analyze and effectively control biological, physical and chemical hazards.2. The production process should be reasonable to avoid cross-contamination.3. The setting of CCP points should be scientific and feasible, and the corrective and verification measures should be appropriate.4. Whether the HACCP plan includes all products applied for registration. | □Compliant□ does not meet□Not applicable | For self-examination use, if necessary. |
| 6.2 Production and processing technology | 1. "National Food Safety Standard Fermented Milk" (GB 19302-2010).2. "National Food Safety Standard Sterilized Milk" (GB 25190-2010).3. "National Food Safety Standard Modulated Milk" (GB 25191-2010). | The process flow chart lists the main process parameters such as heat treatment temperature/time and describes the process.For those with heat treatment process, provide the heat treatment temperature/time curve (if applicable). | 1. Whether the production process of the enterprise conforms to the product definition.2 Whether the temperature/time change curve of sterilized milk is consistent with the sterilization temperature/time declared by the enterprise.3. Whether the temperature of sterilized milk heat treatment meets the requirements of the national standard. | □Compliant□ does not meet | For self-examination use, if necessary. |
| 6.3 Packaging | 1. "National Food Safety Standard General Rules for the Labeling of Prepackaged Foods" (GB 7718-201 1 )2. "National Food Safety Standard General Rules for Nutrition Labeling of Prepackaged Foods" (GB 28050-201 1 ). | Label samples for products to be exported to China.The procedure of airtightness inspection shall at least include inspection points, operators, inspection methods and inspection frequency (applicable to sterilized milk, modulated milk and other sterilized milk). | 1. Product labels should comply with the General Rules for the Labeling of Prepackaged Foods in National Food Safety Standard (GB 7718-201 1 ).2. For products using Tetra Pak, the airtightness testing items should at least include the items listed in the Tetra Pak Package Integrity Inspection Manual. | □Compliant□ does not meet□Not applicable | For self-examination use, if necessary. |
| 6.4 Product shelf life | 1. "National Food Safety Standard General Rules for Labeling of Prepackaged Foods" (GB 7718-2011) 2.5. | Fill in the following informationHow the product is stored \_\_\_\_\_\_.Shelf life \_\_\_\_\_\_\_\_\_.The basis or data to confirm the shelf life of the product. | 1. Whether the basis for confirming the shelf life is consistent with the actual label.2. Whether there is a corresponding relationship between the test conditions of the shelf life and the actual storage and transportation. | □Compliant□ does not meet□Not applicable | For self-examination use, if necessary. |
| **7. Cleaning and disinfection \* (There is no need to fill in the application form, it will be used for self-examination and provided if necessary)** |
| 7.1 Cleaning and disinfection procedures of the production line. | 1. "National Food Safety Standard Dairy Good Manufacturing Practice"(GB 12693-2010) 7.3. | Cleaning and disinfection procedures covering the entire production line.When using CIP (Clean in Place), the provided cleaning and disinfection procedures should include the following:CIP plan, frequency; type of disinfectant used in CIP, action time, concentration, object, temperature; cleaning and disinfection effect verification measures; measures to prevent CIP from contaminating products. (if applicable)If dry cleaning is used, cleaning and disinfection procedures, frequency and verification measures for cleaning and disinfection effects are provided. (if applicable) | 1. Whether the heated surfaces of pipes and equipment are pickled or otherwise removed to remove denatured proteins and salts.2. Cleaning agent residue verification (such as testing conductivity, pH value, etc.).3. Verification of cleaning effect (such as microbial detection, ATP experiment, etc.). . | □Compliant□ does not meet□Not applicable | For self-examination use, if necessary. |
| **8. Self-inspection and self-control \* (no need to fill in the application form, it is used for self-inspection and provided if necessary)** |
| 8.1 Product online control inspection | 8.1 "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB 12693-2010)9.1.1.1, 9.1.1.2, 9.1.1.3. | Product online inspection plan, including the following: specify inspection content, parameters, frequency and verification according to the process sequence. | 1. Online control measures, whether the hazards analyzed by the enterprise are effectively monitored. | □Compliant□ does not meet□Not applicable | For self-examination use, if necessary. |
| 8.2 Finished product inspection | 8.2 "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB 12693-2010) 10. | The testing plan, testing standards and testing reports of the last two batches of final products to be exported to China. |  | 1. □Compliant
2. □ does not meet
3. □Not applicable
 | 1. For self-examination use, if necessary.
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| 1. 8.3 Production line sterility verification program and implementation (if applicable)
 | 1. 1. "National Food Safety Standard Sterilized Milk" (GB 25190-2010 ) 4.6.
2. 2. "National Food Safety Standard Modulated Milk" (GB25191-2010 ) 4.6.1.
3. 3. "National Food Safety Standard Food Microbiological Test Commercial Sterility Test" (GB 4789.26-201 3 ) .
 | * Sterility validation program for sterilized product lines.
 | * 1. The commercial sterility test report implemented in accordance with the method specified in GB/T 4789.26-2013 should be provided .
 | * □Compliant
* □ does not meet
* □Not applicable
 | * For self-examination use, if necessary.
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| **9. Chemicals and pest control \* (no need to fill in the application form, it will be used by self-inspection and provided if necessary)** |
| 9.1 Chemical Control \_ | 1. 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB 12693-2010) 9.2.
 | * Briefly describe chemical usage and storage requirements.
 | * 1. Chemicals should be stored in a special area, strictly managed, and clearly marked.
* 2. Prevent the chemicals used from contaminating the product.
 | □Compliant□ does not meet | * For self-examination use, if necessary.
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| 9.2 Pest control | 1. 1. "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB 12693-2010) 7.5.
 | Pest control method and layout plan, if it is undertaken by a third party, third-party qualifications will be provided . | 1. The influence of pests and rodents on production safety and hygiene should be avoided. | □Compliant□ does not meet | * For self-examination use, if necessary.
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| **10. Product traceability \* (no need to fill in the application form, use it for self-inspection, and provide it if necessary)** |
| 10.1 Product traceability | 1. 1. 12 in "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB 12693-2010).
 | Briefly describe the product traceability procedures, taking a batch of finished product batch numbers as an example to explain how to trace the finished product to the corresponding raw material. | 1. A traceability procedure should be established to achieve two-way traceability of the entire chain of raw materials, production and processing processes, and finished products. | □Compliant□ does not meet | * For self-examination use, if necessary.
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| **11. Personnel management and training \* (There is no need to fill in the application form, it will be used for self-examination and provided when necessary)** |
| 11.1 Personnel health and hygiene management | 1. 7.4 of "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB 12693-2010). | Employee pre- employment health management and employee physical examination requirements . | 1. Before hiring an employee, a medical examination should be carried out and certified as fit to work in a food processing business .2. Employees should undergo regular physical examinations and keep records. | □Compliant□ does not meet | * For self-examination use, if necessary.
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| 11.2 Personnel training | 1. 13 in "National Food Safety Standard Good Manufacturing Practice for Dairy Products" (GB 12693-2010). | Staff annual training plan, content, assessment, records. | 1. The training content should cover the protocol for exporting dairy products to China, Chinese regulations and standards , etc. | □Compliant□ does not meet | * For self-examination use, if necessary.
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| **12. Statement** |
| 12.1 Corporate Statement | 1. Article 9 of " Regulations of the People's Republic of China on the Administration of Registration of Overseas Manufacturers of Imported Food" (Order No. 248 of the General Administration of Customs) . |  | 1. It should have the signature of the legal person and the company seal | □Compliant□ does not meet |  |
| * 12.2 Official Statement
 | 1. Article 8 of " Regulations of the People's Republic of China on the Administration of Registration of Overseas Production Enterprises of Imported Food" (Order No. 248 of the General Administration of Customs) . |  | 1. It should be signed by the competent authority and stamped by the competent authority.2 . The review report of the competent authority of the country (region) where the relevant enterprises are audited and inspected. | □Compliant□ does not meet |  |