

### Appendix 4-3-3

## Registration Conditions and Control Inspection Points of Overseas Manufacturers of Imported Dairy Products

### **(Excluding Pasteurized Milk and Infant Formula Dairy Products)**

Registration number:

Enterprise name:

Address:

Date of filling in:

Note:

1. According to the *Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* (Decree No.248 of the General Administration of Customs of China), the sanitary conditions of overseas manufacturers of dairy products applying for registration in China shall conform to Chinese laws, regulations, standards and norms, and the requirements of the Protocol on Inspection and Quarantine of Dairy Products Exported to China. The table is for the overseas competent authorities of imported dairy products (excluding pasteurized milk and infant formula dairy products) to carry out official inspections on manufacturers of dairy

products based on the listed main conditions, bases and inspection focuses. At the same time, overseas manufacturers of dairy products fill in and submit supporting materials based on the listed main conditions and bases, and carry out self-examination against the inspection focuses for self-assessment before applying for registration.

2. Overseas competent authorities and overseas manufacturers of dairy products shall make the conformity determination based on the actual inspection situation.

3. The submitted materials shall be truly filled out in Chinese or English. The appendices shall be numbered, and their numbers and contents shall accurately correspond to the item numbers and contents in the column of "Filling in Requirements and Supporting Materials". The list of supporting materials shall be attached.

Item	Conditions and bases	Filling in Requirements and Supporting Materials	Focus of examination	Conformity determination	Remarks
<b>1. Enterprise Overview</b>					
1.1 Name, address, registration number, production/export qualification approval agency of enterprise	1. Articles 9 and 10 of the <i>Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food</i> (Decree No. 248 of General Administration of Customs of China).	1.1 Fill in the name, address, registration number of the enterprise, and the name of the production/export qualification approval agency in the <i>Application for Registration of Overseas Manufacturers of Imported Dairy Products</i> (Excluding	1. The information filled in by the applicant shall be consistent with the information in the list of enterprises submitted by the competent authority in the applicant's country.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	

		Pasteurized Milk and Infant Formula Dairy Products)			
1.2 Product applied for registration	<p>1. <i>National Food Safety Standard - Fermented Milk</i> (GB 19302-2010).</p> <p>2. <i>National Food Safety Standard - Sterilized Milk</i> (GB 25190-2010).</p> <p>3. <i>National Food Safety Standard - Modified Milk</i> (GB 25191-2010).</p> <p>4. <i>National Food Safety Standard - Evaporated Milk, Sweetened Condensed Milk and Formulated Condensed Milk</i> (GB 13102-2010).</p> <p>5. <i>National Food Safety Standard - Milk Powder</i> (GB 19644-2010).</p> <p>6. <i>National Food Safety Standard - Whey Powder and Whey Protein Powder</i> (GB 11674-2010).</p> <p>7. <i>National Food Safety Standard - Cream, Butter and Anhydrous Milkfat</i> (GB 19646-2010).</p> <p>8. <i>National Food Safety</i></p>	<p>1.2 List the standards that the products applied for registration shall meet in <i>Application for Registration of Overseas Manufacturers of Imported Dairy Products</i> (Excluding Pasteurized Milk and Infant Formula Dairy Products).</p>	<p>1. The product applied for registration shall conform to relevant standard definitions.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/> Non-conforming</p>	

	<p><i>Standard - Cheese</i> (GB 5420-2010). 9. <i>National Food Safety Standard - Process(ed) Cheese</i> (GB 25192-2010).</p>				
<b>2. Enterprise Location and Workshop Layout* (not required to be filled in the application, used for self-inspection, and provided if necessary)</b>					
2.1 Enterprise location and factory environment	1. Article 3 of <i>National Food Safety Standard - General Hygienic Regulation for Food Production</i> (GB 14881-2013)	Plant plan with the names of the different operational areas. Provide pictures of the environment of the area where the plant is located, showing the surrounding environment information (urban, suburban, industrial, agricultural and residential areas).	1. The plant layout meets the needs of production and processing. 2. There is no pollution source around the plant.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection, available if necessary.
2.2 Design and layout of workshop	1. Articles 5.12 and 5.13 of <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB12693-2010).	Workshop layout. The plan shall show the direction of the flow of people and goods, the functions of different processing zones, and the range of the areas with different degrees of cleanliness.	1. The workshop layout should be reasonable to meet production and processing requirements and avoid cross-contamination.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection, available if necessary.

<b>3. Facilities and Equipment* (not required to be filled in the application, used for self-inspection, and provided if necessary)</b>					
3.1 Production and processing equipment	Article 6.1 of <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB12693-2010).	List of main equipment and facilities and design processing capacity.	1. The enterprise should be equipped with production equipment suitable for the production capacity.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection, available if necessary.
3.2 Storage facility	Articles 8.3.2.3 and 11 of <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB12693-2010).	Photos of raw milk storage equipment, storage capacity and temperature control requirements. (where applicable) Please describe the temperature control requirements and monitoring methods if there is cold storage. (where applicable)	1. Storage facilities can meet the temperature requirements for product storage.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection, available if necessary.
<b>4. Water/Steam/Ice Supply* (not required to be filled in the application, used for self-inspection, and provided if necessary)</b>					
4.1 Water/ice/steam for production and processing (if applicable)	1. Article 5.3.1 of <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB12693-2010).	Provide photos of self-provided water sources or secondary water supply facilities, and explain whether there are food protection measures such as assigning specific persons for management and locking. (if applicable) Provide a monitoring plan for	1. The production water monitoring plan shall cover all water outlets in the plant. 2. Whether the items and methods meet the requirements of the <i>Standards for Drinking Water Quality</i> (GB5749-2006).	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection, available if necessary.

		<p>water used in production and processing and ice/steam (where applicable) in direct contact with food, including bacteriological inspection items, methods, frequency, records, inspection results and the latest 2 inspection reports. Provide boiler additives used in the production of steam in direct contact with food, and explain whether they meet the requirements of food production and processing.</p>	<p>3. Hygiene control procedures shall be formulated and implemented for the secondary water supply facilities, and appropriate food protection measures shall be in place.</p> <p>4. Boiler additives used in the production of steam in direct contact with food shall meet the requirements of food production and processing.</p>		
<b>5. Raw and Auxiliary Materials and Packaging Materials* (not required to be filled in the application, used for self-inspection, and provided if necessary)</b>					
5.1 Raw milk	<p>1. <i>National Food Safety Standard - Raw Milk</i> (GB 19301-2010).</p> <p>2. Article 8.2.2.1 of <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB12693-2010).</p> <p>3. Article 5 of the <i>Regulations of the People's Republic of</i></p>	Raw milk acceptance criteria, including acceptance items and indicators. (if applicable)	<p>1. Raw milk complies with the <i>National Food Safety Standard - Raw Milk</i> (GB 19301-2010) and national requirements.</p> <p>2. The milk is sourced from epidemic free areas.</p>	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	For self-inspection, available if necessary.

	<i>China on the Registration and Administration of Overseas Manufacturers of Imported Food.</i>				
5.2 Dairy products < whole milk (powder), skim milk (powder), whey (powder), etc.>	<p>1. <i>National Food Safety Standard - Milk Powder</i> (GB 19644-2010).</p> <p>2. <i>National Food Safety Standard - Whey Powder and Whey Protein Powder</i> (GB 11674-2010).</p>	<p>List of dairy raw materials used.</p> <p>Dairy product acceptance criteria, including acceptance items, indicators.</p>	1. The raw materials used for dairy products shall comply with the Chinese national food safety standards.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	For self-inspection, available if necessary.
5.3 Other raw materials	<p>1. Ferments: Article 4.1.3 of <i>National Food Safety Standard - Fermented Milk</i> (GB 19302-2010) <i>List of Strains Available for Food</i> (WBJDF [2010] No. 65).</p> <p>2. Food additives Article 9.4.1 of <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB12693-2010).</p> <p>3. The use of food additives and nutrient fortification</p>	List of other raw materials used.	<p>1. Ferments: whether they are within the range of strains approved for use by the Chinese health administration.</p> <p>2. Additives: scope of use and dose of food additives and nutritional fortification substances.</p> <p>3. If jam products are used, the use of additives in jam raw materials shall also comply with the limit</p>	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	For self-inspection, available if necessary.

	substances shall comply with the <i>National Food Safety Standard - Standard for the Use of Food Additives</i> (GB 2760-2014) and the <i>National Food Safety Standard - Standard for the Use of Nutritional Fortification Substances in Foods</i> (GB 14880-2012).		requirements of the <i>National Food Safety Standard - Standard for the Use of Food Additives</i> (GB 2760-2014).		
5.4 Packaging material	1. Article 9.5 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB 12693-2010).	Proof that the inner and outer packaging materials are suitable for dairy packaging.	1. Packaging materials do not affect food safety and product characteristics under specific storage and use conditions.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection, available if necessary.
5.5 Raw material supplier review	1. Article 8.2.1 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB12693-2010).	Review procedure for raw material supplier.	1. The enterprise shall establish the supplier review procedures, and stipulate the selection, review and evaluation procedures for suppliers.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection, available if necessary.
<b>6. Production and Processing Control* (not required to be filled in the application, used for self-inspection, and provided if necessary)</b>					



<p>6.1 HACCP system</p>	<p>1. <i>Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Processing Plant</i> (GB/T 27341-2009).</p>	<p>The production and processing flow chart, hazard analysis worksheet and HACCP plan of all products to be exported to China. Please provide corresponding certificates (if applicable) for certifications such as HACCP and ISO 22000.</p>	<p>1. Biological, physical and chemical hazards should be analyzed and effectively controlled in the HACCP plan. 2. The production process flow should be reasonable to avoid cross-contamination. 3. The setting of CCPs should be scientific and feasible; corrective and verification measures should be appropriate. 4. Whether the HACCP plan includes all products applied for registration.</p>	<p><input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A</p>	<p>For self-inspection, available if necessary.</p>
<p>6.2 Production and processing processes</p>	<p>1. <i>National Food Safety Standard - Fermented Milk</i> (GB 19302-2010). 2. <i>National Food Safety Standard - Sterilized Milk</i> (GB 25190-2010). 3. <i>National Food Safety Standard - Modified Milk</i> (GB 25191-2010).</p>	<p>Process flow with key process parameters such as heat treatment temperature/time and process description. Where heat treatment processes are available, provide heat treatment temperature/time variation curves (if applicable).</p>	<p>1. Whether the production process of the enterprise meets the product definition. 2. Whether the temperature/time variation curve of sterilized milk is consistent with the sterilization temperature/time</p>	<p><input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming</p>	<p>For self-inspection, available if necessary.</p>

			declared by the enterprise. 3. Whether the heat treatment temperature of sterilized milk meets the requirements of the national standard.		
6.3 Packaging	<p>1. <i>National Food Safety Standard - General Standard for the Labeling of Prepackaged Foods</i> (GB 7718-2011)</p> <p>2. <i>National Food Safety Standard - General Rules for Nutrition Labeling of Prepackaged Foods</i> (GB 28050-2011).</p>	<p>Sample labels for products to be exported to China.</p> <p>The procedure for seal inspection shall include, at a minimum, inspection points, operators, methods and frequency of inspection (applicable to sterilized milk, modified milk and milk by other sterilization).</p>	<p>1. Product labeling shall comply with the <i>National Food Safety Standard - General Standard for the Labeling of Prepackaged Foods</i> (GB 7718-2011).</p> <p>2. For products in Tetra Pak packages, the seal test items shall include, at a minimum, the items listed in the Tetra Pak Package Integrity Inspection Manual.</p>	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	For self-inspection, available if necessary.
6.4 Shelf life of product	1. Article 2.5 of the National Food Safety Standard - General Standard for the Labeling of Prepackaged Foods (GB 7718-2011).	<p>Fill in the following information</p> <p>Product storage method: _____.</p> <p>Shelf Life _____.</p> <p>The basis or data for</p>	<p>1. Whether the basis for confirming the shelf life is consistent with the actual label.</p> <p>2. Whether the test conditions of shelf life</p>	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	For self-inspection, available if necessary.

		confirming the shelf life of the product.	correspond to actual storage and transportation.		
<b>7. Cleaning and Disinfection* (not required to be filled in the application, used for self-inspection, and provided if necessary)</b>					
7.1 Cleaning and disinfection procedures for the production line.	1. Article 7.3 of <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB 12693-2010).	<p>Cleaning and disinfection procedures that cover the entire production line.</p> <p>For those using CIP (Clean in Place), the cleaning and disinfection procedures provided shall include:</p> <p>CIP plan and frequency; the variety, duration of action, concentration, object and temperature of disinfectants used for CIP; measures to verify the effectiveness of cleaning and disinfection; measures to prevent contamination of products by CIP. (if applicable)</p> <p>If dry cleaning methods are used, provide cleaning and disinfection procedures, frequency and measures to verify the effectiveness of cleaning and disinfection. (if applicable)</p>	<p>1. Whether the denatured protein and salts on the heated surfaces of pipes and equipment are removed by acid pickling or other methods.</p> <p>2. Detergent residual verification (e.g. testing conductivity, pH)</p> <p>3. Cleaning effectiveness verification (e.g. microbiological tests, ATP experiments).</p>	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	For self-inspection, available if necessary.

<b>8. Self-inspection and Self-control* (not required to be filled in the application, used for self-inspection, and provided if necessary)</b>					
8.1 Product online control inspection	8.1 <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB 12693-2010) Articles 9.1.1.1, 9.1.1.2 and 9.1.1.3.	Product online inspection plan, which includes the list of inspection contents, parameters and frequency and verification by process.	1. Whether the online control measures effectively monitor the hazards analyzed by the enterprise.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	For self-inspection, available if necessary.
8.2. Finished product inspection	8.2 Article 10 of the National Food Safety Standard - Good Manufacturing Practice for Milk Products (GB 12693-2010).	Test solutions and test standards of final products to be exported to China for release and the test reports of the latest 2 batches.		<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	For self-inspection, available if necessary.
8.3 Sterility validation protocol and implementation of the production line (if applicable)	1. Article 4.6 of <i>National Food Safety Standard - Sterilized Milk</i> (GB 25190-2010). 2. Article 4.6.1 of <i>National Food Safety Standard - Modified Milk</i> (GB25191-2010). 3. <i>National Food Safety Standard - Microbiological Examination of Food - Commercial Sterility Test</i> (GB 4789.26-2013).	Sterility validation protocol for sterile product line.	1. A commercial sterility test report in line with the method specified in GB/T 4789.26-2013 shall be provided.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	For self-inspection, available if necessary.
<b>9. Chemicals and Pest Control* (not required to be filled in the application, used for self-inspection, and provided if necessary)</b>					

9.1 Control of chemicals	1. Article 9.2 of the National Food Safety Standard - Good Manufacturing Practice for Milk Products (GB 12693-2010).	Brief description of chemical use and storage requirements.	1. The chemicals shall be stored in special areas, strictly managed and clearly marked. 2. Prevent contamination of products by the chemicals used.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection, available if necessary.
9.2 Pest control	1. Article 7.5 of the National Food Safety Standard - Good Manufacturing Practice for Milk Products (GB 12693-2010).	Provide control methods and layout plans for damage by insects. If the control is undertaken by a third party, provide the qualification of the third party.	1. The impact of damage by insects and rats on production safety and hygiene should be avoided.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection, available if necessary.
<b>10. Product Tracing* (not required to be filled in the application, used for self-inspection, and provided if necessary)</b>					
10.1. Product traceability	1. Article 12 of the National Food Safety Standard - Good Manufacturing Practice for Milk Products (GB 12693-2010).	Describe the product traceability procedure in a brief manner and take the batch number of a batch of finished products as an example to illustrate how to trace raw materials from finished products.	1. Traceability procedures should be established to realize the two-way traceability of the whole chain from raw materials, production and processing processes to finished products.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection, available if necessary.
<b>11. Personnel Management and Training* (not required to be filled in the application, used for self-inspection, and provided if necessary)</b>					
11.1 Personnel Health and Hygiene	1. Article 7.4 of the National Food Safety Standard - Good Manufacturing Practice for	Pre-employment health management and medical examination requirements for	1. Employees should have a medical examination and prove	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection,

Management	Milk Products (GB 12693-2010).	employees.	that they are suitable for working in food processing enterprises before employment. 2. Employees shall have regular physical examinations and keep records.		available if necessary.
11.2 Personnel training	1. Article 13 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB 12693-2010).	Annual training plans, contents, assessments and records for employees.	1. The training shall cover the <i>Protocol on Dairy Products Exported to China</i> , Chinese regulations and standards, etc.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	For self-inspection, available if necessary.
<b>12. Declaration</b>					
12.1 Declaration by enterprise	1. Article 9 of the <i>Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food</i> (Decree No. 248 of General Administration of Customs of China).		1. It shall be signed by the legal person and stamped with official seal of the enterprise.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	
12.2 Official declaration	1. Article 8 of the <i>Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food</i> (Decree No. 248 of		1. It shall be signed by an officer of the competent authority and stamped with the seal of the competent authority. 2. A review report of the	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	

	General Administration of Customs of China).		review inspection of the enterprise by the competent authority of the country (region).		
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