

## Appendix 4-3-1

# Registration Conditions and Control Inspection Points of Overseas Manufacturers of Imported Pasteurized Milk

Registration number:

Enterprise name:

Address:

Date of filling in:

Note:

1. According to the *Regulations 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 pasteurized milk to carry out official inspections on manufacturers of pasteurized milk based on the listed main conditions, bases and inspection focuses. At the same time, overseas

manufacturers of pasteurized milk 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 pasteurized milk production enterprises 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 the 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 the 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 the General Administration of	1.1 Fill in the name, address and 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</i>	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	

	Customs of China).	<i>Pasteurized Milk.</i>			
1.2 Product applied for registration	1. <i>National Food Safety Standard - Pasteurized Milk (GB 19645).</i>	1.2 Specify the criteria that the product applied for registration meets in Article 1.8 of the <i>Application for Registration of Overseas Manufacturers of Imported Pasteurized Milk.</i>	1. The product applied for registration shall conform to relevant standard definitions.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	
<b>2. Enterprise Location and Workshop Layout</b>					
2.1 Enterprise location and factory environment	1. Article 3 of <i>National Food Safety Standard - General Hygienic Regulation for Food Production (GB 14881)</i>	2.1.1 Provide a plant plan, indicating the names of different operation areas.  2.1.2 Provide pictures of the environment of the area where the plant is located, indicating the ambient 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	
2.2 Design and layout of workshop	1. Articles 5.12 and 5.13 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products (GB12693).</i>	2.2 Provide workshop layout plans. 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	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	

		with different degrees of cleanliness.			
<b>3. Facility and Equipment</b>					
3.1 Production and processing equipment	Article 6.1 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB12693).	3.1 Provide a 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	
3.2 Storage facility	Articles 8.3.2.3 and 11 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB12693).	3.2.1 Provide photos of raw milk storage equipment, storage capacity and temperature control requirements. (where applicable)  3.2.2 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	
<b>4. Supply of Water/Steam/Ice</b>					
4.1 Water/ice/steam for production and processing (if	1. Article 5.3.1 of the <i>National Food Safety Standard - Good Manufacturing Practice for</i>	4.1.1 Provide photos of self-provided water sources or secondary water supply facilities, and explain whether	1. The production water monitoring plan shall cover all water outlets in the plant.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	

applicable)	<i>Milk Products</i> (GB12693).	<p>there are food protection measures such as assigning specific persons for management and locking. (if applicable)</p> <p>4.1.2 Provide a monitoring plan for 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.</p> <p>4.1.3 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>2. Whether the items and methods comply with the requirements of the <i>National Food Safety Standard - Standards for Drinking Water Quality</i> (GB5749).</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</b>					
5.1 Raw milk	<p>1. <i>National Food Safety Standard - Raw Milk</i> (GB 19301).</p> <p>2. Article 8.2.2.1 of the</p>	5.1 Provide raw milk acceptance criteria, including acceptance items and indicators. (if applicable)	1. Raw milk complies with the <i>National Food Safety Standard - Raw Milk</i> (GB 19301-2010)	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	

	<p><i>National Food Safety Standard - Good Manufacturing Practice for Milk Products (GB12693).</i></p> <p>3. Article 5 of the <i>Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food.</i></p>		<p>and national requirements.</p> <p>2. The milk is sourced from epidemic free areas.</p>		
<p>5.2 Dairy products &lt; whole milk (powder), skim milk (powder), whey (powder), etc.&gt;</p>	<p>1. <i>National Food Safety Standard - Milk Powder (GB 19644).</i></p> <p>2. <i>National Food Safety Standard - Whey Powder and Whey Protein Powder (GB 11674).</i></p>	<p>5.2.1 Provide the list of dairy raw materials used.</p> <p>5.2.2 Provide acceptance criteria for dairy products, including acceptance items and indicators.</p>	<p>1. The raw materials used for dairy products shall comply with the Chinese national food safety standards.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/> N/A</p>	
<p>5.3 Other raw materials</p>	<p>1. The use of food additives and nutrient fortification substances shall comply with the <i>National Food Safety Standard - Standard for the Use of Food Additives (GB 2760)</i> and the <i>National Food Safety Standard - Standard for the Use of Nutritional</i></p>	<p>5.3 Provide the list of other raw materials used.</p>	<p>1. Additives: scope of use and dose of food additives and nutritional fortification substances.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/> N/A</p>	

	<i>Fortification Substances in Foods</i> (GB 14880).				
5.4 Packaging material	1. Article 9.5 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB 12693).	5.4 Provide 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	
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> (GB 12693).	5.5 Provide the review procedures for raw material suppliers.	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	
<b>6. Production and Processing Control</b>					
6.1 HACCP system	1. <i>Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Processing Plant</i> (GB/T 27341)	6.1.1 Provide the production and processing flow chart, hazard analysis worksheet and HACCP plan of all products to be exported to China.  6.1.2 Please provide corresponding certificates (if applicable) for certifications such as HACCP and ISO 22000.	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	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	

			verification measures should be appropriate. 4. Whether the HACCP plan includes all products applied for registration.		
6.2 Production and processing processes	<p>1. National Food Safety Standard - Pasteurized Milk (GB 19645).</p> <p>2. Pasteurized milk: Pasteurization conditions in the <i>Identification of Reconstituted Milk in Pasteurized and UHT Milk</i> (NY/T 939-2016) of the Ministry of Agriculture: the processing of low-temperature long time (62 °C ~ 65 °C for 30 min) or high-temperature short time (72 °C ~ 76 °C for 15s; or 80 °C ~ 85 °C for 10s ~ 15s).</p>	<p>6.2.1 Provide a process flow with key process parameters such as heat treatment temperature/time and process description.</p> <p>6.2.2 Where heat treatment processes are available, provide heat treatment temperature/time variation curves (if applicable).</p> <p>6.2.3 Where the extended shelf-life (ESL) process is used, the key process parameters shall be stated and the process shall be described, and a description or supporting material that the ESL process can meet the requirements of relevant Chinese standards shall be</p>	<p>1. Whether the production process of the enterprise meets the product definition.</p> <p>2. Whether the pasteurization temperature/time variation curve of pasteurized milk is consistent with the sterilization temperature/time declared by the enterprise.</p> <p>3. Whether the heat treatment temperature of sterilized milk meets the requirements of the national standard.</p>	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	



		provided.			
6.3 Packaging	<p>1. <i>National Food Safety Standard - General Standard for the Labeling of Prepackaged Foods</i> (GB 7718).</p> <p>2. <i>National Food Safety Standard - General Rules for Nutrition Labeling of Prepackaged Foods</i> (GB 28050).</p>	<p>6.3.1 Provide sample labels for products to be exported to China.</p> <p>6.3.2 Provide the procedure for seal inspection, which shall include, at a minimum, inspection points, operators, methods and frequency of inspections (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).</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>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/> N/A</p>	
6.4 Shelf life of product	<p>1. Article 2.5 of the <i>National Food Safety Standard - General Standard for the Labeling of Prepackaged Foods</i> (GB 7718-2011).</p>	<p>6.4.1 Fill in the following information Product storage method: _____. Shelf life _____.</p> <p>6.4.2 Provide the basis or data for confirming the shelf life of the product.</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 correspond to actual storage and transportation.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/> N/A</p>	
<b>7. Cleaning and Disinfection</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).	7.1.1 Provide the cleaning and disinfection procedures that cover the entire production line. 7.1.2 For those using CIP (Clean in Place), the cleaning and disinfection procedures provided shall include: 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) 7.1.3 If dry cleaning methods are used, provide cleaning and disinfection procedures, frequency and measures to verify the effectiveness of cleaning and disinfection. (if applicable)	1. Whether the denatured protein and salts on the heated surfaces of pipes and equipment are removed by acid pickling or other methods. 2. Detergent residual verification (e.g. testing conductivity, pH, etc.) 3. Cleaning effectiveness verification (e.g. microbiological tests, ATP experiments, etc.)	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	
<b>8. Self-inspection and Self-control</b>					
8.1 Product online control inspection	8.1 <i>National Food Safety Standard - Good Manufacturing Practice for</i>	8.1 Provide a product online inspection plan, which includes the list of inspection	1. Whether the online control measures effectively monitor the	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	

	<i>Milk Products</i> (GB 12693-2010). Articles 9.1.1.1, 9.1.1.2 and 9.1.1.3.	contents, parameters and frequency and verification by process.	hazards analyzed by the enterprise.		
8.2. Finished product inspection	8.2 Article 10 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB 12693-2010).	8.2 Provide the 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	
<b>9. Chemical and Pest Control</b>					
9.1 Control of chemicals	1 Article 9.2 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB 12693-2010).	9.1 Briefly describe the requirements of chemical use and storage.	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	
9.2 Pest control	1. Article 7.5 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB 12693-2010).	9.2 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	
<b>10. Product Tracing</b>					
10.1. Product traceability	1. Article 12 of the <i>National Food Safety Standard - Good Manufacturing Practice for</i>	10.1. Describe the product traceability procedure in a brief manner and take the	1. Traceability procedures should be established to realize the	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	

	<i>Milk Products</i> (GB 12693-2010).	batch number of a batch of finished products as an example to illustrate how to trace raw materials from finished products.	two-way traceability of the whole chain from raw materials, production and processing processes to finished products.		
<b>11. Personnel Management and Training</b>					
11.1 Personnel Health and Hygiene Management	1. Article 7.4 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB 12693-2010).	11.1 Provide pre-employment health management and medical examination requirements for employees	1. Employees should have a medical examination and prove that they are suitable for working in food processing enterprises before employment. 2. Employees shall have regular physical examinations and keep records.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	
11.2 Personnel training	1. Article 13 of the <i>National Food Safety Standard - Good Manufacturing Practice for Milk Products</i> (GB 12693-2010).	11.2 Provide annual training plan, content, assessment and records of 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	
<b>12. Declaration</b>					
12.1 Declaration by enterprise	1. Article 9 of the <i>Regulations of the People's Republic of</i>		1. It shall be signed by the legal person and	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	

	<i>China on the Registration and Administration of Overseas Manufacturers of Imported Food.</i>		stamped with official seal of the enterprise.		
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>		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 review inspection of the enterprise by the competent authority of the country (region).	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	