

#### Appendix 4-3-4

## Registration Conditions and Control Inspection Points of Overseas Manufacturers of Imported Health Food

Registration number:

Enterprise name:

Address:

Date of filling in:

Notes:

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 health food applying for registration in China shall conform to Chinese laws, regulations, standards and norms. The table is for the overseas competent authorities of imported health food to carry out official inspections on manufacturers of health food based on the listed main conditions, bases and inspection focuses. At the same time, overseas manufacturers of health food 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 health food 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 Basic information of enterprise	<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)	Fill in the Basic Information Form for Overseas Manufacturers of Imported Health Food.	Focus on whether the registered name, address, registration number, etc. are consistent with the registration information submitted by the official authority	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	

<p>1.2 Information on products to be exported to China</p>	<p>Article 76 of the <i>Food Safety Law of the People's Republic of China</i>: Health food using raw materials other than those listed in the catalogue of health food raw materials and health food imported for the first time shall be registered with relevant food safety supervision and management department under the State Council. However, health foods imported for the first time that are supplemental vitamins, minerals and other nutrients shall be reported to the food safety supervision and management department under the State Council for the record. Other health foods shall be reported to the food safety supervision and management department of the people's government of the province, autonomous region or municipality directly under the Central Government for the record. Imported health food shall be those authorized for sale by the competent authorities of the exporting country (region).</p>	<p>1.2.1. Product information, including product name, function descriptions, packaging specifications, packaging form and corresponding HS code and classification code; 1.2.2. Imported health food registration certificates or filing certificates; 1.2.3. Documents certifying that the competent authority of the exporting country (region) has granted permission to market the goods.</p>	<p>1. Focus on whether the products have imported health food registration certificates or filing vouchers, and whether the product names, function descriptions, packaging specifications and packaging types of the products are consistent with those contained in the imported health food registration certificates or filing vouchers; 2. Review whether the product is permitted by the competent authorities of the exporting country (region) for marketing and sale.</p>	<p><input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A</p>	
<p><b>2. Raw and Auxiliary Materials and Packaging Materials</b></p>					

<p>2.1 Acceptance of raw and auxiliary materials</p>	<p>2.1.1 <i>National Food Safety Standard - Good Manufacture Practice for Health Food</i> (GB17405-1998) (6.2 Raw materials must meet food hygiene requirements. The variety, source, specification and quality of raw materials shall be consistent with the approved formula and product corporate standards.</p> <p>2.1.2 Valid inspection reports must be obtained for purchased raw materials in accordance with relevant regulations; Approval certificates (copies) from the Ministry of Health must be obtained for raw materials belonging to new food resources.</p> <p>2.1.3 Strain identification reports, stability reports, and certification documents certifying that the strain does not contain drug resistance factors must be obtained for mycelium prepared by artificial fermentation or the mixture of mycelium and fermentation products and microecological raw materials.</p> <p>2.1.4 A variety identification report must be obtained for raw materials such as algae, animals and animal tissue organs. The test reports of physical and chemical properties and</p>	<p>2.1 Provide raw material acceptance standards, including indicators, limits, and acceptance requirements.</p>	<p>Raw material acceptance standards shall refer to the raw material standards submitted when the enterprise applies for health food approval certificates or health food filing certificates.</p>	<p><input type="checkbox"/> Conforming  <input type="checkbox"/> Non-conforming  <input type="checkbox"/> N/A</p>	
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	<p>contents shall be obtained for raw materials being a single effective substance extracted from animals/plants, or biological or chemical compounds.</p> <p>2.1.5 The content test report shall be obtained for raw materials containing stimulants or hormones; Information on the irradiation dose shall be obtained for raw materials subject to radioactive radiation.)</p> <p>2.1.6 <i>National Food Safety Standard - General Hygienic Regulation for Food Production</i> (GB14881-2013)  (7.2.1 The supplier's licenses and product qualification certificates shall be checked for purchased food raw materials; food raw materials for which qualification certificates cannot be provided shall be inspected as per food safety standards.</p> <p>2.1.7 Food raw materials must be accepted before use. After acceptance, unqualified food raw materials shall be placed separately from qualified products in the designated area and clearly marked, and shall be promptly returned or replaced.</p> <p>2.1.8 Sensory examination shall be</p>				
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	<p>carried out before processing, if necessary, laboratory examination shall be carried out; if the indicators involving food safety items are found to be abnormal after testing, the food raw materials shall not be used; only the determined applicable food raw materials shall be used.</p> <p>2.1.9 Qualification certificates of products shall be checked at the time of procurement of food packaging materials, containers, detergents, disinfectants and other food-related products, and the supplier's license shall also be checked for food-related products under licensing control. Food-related products such as food packaging materials must be accepted before use.)</p>				
2.2 Use of food raw materials of animal origin or plant origin	<p>2.2.1 <i>National Food Safety Standard - General Hygienic Regulation for Food Production</i> (GB14881-2013) (7.2.1 The supplier's licenses and product qualification certificates shall be checked for purchased food raw materials; food raw materials for which qualification certificates cannot be provided shall be inspected as per food safety standards.)</p> <p>2.2.2 <i>National Food Safety Standard -</i></p>	<p>2.2.1 Provide the product ingredients in an order of addition, from largest to smallest, with the proportion indicated;</p> <p>2.2.2 If the main raw materials (how to define the proportion of the main raw material) contain raw milk, vegetables (including cultivated edible fungus), meat and meat products, bee products, aquatic products, bird's nest, the</p>	<p>1. Focus on the risk of epidemic diseases in food raw materials of animal and plant origin, and whether subsequent production processes can remove the risk if such materials come from the epidemic area;</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/> N/A</p>	

	<p><i>Good Manufacture Practice for Health Food</i> (GB17405-1998) (6.2 Raw materials must meet food hygiene requirements. The variety, source, specification and quality of raw materials shall be consistent with the approved formula and product corporate standards.)</p>	<p>country of origin of the ingredients shall be provided; 2.2.3 If soybean is used as the main raw material, whether it is genetically modified soybean shall be indicated.</p>	<p>2. If soybeans are used as raw materials, please pay attention to whether they are genetically modified, and soybeans and their processed products shall be treated with high temperature and other processes to eliminate anti-nutritional factors;</p>		
2.3 Other raw materials (if food additives are used, they need to be labeled according to GB2760 types) (if applicable)	<p>1. <i>National Food Safety Standard - Standard for the Use of Food Additives</i> (GB 2760-2014). 2. <i>National Food Safety Standard - General Hygienic Regulation for Food Production</i> (GB14881-2013) (7.3.1 In purchasing food additives, the supplier's license and product qualification certificate shall be inspected. Food additives must be accepted before use.)</p>	<p>Provide the name of the additive used according to the types in the <i>National Food Safety Standard - Standard for the Use of Food Additives</i> (GB 2760-2014).</p>	<p>The enterprise shall provide a complete list of raw materials.</p>	<p><input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A</p>	
2.4 Packaging materials	<p>1. <i>National Food Safety Standard - Good Manufacture Practice for Health Food</i> (GB17405-1998) (7.4</p>	<p>Describe in detail the composition of the inner packaging material of the product and list the quality and</p>	<p>Focus on whether the enterprise has provided information</p>	<p><input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A</p>	

	<p>Food containers, packaging materials, detergents and disinfectants that meet the hygiene standards and hygiene management measures shall be used.</p> <p>2. The raw materials used, such as empty capsules and sugar coating, must meet hygienic requirements, and the use of non-food coloring is prohibited.</p> <p>3. All kinds of glass bottles (tubes), plastic bottles (tubes), bottle caps, bottle pads, bottle stoppers and aluminum-plastic packaging materials used for product packaging, which are directly in contact with inner packaging materials of products, shall be cleaned, dried and sterilized by appropriate methods, and shall be placed in a clean room for cooling after sterilization. If the storage time exceeds the specified period, they shall be washed and sterilized again.)</p>	safety standards of the inner packaging material.	on the safety certification of the inner packaging materials, such as the enterprise declaration.		
<b>3. Production Process Information</b>					
3.1 Provide a detailed production process flow diagram,	<p><i>National Food Safety Standard - Good Manufacture Practice for Health Food (GB17405-1998) (7.1.1</i></p> <p>The factory shall develop production process procedures and job operation procedures according to the</p>	Provide a detailed flow diagram, which shall contain process parameters and provide a process description.	Focus on whether the enterprise's production process meets the product definition.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	



<p>which shall contain process parameters and provide a process description.</p>	<p>requirements of this standard and in conjunction with the production process characteristics of its own products.</p> <p>The procedures shall meet the process requirements of no loss, no destruction and no transformation of functional composition and no harmful intermediates in the processing of health food, and the content shall include the product formula, the preparation of each component, the main technical conditions of the finished product processing process and the quality and health monitoring points of key processes, such as temperature, pressure, time, pH value, quality index of intermediate products, etc. in the finished product processing process.</p> <p>The procedures shall set out specific operational requirements for each major production process and clarify the job responsibilities of each workshop, process and individual.)</p>				
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<p>3.2 Cleanliness level of the plant</p>	<p>1. <i>National Food Safety Standard - Good Manufacture Practice for Health Food</i> (GB17405-1998) (5.2.2 Cleanliness levels must be divided according to production technology, hygiene and quality requirements. In principle, they are divided into general production areas and 100,000-level areas. The cleanliness-level area shall be equipped with appropriate purified air conditioning facilities with filtration devices. The level and number of air changes are shown in Table 1 2. The purification level must meet the needs of air purification for the production and processing of health food. The production of tablets, capsules, pills, and oral liquids that cannot be sterilized in the final container shall be in a 100,000-level clean plant.)</p>	<p>1. Provide the cleanliness level of the plant; 2. What methods are used to maintain air cleanliness.</p>	<p>If using air filtration devices, pay attention to the replacement frequency of filters at all levels.</p>		
<p>3.3 Workshop layout and cross-contamination control</p>	<p>1. <i>National Food Safety Standard - Good Manufacture Practice for Health Food</i> (GB17405-1998) (7.3.2 Production operations shall be reasonably connected, quick and easy to transfer, and prevent cross-contamination. Separate</p>	<p>1. Workshop layout and personnel and logistics diagram; 2. Cross-contamination control measures.</p>	<p>1. Pay attention to the setting of clean areas at all levels in the workshop; 2. Whether there is cross-contamination of personnel access</p>		

	<p>processes shall be set up for raw material handling, intermediate product processing, cleaning and disinfection of packaging materials and containers, packaging and inspection of finished products. The same workshop shall not produce different products at the same time; containers for different processes shall be clearly marked and shall not be mixed.</p> <p>2. Production operators shall strictly follow the different requirements of general production areas and clean areas to improve personal hygiene. When there is a risk of product contamination due to a change of job, work clothes, shoes and hats must be changed and re-sterilized. Work clothes, hats and shoes used in the clean area must be strictly cleaned and disinfected, changed daily, and only allowed to be worn in the clean area, not allowed to be taken out of the area.</p> <p>3. Raw and auxiliary materials entering the production area must enter through the material channel. All materials entering the clean plant and workshop must be removed from</p>		<p>and personal hygiene, logistics access, etc.;</p> <p>3. Whether the inner and outer package areas are effectively segregated.</p>		
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	<p>the outer packaging, and if the outer packaging cannot be removed, it must be scrubbed clean or provided with an indoor packaging drum.</p> <p>4. Product pressing, encapsulation, dissolved medicine packaging, filling of liquid products shall be carried out in clean rooms, and the temperature and humidity of the operation room shall be controlled. Manual encapsulation shall be carried out in a perspex hood of the appropriate cleanliness level, with an operating table not lower than 0.7 m;</p> <p>5. The prepared materials shall be placed in a clean and sealed container, and shall enter the processes of filling, pressing or encapsulation in time, and the storage period shall not exceed the specified period.)</p>				
3.4 Provide cleaning and disinfection procedures that cover the entire production line.	<p>1. <i>National Food Safety Standard - Good Manufacture Practice for Health Food</i> (GB17405-1998) (7.3 Before dosing the product, check whether the dosing pots and containers and pipes are cleaned and meet the standards required by the process. Fermenters, vessels and pipelines used for production using</p>	Provide the cleaning and disinfection procedures that cover the entire production line.	Focus on cleaning and disinfection effectiveness verification.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	

	<p>the fermentation process must be thoroughly cleaned and disinfected before being used for production. Cleaning and disinfection records shall be kept for each shift.)</p> <p>2. <i>National Food Safety Standard - General Hygienic Regulation for Food Production</i> (GB14881-2013) (5.1.3 Cleaning and disinfection facilities: Adequate special cleaning facilities for food, utensils and equipment shall be provided, if necessary, suitable disinfection facilities shall be provided. Measures shall be taken to avoid cross-contamination from cleaning and disinfection utensils.</p> <p>8.2.1 Cleaning and disinfection</p>				
3.5 Provide a list of major equipment and production capacity.	<p>1. <i>National Food Safety Standard - Good Manufacture Practice for Health Food</i> (GB17405-1998) (5.2.5 Plant, equipment layout and process flow shall be reasonably connected, well-constructed and able to meet the requirements of production process and quality and hygiene; the plant shall have sufficient space and places to accommodate equipment and materials; storage rooms for intermediate products and products to</p>	Provide the name, model, design processing capacity and pictures of key process equipment.	<p>1. The enterprise shall have processing equipment corresponding to the production process.</p> <p>2. Equipment, utensils and other surfaces in contact with food shall be made of smooth, non-absorbent, easy to clean and maintain</p>	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	

	<p>be packaged shall comply with the production requirements.)</p> <p>2. <i>National Food Safety Standard - General Hygienic Regulation for Food Production</i> (GB14881-2013) (5.2.1 Production equipment)</p>		and disinfect.		
3.6 Provide a hazard analysis worksheet and HACCP plan.	<p>1. <i>National Food Safety Standard - General Hygienic Regulation for Food Production</i> (GB14881-2013) (8.1.1 The key links of food safety in the production process shall be identified through hazard analysis methods and control measures for key links of food safety shall be established. In the area where the key link is located, relevant documentation shall be available to implement control measures, such as dosage (feeding) tables and job operating procedures.</p> <p>2. Encourage the use of Hazard Analysis and Critical Control Point (HACCP) system to control food safety in the manufacturing process.)</p> <p>3. <i>National Food Safety Standard - Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Processing Plant</i> (GB/T 27341-2009).</p>	<p>1. Production and processing hazard analysis sheets and HACCP plan.</p> <p>2. Provide monitoring records of CCP points, and provide measures and records related to deviations from critical limits of CCP, if any.</p>	<p>1. Focus on the setting and critical limits of CCP points and the implementation of correction and validation.</p> <p>2. Whether the HACCP plan includes all products applied for registration.</p>	<p><input type="checkbox"/> Conforming</p> <p><input type="checkbox"/> Non-conforming</p> <p><input type="checkbox"/> N/A</p>	

<p>3.7 Product sterilization</p>	<p><i>National Food Safety Standard - Good Manufacture Practice for Health Food (GB17405-1998) (7.5</i>  Product sterilization.  Effective sterilization or disinfection equipment and methods shall be used for the sterilization of all types of products. For products that need to be sterilized but cannot be autoclaved, fine filtration, microwave and irradiation can be used according to different processes and food hygiene requirements to ensure the sterilization effect. At the time of using irradiation sterilization methods, the irradiation absorption volume and time shall be strictly controlled in accordance with the provisions of the <i>Measures for the Hygienic Management of Irradiated Foods</i>.  Reliability verification shall be carried out regularly for temperature uniformity and repeatability in sterilization or disinfection devices, and periodic calibration shall be conducted for temperature, pressure and other testing instruments. Indicators such as temperature, pressure and time shall be accurately</p>	<ol style="list-style-type: none"> <li>1. If thermal sterilization process is adopted, it is necessary to provide proof materials of thermal sterilization effectiveness and specific sterilization temperature and time requirements;</li> <li>2. For products that need to be sterilized and cannot be autoclaved, provide the sterilization method used;</li> <li>3. If using irradiation sterilization, please provide the irradiation absorption volume and time.</li> </ol>	<p>Focus on the effectiveness of sterilization methods.</p>	<p><input type="checkbox"/> Conforming  <input type="checkbox"/> Non-conforming  <input type="checkbox"/> N/A</p>	
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	recorded during sterilization or disinfection operations.)				
<b>4. Product Quality and Safety Control System</b>					
4.1 Product online control inspection	<i>National Food Safety Standard - Good Manufacture Practice for Health Food</i> (GB17405-1998) (9.5.1 Identify key control points for quality and hygiene during processing, and monitor the following links at least and make records.)	A complete product online inspection plan shall be submitted, which shall specify the inspection content, parameters, frequency and verification frequency by process.	1. Whether the online control measures effectively monitor the hazards analyzed by the enterprise; 2. Focus on the consistency of online checkpoint parameters and frequency with the HACCP plan and process flow. 3. If there are metal detectors, thermometers, etc., pay attention to the calibration and maintenance records.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	
4.2 Testing and release of final products	1. <i>National Food Safety Standard - Good Manufacture Practice for Health Food</i> (GB17405-1998) The finished products must be inspected batch by batch for sensory, hygiene and quality indicators, and those that are qualified shall not leave	Provide test plans, test standards and release requirements for final product release.	The final product inspection report shall cover the limit requirements of the <i>National Food Safety Standard - Health Food</i> (GB	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	



	<p>the factory.  It shall have the ability to detect the main efficacy factors or efficacy components of products, and test them according to the efficacy factors or main efficacy components of products produced by each feeding. Those unqualified products are not allowed to leave the factory.  Each batch of products shall have retained samples, which shall be stored in dedicated sample storage (or area), classified by species and batch number, and clearly marked.  Product stability tests shall be performed periodically.  The packaging materials, markings and instructions of the products must be inspected and those that are unqualified must not be used.  Inspect and manage the storage conditions of finished product warehouse and do not use warehouses that do not meet the storage conditions.)  2. <i>National Food Safety Standard - General Hygienic Regulation for Food Production</i> (GB14881-2013)  (9.1 The inspection for raw materials and products shall be carried out by</p>		16740-2014).		
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<p>self-inspection or entrusted to a food inspection agency with appropriate qualifications, and a food factory inspection record system shall be established.</p> <p>Inspection room and inspection ability suitable for the inspected items are necessary for self-inspection; Inspection shall be carried out by qualified inspectors according to the prescribed inspection methods; Inspection instruments and equipment shall be verified on schedule.</p> <p>The inspection room shall have a sound management system and the original records and test reports of each test shall be properly maintained. A product sample retention system shall be established and samples shall be retained in a timely manner.</p> <p>The product characteristics, process characteristics, raw material control and other factors shall be taken into account to reasonably determine the inspection items and inspection frequency to effectively verify the control measures in the production process. Net content, sensory requirements, and other inspection</p>				
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	<p>items susceptible to changes in the production process shall be tested more frequently than other test items. For the same variety of products with different packaging, the inspection items not affected by the packaging specifications and packaging form can be inspected together.)</p>				
4.3 Basis or data for confirming the shelf life of the product	<p>1. <i>National Food Safety Standard - Good Manufacture Practice for Health Food</i> (GB17405-1998) (9.6.4 Product stability experiments shall be conducted regularly.)</p> <p>2. <i>National Food Safety Standard - General Standard for the Labeling of Prepackaged Foods</i> (GB 7718-2011) (2.5 Shelf life: refers to the period during which a prepackaged food maintains its quality under the storage conditions specified on the label. During this period, the product is fully suitable for sale and maintains the characteristic qualities not required to be stated or already stated in the label.)</p> <p>Refer to the <i>T/CNFIA001-2017 General Guide to Food Shelf Life</i></p>	Provide the basis or data for confirming the shelf life of the product	<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>	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming <input type="checkbox"/> N/A	
4.4 Protection	<p>1. <i>National Food Safety Standard - Good Manufacture Practice for</i></p>	Protection requirements for product shipment to sales process;	Concern about the integrity of the	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	

<p>requirements for product shipment to sales process</p>	<p><i>Health Food</i> (GB17405-1998) (8.1 General hygiene requirements for storage and transport shall meet the requirements of the <i>National Food Safety Standard - General Hygienic Regulation for Food Production</i> (GB14881-2013).</p> <p>2. The storage method and environment of finished products shall be away from light and rain, and the temperature and humidity shall be controlled in the appropriate range, with impact and vibration avoided.</p> <p>3 Products containing biologically active substances shall be stored and transported in a cold chain using appropriate refrigeration measures.</p> <p>4. Health food stored at non-normal temperatures (such as some microecological health foods) shall be stored and transported at the required temperature according to the different characteristics of the products.</p> <p>5. The warehouse shall have a system of receiving and shipping inspections. The principle of "first produced products shall be sold first" shall be implemented when finished products are delivered.</p> <p>6. There shall be stock records for</p>	<p>An exercise plan for a mock recall can be submitted.</p>	<p>product traceability chain; Whether the traceability code is operable.</p>	<p><input type="checkbox"/> N/A</p>	
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	<p>incoming finished products; there shall be shipping records for outgoing finished goods, including at least batch number, shipping time, place, object, quantity, etc., so that problems can be found and products can be recovered in time.)</p> <p>7. <i>National Food Safety Standard - General Hygienic Regulation for Food Production</i> (GB14881-2013) (10. Storage and transportation of food)</p> <p>8. <i>GB/T 27320 Food Defense Plan and Guidelines for Its Application - Food Processing Establishments</i>;</p>				
<b>5. Declaration</b>					
5.1 Declaration by enterprise	1. Articles 8 and 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	
5.2 Confirmation by competent authority	1. Articles 8 and 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		1. It shall be signed by an officer of the competent authority and stamped with the seal of the competent authority.	<input type="checkbox"/> Conforming <input type="checkbox"/> Non-conforming	

	of China).				
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