Annex 4-3-4

Registration Conditions and Essential Check Points for Overseas Manufacturers of Imported Functional Food

Registration No.:

Company Name:

Company Address:

Date of filling this form:

Instructions for filling out this form:

1. According to the *Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* (Decree 248 of the General Administration of Customs), the hygienic conditions of overseas functional food manufacturers applying for registration with China shall comply with the relevant provisions of Chinese laws, regulations and standards. This form is provided for the overseas competent authorities of imported functional food to carry out official inspection on functional food manufacturers according to the main conditions and bases listed herein and with reference to the essential check points; At the same time, the overseas functional food manufacturers, after filling in and submitting supporting materials according to the main conditions and bases listed, can carry out

self-inspection with reference to the essential check points, which can be used as the self-assessment of the company before applying for registration.

2. The overseas competent authorities and the overseas functional food manufacturers shall make a truthful conformity determination based on the actual inspection.

3. Materials submitted shall be filled out in Chinese or English, and the content shall be true and complete. The annexes shall be numbered, and the number and content of which shall correspond accurately with the item number and content in the column "Fill-in Requirements and Supporting Materials". In addition, the directory of the annexes of supporting materials shall be submitted.

Items	Conditions and Basis	Fill-in Requirements and Supporting Materials	Essential Inspection Points	Conformity Determination	Remarks
1. Basic Information of the Company					
1.1 Basic information on the company	*Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* (Decree 248 of the General Administration of Customs)	To fill in the form regarding the basic information of overseas manufacturers of imported functional food.	Focus shall be made on whether the registration name, address, registration number, etc. are consistent with those submitted by the official authority.	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture

					and labelling compliant with Australian Standards. Products approved for sale in Australia.
1.2 Information of products to be exported to China	Article 76 of the *Food Safety Law of the People's Republic of China* Functional food that uses raw materials not included in the list of raw materials for functional food and functional food imported for the first time shall be registered with the food safety supervision and administration department under the State Council. However, if a functional food imported for the first time contains nutrients such as vitamins or minerals, it shall be reported to the food safety supervision and administration department under the State Council for the record. Other functional foods shall be reported to the food safety supervision and administration departments of the	1.2.1. Product information, including product name, function declared, packaging specifications, packaging form and corresponding HS code and classification code. 1.2.2. Registration certificate or filing certificate for imported functional food 1.2.3. Documentation certifying marketing authorization by the competent authority of the exporting country (region).	1. Focus shall be made on whether the product has an imported functional food registration certificate or a filing certificate, and whether the product name, function declared, packaging specifications and packaging type of the product are consistent with those contained in the imported functional food registration certificate or filing certificate.	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian Standards. Products approved for sale in Australia.

	people's governments of provinces, autonomous regions and municipalities directly under the Central Government for the record. The imported functional food shall be a product approved for marketing by the competent authority of the exporting country (region).		2. Review whether the product is a product approved for marketing by the competent authority of the exporting country (region).		
2. Raw, Auxiliary and Packaging Materials					
2.1 Acceptance of raw and auxiliary materials	2.1.1 *National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (6.2 The raw materials must comply with food hygiene requirements. The variety, source, specification and quality of the raw materials shall be consistent with the approved formulation and company standards on the products. 2.1.2 When purchasing raw materials, a valid test certificate must be obtained in accordance with relevant regulations; For raw materials that are new food resources, a certificate of approval from the Ministry of Health must be obtained (photocopy). 2.1.3 For the mycelium or the mixture of the mycelium and the fermentation products prepared by artificial	2.1 To provide raw material acceptance standards, including indicators, limits, and acceptance requirements.	The raw material acceptance standard shall be compared with the raw material standard submitted when the company applies for the approval certificate of functional food or the record certificate of functional food	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian Standards. Products approved for sale in Australia.

	fermentation with fungi as raw materials, as well as micro biological raw materials, the strain identification report, the stability report and supporting data that the strain does not contain drug resistance factors must be obtained. 2.1.4 Where algae, animals and animal tissues and organs are used as raw materials, variety identification reports must be obtained. If a single active substance extracted from animals or plants or a biological or chemical synthesis is used as a raw material, a test report on the physical and chemical properties and content of the substance shall be obtained. 2.1.5 For raw materials containing stimulants or hormones, the test report on their content shall be obtained; For radioactively irradiated raw materials, the relevant information on the irradiation dose shall be obtained) 2.1.6 *National Food Safety Standard - the General Hygiene Specification for Food Production* (GB14881-2013) (7.2.1 The supplier's license and product qualification certificates shall be inspected when purchasing				

	raw-food material; Raw-food materials that cannot be provided with the qualification certificate shall be inspected according to the food safety standards. 2.1.7 Raw-food material must pass acceptance before use. Raw-food material that fail to pass the acceptance shall be placed separately with qualified products in the designated area and clearly marked, and shall be returned, exchanged, etc. in a timely manner. 2.1.8 Organic testing shall be carried out before processing, and laboratory testing shall be carried out when necessary; If the inspection finds that the indicators of food safety items are abnormal, it is not allowed to be used; Only the raw-food material that are suitable upon determination shall be used. 2.1.9 Qualification certificates of the products shall be verified when purchasing food-related products such as food packaging materials, containers, detergents, disinfectants, etc., and the supplier's license shall be verified regarding food-related products subject to the license				

	management. Food-related products such as food packaging materials shall be used only upon acceptance).				
2.2 Use of animal-derived or plant-derived raw-food material	2.2.1 *National Food Safety Standard - the General Hygiene Specification for Food Production* (GB14881-2013) (7.2.1 The supplier's license and product qualification certificates shall be inspected when purchasing raw-food material; Raw-food materials that cannot be provided with the qualification certificate shall be inspected according to the food safety standards.) 2.2.2 *National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (6.2 The raw materials must comply with food hygiene requirements. The variety, source, specification and quality of the raw materials shall be consistent with the approved formulation and company standards on the products.)	2.2.1 To provide product ingredients in the order of addition volume from most to least, and indicate the proportion. 2.2.2 If the main raw materials (In what way the proportion of main raw materials is defined) contains raw milk, vegetables (including cultivated edible fungi), meat and meat products, bee products, aquatic products, cubilose, the country of origin of the raw materials shall be provided. 2.2.3 If soybeans are used as the main raw material, whether they are genetically modified soybeans shall be indicated.	1. Focus shall be made on the epidemics risk of raw materials of animal-derived and plant-derived food, if such raw materials are from the epidemic area, attention shall be paid to check whether the subsequent manufacturing process can eliminate the risk. 2. If soybean is used as raw material, attention shall be paid to check whether it is genetically modified soybean, and whether soybean and its processed products are treated by high temperature and	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian Standards. Products approved for sale in Australia.

			other processes to eliminate anti-nutrient factors.		
2.3 Other raw materials (if food additives are used, labeled according to GB2760) (where applicable)	1. *National Food Safety Standard - Standard for the Use of Food Additives* (GB 2760-2014). 2. *National Food Safety Standard - the General Hygiene Specification for Food Production* (GB14881-2013) (7.3.1 The supplier's license and product qualification certificates shall be inspected when purchasing food additives. Food additives must pass acceptance before use.)	To provide the names of the additives used in accordance with the *National Food Safety Standard - Standard for the Use of Food Additives* (GB 2760-2014).	Complete list of raw materials shall be provided by the company.	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian Standards. Products approved for sale in Australia.
2.4 Packaging materials	1. *National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (7.4 Containers, packaging materials, detergents, disinfectants that comply with hygienic standards and hygienic management measures shall be used. 2. The raw materials such as empty	Describe the composition of the inner packaging materials of the product in detail, and list the quality and safety standards for the inner packaging materials.	Focus shall be made on whether the company has provided materials proving the safety of inner packaging materials, such as a corporate statement.	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture

	capsules and sugar coats used must comply with hygiene requirements, and the use of non-edible pigment is prohibited. 3. For various glass bottles (tubes), plastic bottles (tubes), bottle caps, bottle pads, bottle stoppers, aluminum plastic packaging materials used for product packaging, all the inner packaging materials that come into direct contact with the product shall be washed, dried and sterilized by appropriate methods. After sterilization, they shall be cooled in a clean room for use. Where the storage time exceed the specified period, they shall be rewashed and sterilized)				and labelling compliant with Australian Standards. Products approved for sale in Australia.
3. Information on Manufacturing Process					
3.1 To provide a detailed manufacturing process flow diagram that includes process parameters	*National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (7.1.1 The factory shall formulate production process procedures and post operation procedures in accordance with the requirements of this specification and in combination with the production process characteristics of its own products. The procedure shall comply with	To provide a detailed flow chart that includes process parameters and describes the process.	Focus on whether the manufacturing process of the company meets the product definition.	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with

and describes the process.	the process requirements of not losing, not destroying and not converting functional component, and not producing harmful intermediates in the process of processing functional food. The content of the procedure shall include the product formula, the preparation of each component and the main technical conditions during processing of finished products, as well as quality and hygiene monitoring points for critical processes, such as the temperature, pressure, time and pH value during processing of finished products, and quality indicators for the intermediate products. The procedure shall stipulate the specific operational requirements for each main production process, and clarify the responsibilities of each workshop, process and post.				Australian Standards. Products approved for sale in Australia.
3.2 Cleanliness class of plants	1. *National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (5.2.2 The cleanliness class must be divided according to the production process, hygiene and quality requirements. In principle, it is divided into general production area	1. To provide cleanliness class of the factory. 2. To indicate the method adopted to maintain air cleanliness.	If an air filter unit is used, attention shall be paid to the frequency of changing filter screens.		Product is regulated as a medicine in Australia. Product manufacture

	and 100,000 level area. The clean area shall be equipped with corresponding purified air conditioning facilities with filtration units. Please refer to Table 1 for classification and ventilation frequency. 2. The level of purification must meet the need for air purification in the production and processing of functional foods. Products such as tablets, capsules, pills and oral solutions that cannot be sterilized in the final container shall be manufactured in a 100,000-grade clean plant.)				and labelling compliant with Australian Standards. Products approved for sale in Australia.
3.3 Workshop layout and cross pollution control	1. *National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (7.3.2 The connection between production and operation shall be rational, and the transmission shall be fast and convenient to prevent cross-contamination. Raw material handling, intermediate product processing, packaging material and container cleaning, disinfection, finished product packaging, inspection and other processes shall	1. To provide floor plans of workshops, people and material flow diagrams; 2. Measures taken to control cross-contamination.	1. Pay attention to the setting of cleaning areas at all levels in the workshop; 2. Whether there is cross contamination in terms of personnel in and out, personal hygiene, logistics in and out, etc.; 3. Whether inner packaging area and		Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian

	be set separately. The same workshop shall not simultaneously produce different products; The containers of different processes shall be clearly marked and shall not be mixed. 2. Production operators shall do a good job in personal hygiene in strict accordance with the different requirements of the general production area and the clean area. When it is possible to cause product contamination due to changing posts, the work clothes, shoes and hats must be changed and disinfected again. The working clothes, hats, shoes, etc. used for the clean area must be strictly washed and disinfected, changed daily, and only allowed to be worn in the clean area, and not taken out of the area. 3. Raw and auxiliary materials must pass through the material passage to enter the production area. Materials entering the clean plant and workshop must be removed from the outer packaging. If the outer packaging cannot be removed, it must be scrubbed clean or replaced with indoor packaging drums. 4. Tabletting, capsules split charging,		outer packaging area are effectively isolated.		Standards. Products approved for sale in Australia.

	filling of granule and liquid products, etc., shall be carried out in the clean room, and the temperature and humidity of the operating room shall be controlled. The manual filling of capsules shall be carried out in an organic glass enclosure with corresponding cleanliness class, and the operating table shall not be less than 0.7m; 5. The prepared material must be placed in a clean and tight container, and timely entered into the filling, tabletting or capsule split charging and other processes. For materials need to be stored, the specified period shall not be exceeded.)				
3.4 To provide cleaning and disinfection procedures covering the entire production line.	1. *National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (7.3 Before burdening, it is necessary to check whether the burdening pots and container pipes are clean and conform to the standards required by the process. Fermentation cylinder, containers and pipes used for production by the fermentation process must be thoroughly cleaned and disinfected before they can be used for production. Equipment shall	To provide washing and disinfection procedures that cover the entire production line.	Focus on verifying the effectiveness of cleaning and disinfection.	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian

	be cleaned and disinfection records shall be kept for each shift.) 2. *National Food Safety Standards - the General Hygienic Specifications for Food Production* (GB14881-2013) (5.1.3 Cleaning and disinfection facilities Adequate special cleaning facilities shall be provided for food, utensils and equipment, and appropriate disinfection facilities shall be provided when necessary. Measures shall be taken to avoid cross contamination caused by cleaning and disinfection tools. 8.2.1 Cleaning and disinfection)				Standards. Products approved for sale in Australia.
3.5 To provide a list of major production equipment and production capacity.	1. *National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (5.2.5 Plant, equipment layout and process flow shall be properly connected, and the architectural structure shall be sound and able to meet the requirements for production process, quality and hygiene; There shall be sufficient space in the plant to accommodate equipment and materials; The storage room used for intermediate products and to-be-packaged products shall be	To provide the name, model, designed processing capacity and pictures of key process equipment.	1. Companies shall be equipped with processing equipment matched with their production process. 2. Surfaces of equipment, tools and utensils in contact with food shall be made of smooth, non-absorbent, easy to clean, maintain and disinfect	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian Standards.

	adapted to the production requirements). 2. *National Food Safety Standard - the General Hygienic Specifications for Food Production* (GB14881-2013) (5.2.1 Production equipment)		materials.		Products approved for sale in Australia.
3.6 To provide hazard analysis worksheet and HACCP schedule.	1. *National Food Safety Standard - the General Hygienic Specifications for Food Production* (GB14881-2013) (8.1.1 The key links of food safety in the production process shall be identified through hazard analysis method, and the control measures for the key links of food safety shall be set up. In the area where the key links are located, relevant documents shall be provided to implement the control measures, such as the burden (feeding) sheet, operation procedures for posts, etc. 2. Hazard Analysis and Critical Control Point System (HACCP) is encouraged to be used for food safety control in the manufacturing process. 3. *National Food Safety Standard - Hazard Analysis and Critical Control Point System - General Requirements for Food Processing Plant* (GB/T 27341-2009)	1. Hazard analysis sheet regarding production and processing and HACCP schedule. 2. To provide monitoring records regarding CCP. If any, please provide measures taken for and records on deviations from critical limit of CCP.	1. Focus on the setting and critical limit of CCP and the implementation of remediation and validation. 2. Does the HACP schedule cover all products applied for registration?	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian Standards. Products approved for sale in Australia.

3.7 Product sterilization	*National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (7.5 Product sterilization The sterilization of various products shall be carried out using effective sterilizing equipment and methods. For products that need to be sterilized but cannot be autoclaved, fine filtration, microwave, irradiation and other methods can be used according to different processes and food hygiene requirements to ensure sterilization effect. When irradiation sterilization is used, the irradiation dose and time shall be strictly controlled in strict accordance with the provisions of the *Administrative Measures for the Hygiene of Irradiated Foods*. Regular reliability verification of temperature uniformity and repeatability of the sterilization device shall be carried out, and the temperature, pressure and other test instruments shall be regularly checked. Temperature, pressure, time, and other indicators shall be accurately recorded during sterilization.)	1. If thermal sterilization process is used, it is necessary to provide the materials proving the effectiveness of thermal sterilization and the specific sterilization temperature and time requirements; 2. For products that need to be sterilized but cannot be autoclaved, the sterilization methods used shall be provided; 3. If radiation sterilization is used, please provide the absorbed dose and time of irradiation.	Focus on the effectiveness of sterilization methods.	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian Standards. Products approved for sale in Australia.

4. Product Quality and Safety Control System					
4.1 On-line product control and inspection	*National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (9.5.1 Identify key control points for quality and hygiene during processing, monitor at least the following links, and keep records.)	To provide the complete on-line product inspection plan, specifying the inspection content, parameters, frequency and validation frequency in the light of the working procedures.	1. Whether the on-line control measures effectively monitor the hazards analyzed by the company. 2. Focus on the consistency of parameters and frequency of the on-line check set points with HACCP plan and process flow. 3. If there are metal detectors, thermometers, etc., attention shall be paid to calibration and maintenance records.	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian Standards. Products approved for sale in Australia.
4.2 Testing and approval of final products	1. *National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) Sensory, hygiene and quality indicators must be inspected on a batch-by-batch basis for finished products, and those unqualified shall	To provide test plans, testing standards and requirements for the approval of final products.	The inspection report regarding final products shall cover the limit requirements of the *National Food Safety Standard - Health*	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product

	not leave the factory. Companies shall have the ability to detect the main functional factors or functional ingredients of the product, and shall carry out inspection according to the functional factors or main functional ingredients of the product produced by each feeding. Those unqualified shall not leave the factory. Samples shall be reserved for each batch of products, which shall be stored in a special sample retention repository (or area), stored by variety and batch number, and clearly marked. Product stability tests shall be performed regularly. The packaging materials, signs and instructions of the products must be inspected, and those unqualified shall not be used. Check and manage the storage conditions of finished product warehouses, and warehouses that do not meet the storage conditions shall not be used.) 2. *National Food Safety Standard - the General Hygienic Specifications for Food Production*		*Food* (GB 16740-2014).		manufacture and labelling compliant with Australian Standards. Products approved for sale in Australia.

	(GB14881-2013) (9.1Raw materials and products shall be inspected by the companies themselves or food inspection institutions with corresponding qualifications, and a food ex-factory inspection record system shall be established. For self-inspection, there shall be inspection room and inspection ability suitable for the inspection items; It shall be inspected by qualified inspectors according to the prescribed inspection methods; The inspection instruments and equipment shall be inspected on schedule. There shall be a sound management system for the inspection room, and the original records and reports of each inspection shall be properly kept. A product sample retention system shall be established to retain samples in a timely manner. The product characteristics, process characteristics, raw material control conditions and other factors shall be comprehensively considered to reasonably determine the inspection items and inspection frequency to effectively verify the control measures in the production process.				

	The testing frequency of the net content, sensory requirements and other testing items that are susceptible to change due to the production process shall be greater than that of the other testing items. For products in different packages of the same variety, inspection items that are not affected by packaging specifications and packaging forms may be inspected together.)				
4.3 Product shelf-life determination basis or data	1. *National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (9.6.4 Product stability experiments shall be conducted regularly.) 2. *National Food Safety Standards - General Standard for the Labeling of Prepackaged Foods* (GB 7718-2011) (2.5 Shelf-life The period during which prepackaged foods are maintained in quality under storage conditions specified on the label. During this period, the product is perfectly fit for sale and maintains the specific qualities that are not required to be or have already been described in the label.) Refer to *T/CNFIA001-2017 General Guideline for Food Shelf Life*	To provide product shelf-life determination basis or data	1. Whether the shelf-life determination basis is consistent with the actual marks. 2. Whether the shelf-life test conditions correspond to the actual storage and transportation.	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian Standards. Products approved for sale in Australia.

4.4 Protective requirements during product delivery to sales.	1. *National Food Safety Standard - Good Manufacturing Practice for Health Food* (GB17405-1998) (8.1 The general hygiene requirements for storage and transportation shall meet the requirements of the *National Food Safety Standard - the General Hygienic Specifications for Food Production* (GB14881-2013). 2. The storage mode and environment of finished products shall be protected from light and rain, temperature and humidity shall be controlled within an appropriate range, and strike and vibration shall be avoided. 3 Products containing bioactive substances shall be refrigerated and stored and transported in a cold chain. 4 Functional foods stored under extraordinary temperatures (such as some micro-ecological functional foods) shall be stored and transported at the required temperature according to the different characteristics of the product. 5 A receiving and delivering inspection system shall be established for the warehouses. The principle of	Protective requirements during product delivery to sales; A simulated recall drill plan can be submitted.	Focus on the integrity of product traceability chain. Whether the setting of traceability code is actionable.	□ Compliance □ Non conformance □ N/A	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian Standards. Products approved for sale in Australia.

	"products produced first shall be sold first" shall be carried out when finished products leave the factory. 6. Inventory records shall be kept for the warehousing of finished products, and shipment records shall be kept for ex-warehouse of finished products, with contents including at least the batch number, shipment time, location, object, quantity, etc., so that products can be recovered in case of problems in a timely manner.) 7 *National Food Safety Standard - the General Hygienic Specifications for Food Production* (GB14881-2013) (10 Storage and transportation of food) 8. GB/T 27320 *Food Defense Plan and Guidelines for Its Application - Food Processing Establishments*;				
5. Representation					
5.1 Corporate representation	1. Articles 8 and 9 of *Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* (Decree 248 of the General Administration of Customs).		1. Being signed by the legal person and sealed by the company.	□ Compliance □ Non conformance	Product is regulated as a medicine in Australia. Product manufacture

					and labelling compliant with Australian Standards. Products approved for sale in Australia.
5.2 Confirmation by competent authority	1. Articles 8 and 9 of *Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* (Decree 248 of the General Administration of Customs).		1. Being signed by the personnel from the competent authority and sealed by the competent authority.	□ Compliance □ Non conformance	Product is regulated as a medicine in Australia. Product manufacture and labelling compliant with Australian Standards. Products approved for sale in Australia.