Annex 5-4-1

**Registration Conditions for Overseas Manufacturers of Imported Aquatic Products**

**and comparison checkpoints**

**Registration number:**

**Company’s Name:**

**Company’s Address:**

**Form filling Date:**

**Instructions for filling out the form:**

1.According to the "Regulations of the People's Republic of China on the Administration of Registration of Overseas Manufacturers of Imported Foods" (Order No. 248 of the General Administration of Customs), the sanitary conditions of overseas aquatic product manufacturers applying for registration in China shall comply with the relevant provisions of Chinese laws, regulations and standards and must comply with the requirements of the Protocols of the Inspection and Quarantine of Aquatic Products Exported to China. This form is for the overseas authorities in charge of imported aquatic products to conduct official inspections on aquatic product production enterprises according to the listed main conditions and bases and according to the review points. At the same time, overseas aquatic product manufacturers should fill in and submit supporting materials according to the listed main conditions and bases. Self-examination can also be carried out against the review points for self-assessment before an enterprise applies for registration.

2. Overseas competent officials and overseas aquatic product manufacturers should truthfully make compliance judgments based on the actual situation of the comparison inspection.

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

4. "Aquatic products" refers to aquatic animal and plant products and their by-products for human consumption, including jellyfish, molluscs, crustaceans, echinoderms, cephalopods, fish, amphibians, reptiles, aquatic mammals and other aquatic animals and their by-products, as well as algae and other marine plants and their by-products, excluding live aquatic animals and aquatic animals and plants reproduction materials.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Item | Conditions and bases | Fill in the requirements and supporting materials | Review points | Compliance determination | Remarks |
| **1. Basic information of the enterprise** | | | | | |
| 1. Basic information of the enterprise | 1. Articles 5, 6, 7 and 8 of "Regulations of the People's Republic of China on the Administration of Registration of Overseas Manufacturers of Imported Foods" (Order No. 248 of the General Administration of Customs)  2. "Administrative Measures of the People's Republic of China on Import and Export Food Safety" (Order No. 249 of the General Administration of Customs).  3. Protocol on inspection and quarantine of aquatic products exported to China signed by the competent authority of the applicant country and the General Administration of Customs. | 1.1 Fill in the basic information form of overseas manufacturers of imported aquatic products. | 1. Enterprises should fill in the information truthfully, and the basic information should be consistent with the information submitted by the competent authorities of the exporting country, and should be consistent with the actual production and processing conditions.  2. The aquatic products to be exported to China shall comply with the product scope stipulated in the relevant agreements, protocols, and memorandums on the inspection and quarantine of aquatic products exported to China.  3. Human resources (enterprise and official) should be able to meet the requirements of enterprise production and processing and the official inspections and supervisions.  4. The refrigeration storage capacity should meet the capacity of continuous production and storage of frozen/chilled aquatic products. | □Compliant with the requirements  □ does not meet the requirements |  |
| **2. Enterprise location and workshop layout** | | | | | |
| 2.1 Site selection and factory environment | 1. Articles 3.1 and 3.2 of "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Articles 3.1 and 3.2 of "Hygienic Specifications for the Production of Aquatic Products" (GB 20941). | 2.1.1 Provide a floor plan of the factory area and indicate the names of different operating areas.  2.1.2 Provide pictures of the environment in which the factory is located, and the pictures should indicate the surrounding environment information (urban, suburban, industrial, agricultural and residential areas). | 1. The layout of the factory area meets the needs of production and processing.  2. There is no pollution source around the factory. | □Compliant with the requirements  □ does not meet the requirements |  |
| 2.2 .Workshop layout | 1. Article 4.1 in "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Article 4.1 of "Hygienic Specifications for the Production of Aquatic Products"  (GB 20941). | 2.2 Provide a floor plan of the workshop, mark the flow of people, logistics, water flow, processing flow, and different cleaning areas. | 1. The layout of the workshop is reasonable, meets the production and processing requirements, and avoids cross-contamination. | □Compliant with the requirements  □ does not meet the requirements |  |
| **3. Facilities and equipment** | | | | | |
| 3.1 .Production and processing equipment | 1. Article 5.2.1 in "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Article 5.2.1 in "National Food Safety Standards and Hygienic Specifications for the Production of Aquatic Products"  (GB 20941) . | 3.1 Provide a list of major equipment and facilities, and design and processing capabilities. | 1. Enterprises should be equipped with production equipment suitable for production capacity. | □Compliant with the requirements  □ does not meet the requirements |  |
| 3.2 Storage facilities | 1. Article 10 in "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Article10.2 in "National Food Safety Standards and Hygienic Specifications for the Production of Aquatic Products"  (GB 20941) | 3.2 If there is a cold storage, please describe the temperature control requirements and monitoring methods. (if applicable). | 1. Storage facilities can meet the product storage temperature requirements. | □Compliant with the requirements  □ does not meet the requirements |  |
| **4. Water/Ice/Steam** | | | | | |
| 4.1 Process water/steam/ice (if applicable) | 1. "Sanitation Standard for Drinking Water" (GB 5749)  2. Article 5.1.1 in "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941).  3. Article 5.1.1 in "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881). | 4.1.1 Provide photos of self-provided water sources or secondary water supply facilities, and indicate whether there is a special person responsible for food protection measures such as locking. (if applicable)  4.1.2 Provide a monitoring plan for production and processing water and ice/steam (if applicable) in direct contact with food, including the items, methods, frequency, records, test results and the last two test reports of bacteriological inspection.  4.1.3 Provide boiler additives used in the production of steam directly in contact with food, and indicate whether they meet the requirements of food production and processing. | 1. The production water monitoring plan should cover all water outlets in the factory.  2. Whether the project and method meet the requirements of "Drinking Water Standard" (GB5749).  3. The secondary water supply facilities shall formulate and implement sanitation control procedures and have appropriate food protection measures.  4. Boiler additives used in the production of steam directly in contact with food shall meet the requirements of food production and processing. | □Compliant with the requirements  □ Does not meet the requirements  □Not applicable |  |
| **5. Raw materials and packaging materials** | | | | | |
| 5.1 Acceptance of raw and auxiliary materials | 1. Article 7 in "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Article 7 in "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941). | 5.1 Provide acceptance measures for raw materials and additives, including acceptance criteria and acceptance methods. | 1. Acceptance criteria for raw materials and additives and compliance with Chinese regulations and standards. | □Compliant with the requirements  □ Does not meet the requirements |  |
| 5.2 Source of raw materials | 1. Article 7.2 of "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941).  2. Non-muscle tissues such as viscera, eggs, skin, fins, scales, bones, and shells of aquatic animals are used as raw materials for aquatic products, and shall comply with the National Food Safety Standards.  Fresh and Frozen Aquatic Products of Animal Origin" (GB 2733).  3. The raw materials of animal aquatic products should comply with the "National Food Safety Standard - Fresh and Frozen Animal Origin Aquatic Products" (GB 2733)  4. The raw materials of algae products should comply with the "National Food Safety Standard - Algae and Its Products" (GB 19643).  5. "National Food Safety Standard - Limit of Pathogenic Bacteria in Food" (GB29921) Table 1.  6. Articles 3.6 and 3.7 in "National Food Safety Standard Animal Aquatic Products" (GB10136). | 5.1 Provide acceptance measures for raw materials and additives, including acceptance criteria and acceptance methods.  5.2.1 If the raw materials are raw materials of aquatic products with biological toxins or raw materials of raw aquatic products, please provide the latest test report. (where applicable)  5.2.2 If it is a fishing vessel, provide the official license certificate for the fishing vessel's operating area, operating time, fishing species and description of fishing methods. (where applicable)  5.2.3 If it is a breeding material, provide the qualification certificate of the breeding farm. (where applicable) | 1. The raw materials of aquatic products with biological toxins, such as bivalve shellfish and puffer fish, should be tested for toxins, and the acceptance and treatment should be carried out in accordance with relevant regulations to ensure the safety of raw materials.  2. The raw materials used should meet the requirements of the relevant agreements, protocols, and memorandums on the inspection and quarantine of aquatic products exported to China. | □Compliant with the requirements  □ Does not meet the requirements  □Not applicable |  |
| 5.3 Raw bivalve mollusks (where applicable | 1. Article 7.2 of "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941).  2. Table 1.  3. Article 3.6 and 3.7 in "National Food Safety Standard - Limit of Pathogenic Bacteria in Food" (GB29921)  "National Food Safety Standard Animal Aquatic Products" (GB10136- 2015). | 5.3.1 Provide a description of the location of the sea area where the shellfish raw materials are sourced and the official license certificate of the bivalve harvester.  5.3.2 Provide the purification treatment party for shellfish raw materials.  5.3.3 Provide shellfish toxin monitoring measures for shellfish raw materials. | 1. Bivalve mollusks should be sourced from officially permitted farming or fishing waters and decontaminated if necessary. Farmers or fishers of shellfish raw materials should have a license from the official competent authority.  2. Regularly conduct shellfish toxin testing on shellfish raw materials to verify the safety of raw materials. | □Compliant with the requirements  □ Does not meet the requirements  □Not applicable |  |
| 5.4 Food preparations (if applicable) | 1. Article 7.3 of "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Article 7.3 of "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941).  3. "National Food Safety Standard - Standard for the Use of Food Additives" (GB 2760). | 5.4 List of food additives used in production and processing (including name, purpose, added amount, etc.) | 1. The food additives used in production comply with China's regulations on the use of food additives. | □Compliant with the requirements  □ Does not meet the requirements  □Not applicable |  |
| 5.5 Packaging Materials | 1. Article 8.5 in "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Article 8.5 in "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941).  3. Relevant bilateral inspection and quarantine agreements, memoranda and protocols. | 5.5.1 Provide evidence that the inner and outer packaging materials are suitable for product packaging.  5.5.2 Provide the finished product label style to be exported to China. | 1. Packaging materials do not affect the safety and product characteristics of food under specific storage and use conditions.  2. The packaging label shall comply with the requirements of bilateral inspection and quarantine agreements, memorandums and protocols. | □Compliant with the requirements  □ Does not meet the requirements |  |
| **6. Production and processing control** | | | | | |
| 6.1. The establishment and operation of HACCP system | 1. Article 8.1 of "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941).  2. "Hazard Analysis and Critical Control Points (HACCP) System General Requirements for Food Production Enterprises" (GB/T 27341). | 6.1.1. Provide the production and processing process flow chart, hazard analysis worksheet and HACCP plan of all products to be exported to China.  6.1.2. Provide CCP monitoring records, deviation correction records, and verification records sample sheets. | 1. The HACCP plan shall analyze and effectively control biological, physical and chemical hazards.  2. The production process should be reasonable to avoid cross-contamination.  3. The setting of CCP points should be scientific and feasible, and the corrective and verification measures should be appropriate. | □Compliant with the requirements  □ Does not meet the requirements  □Not applicable |  |
| 6.2.Temperature Control | 1. Articles 8.2.2.1.4 and 8.2.2.1.6 of "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941).  2. Article 8.2.2.2.1 (applicable to refrigerated aquatic products) in "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941). | 6.2.1 Provide the method of thawing raw materials, and the temperature control requirements for thawing time (if applicable).  6.2.2 Provide temperature control requirements and temperature monitoring equipment for processing workshops and warehouses. (Applicable to refrigerated aquatic products). | 1. Control the thawing time and temperature of raw materials.  2. The processing workshop of refrigerated aquatic products should have temperature control measures. The processed aquatic products should be moved to the refrigerated environment as soon as possible, and the refrigerating room should be equipped with temperature indicators. | □Compliant with the requirements  □ Does not meet the requirements  □Not applicable |  |
| 6.3 Frozen aquatic products | 1. 8.2.2.2.2 of "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941). | 6.3.1 Provide the freezing method, time and freezing temperature control requirements of frozen aquatic products and the basis for their determination.  6.3.2 For raw edible and aquatic products, provide the temperature and time for cold treatment. | 1. Determine the freezing time and temperature according to the thickness, shape and production volume of aquatic products to ensure that they pass through the largest ice crystal production zone as soon as possible.  2. Raw food and aquatic products should have sufficient cold treatment methods to ensure that parasites that are harmful to the human body are killed. Store frozen for 7 days at ambient temperature below -20°C;  3. Freeze to solid at -35°C or below ambient temperature, and store at -35°C or below ambient temperature for 15 hours;  4. Freeze to solid at -35°C or below ambient temperature and store at -20°C or below ambient temperature for 24 hours. | □Compliant with the requirements  □ Does not meet the requirements  □Not applicable |  |
| 6.4 Dried aquatic products (where applicable) | 1. Article 8.2.2.2.3 in "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941). | 6.4 Provide the drying time, drying temperature, ambient humidity, water activity of finished products and packaging and storage methods for the processing of dried aquatic products. | 1. It should be ensured that the water activity of the dry product is within a safe range. | □Compliant with the requirements  □ Does not meet the requirements  □Not applicable |  |
| 6.5 Pickled aquatic products (where applicable | 1. Article 8.2.2.2.4 in "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941). | 6.5 Provide the sugar/salinity of pickled aquatic products. | 1. Proper salinity should be used in the production of pickled products to prevent the reproduction of non-halophilic bacteria. | □Compliant with the requirements  □ Does not meet the requirements  □Not applicable |  |
| 6.6 Canned aquatic products (where applicable) | 1. Article 8.2.2.2.5 in "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941). | 6.6.1 Provide the sterilization temperature and time requirements for canned aquatic products of different specifications, and the latest sterilization/temperature record.  6.6.2 Provide heat penetration and heat distribution reports for sterilization containers of canned aquatic products of different specifications. | 1. Canned aquatic products should ensure sufficient sterilization temperature and sterilization time. | □Compliant with the requirements  □ Does not meet the requirements |  |
| **7. Cleaning and disinfection** | | | | | |
| 7.1 Cleaning and disinfection | 1.Article 8.2.1 of "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Article 8.2.1 of "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941). | 7.1 Provide cleaning and disinfection measures, including cleaning and disinfection methods and frequencies, and verification of cleaning and disinfection effects. | 1. Cleaning and disinfection measures should be able to eliminate cross-contamination and meet hygienic requirements. | □Compliant with the requirements  □ Does not meet the requirements |  |
| 7.2.Environmental Microbial Monitoring | 1. Articles 8.2.2.1.2 and 8.2.2.1.3 in "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941). | 7.2 Provide the product microbiological monitoring plan for the environment and production process, including monitoring items, frequency, determination standards, and corrective measures for positive results. | 1. The focus of monitoring should cover areas where microorganisms are easy to hide and breed.  2. Sampling point setting. In the event of major maintenance, construction activities, or deteriorating sanitary conditions, add necessary sampling points to the monitoring plan.  3. Whether to adjust the frequency of environmental monitoring plan implementation based on test results and the severity of pollution risks.  4. Corrective measures for positive results. | □Compliant with the requirements  □ Does not meet the requirements |  |
| **8. Chemical, waste, pest control** | | | | | |
| 8.1. Chemical Control | 1. Article 8.3 in "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881-2013).  2. Article 8.3 in "Hygienic Specifications for the Production of Aquatic Products" (GB 20941). | 8.1. Briefly describe chemical usage and storage requirements. | 1. Prevent the chemicals used from contaminating the product. | □Compliant with the requirements  □ Does not meet the requirements  □Not applicable |  |
| 8.2. Waste Management | 1. Article 8.1.4 of "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB 20941). | 8.2.1 Provide the identification pictures of edible product containers and waste storage containers in the workshop.  8.2.2 Briefly describe the requirements for waste disposal procedures. | 1. The edible product containers and waste storage containers in the workshop should be clearly marked and distinguished.  2. Waste should be stored separately and disposed of in time to avoid pollution to production. | □Compliant with the requirements  □ Does not meet the requirements |  |
| 8.3. Pest control | 1. Article 6.4 of "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881) | 8.3 Provide pest control methods and layout plans, and provide third-party qualifications if undertaken by a third party. | 1. The influence of pests and rodents on production safety and hygiene should be avoided. | □Compliant with the requirements  □ Does not meet the requirements |  |
| **9. Product traceability** | | | | | |
| 9.Traceability and recall | 1.Article 11 in "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Article 11 in "Hygienic Specifications for the Production of Aquatic Products" (GB 20941). | 9. Briefly describe the product traceability procedure, taking a batch of finished product batch numbers as an example to explain how to trace back from finished product to raw material. | 1. A traceability procedure should be established to achieve two-way traceability of the entire chain of raw materials, production, processing processes, and finished products. | □Compliant with the requirements  □ Does not meet the requirements |  |
| **10. Personnel management and training** | | | | | |
| 10.1. Personnel health and hygiene management | 1. Article 6.3 of "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Article 6.3 in "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB20941). | 10.1 Provide pre-employment health management and employee physical examination requirements. | 1. Before hiring an employee, a medical examination should be carried out and certified as fit to work in a food processing business.  2. Employees should undergo regular medical examinations and keep records. | □Compliant with the requirements  □ Does not meet the requirements |  |
| 10.2. Personnel training | 1.Article 12 in "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Article 12 in "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB20941). | 10.2 Provide employees with annual training plan, content, assessment and records. | 1. The training content should cover the inspection and quarantine memorandums, agreements and protocols of aquatic products exported to China, and Chinese regulations and standards. | □Compliant with the requirements  □ Does not meet the requirements |  |
| **11. Self-check and self-control** | | | | | |
| 11. Finished product inspection | 1. Article 9 in "National Food Safety Standard - General Hygienic Specification for Food Production" (GB14881).  2. Article 9 in "National Food Safety Standard - Hygienic Specification for the Production of Aquatic Products" (GB20941).  3. "National Food Safety Standard Fresh and Frozen Animal Aquatic Products" (GB 2733).  4. "National Food Safety Standard - Animal Aquatic Products" (GB 10136).  5. "National Food Safety Standard - Aquatic Condiments" (GB 10133).  6. "National Food Safety Standard Algae and Its Products" (GB 19643).  7. "National Standard for Food Safety Standard for Use of Food Additives" (GB 2760).  8. "National Food Safety Standard Limits of Mycotoxins in Food" (GB 2761).  9. "National Food Safety Standard Limits of Contaminants in Food" (GB 2762).  10. National Food Safety Standard Maximum Residue Limit of Pesticides in Food (GB 2763).  "National Food Safety Standard - Standard for Restricted Concentration of Radioactive Substances in Food" (GB 14882).  "National Food Safety Standard Dried Sea Cucumber" (GB 31602). | 11.1. Provide the items, indicators, inspection methods and frequency of finished product inspections.  11.2. The enterprise has its own laboratory, and submits the certificate of enterprise laboratory capability and qualification; the enterprise entrusts a third-party entrusted laboratory to provide the entrusted laboratory qualification. | 1. The finished product inspection items conform to China's standard requirements. | □Compliant with the requirements  □ Does not meet the requirements |  |
| **12. Statements** | | | | | |
| 12.1. Corporate Statement | 1. Articles 8 and 9 of "Regulations of the People's Republic of China on the Administration of Registration of Overseas Production Enterprises of Imported Food". | 12.1 Fill in the "Application for Registration of Overseas Manufacturers of Imported Aquatic Products". | It should be signed by the legal person and stamped by the company. | □Compliant with the requirements  □ Does not meet the requirements |  |
| 12.2 .Confirmation by the competent authority | 1. Articles 8 and 9 of "Regulations of the People's Republic of China on the Administration of Registration of Overseas Production Enterprises of Imported Food". | 12.2 Fill in the "Application Form for Registration of Overseas Manufacturers of Imported Aquatic Products". | It should be signed and stamped by the competent authority. | □Compliant with the requirements  □ Does not meet the requirements |  |