Part IV Main Registration Conditions and Inspection Focuses for Overseas Manufacturers of Imported Aquatic Products

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Item | Conditions and bases | | Filling requirements and supporting materials | Focus of examination | Conformity determination | Remarks |
| **1. Enterprise Overview** | | | | | | |
| 1. Enterprise Overview | 1. Articles 6 and 7 of the *Regulations on the Registration Administration of Overseas Manufacturers of Imported Food*  2. *Measures for the Supervision and Administration of Inspection and Quarantine of Imported and Exported Aquatic Products*  3. Protocol on Inspection and Quarantine of Aquatic Products Exported to China signed by and between the competent authority of the applicant country and the General Administration of Customs | | 1.1 Fill out Table 1 - Basic Information of Overseas Manufacturers of Imported Aquatic Products. | 1. Enterprises should truthfully fill in the information. The basic information should be consistent with that submitted by the competent authority of the exporting country and with the actual production and processing.  2. Aquatic products to be exported to China shall conform to the product scope stipulated in relevant agreements, protocols and memorandums on inspection and quarantine of aquatic products exported to China. | □ Yes  □ No |  |
| **2. Enterprise Location and Workshop Layout** | | | | | | |
| 2.1 Site Selection and Plant Environment | | 1. Articles 3.1 and 3.2 of the *General Hygienic Regulation for Food Production* (GB14881).  2. Articles 3.1 and 3.2 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 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. | □ Yes  □ No |  |
| 2.2 Workshop Layout | | 1. Article 4.1 of the *General Hygienic Regulation for Food Production* (GB14881).  2. Article 4.1 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 2.2 Provide a workshop plan, indicating people flow, material flow, water flow, processing flow and different cleaning areas. | 1. The workshop layout should be reasonable to meet production and processing requirements and avoid cross contamination. | □ Yes  □ No |  |
| **3. Facility and Equipment** | | | | | | |
| 3.1 Production and Processing Equipment | | 1. Article 5.2.1 of the *General Hygienic Regulation for Food Production* (GB14881).  2. Article 5.2.1 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 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. | □ Yes  □ No |  |
| 3.2 Storage Facility | | 1. Article 10 of the General Hygienic Regulation for Food Production (GB14881).  2. Article 10.2 of the Hygienic Regulation for Aquatic Products Production (GB 20941). | 3.2 Please describe the temperature control requirements and monitoring methods if there is a cold storage. (where applicable) | 1. Storage facilities can meet the temperature requirements for product storage. |  |  |
| **4. Water/Ice/Steam** | | | | | | |
| 4.1 Water/ice/steam for production and processing (if applicable) | | 1. *Standards for Drinking Water Quality* (GB 5749)  2. Article 5.1.1 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941).  3. Article 5.1.1 of the *General Hygienic Regulation for Food Production* (GB14881). | 4.1.1 Provide photos of self-provided water sources or secondary water supply facilities, and explain whether there are food protection measures such as assigning specific persons for management and locking. (if applicable)  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 last 2 inspection reports.  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. | 1. The production water monitoring plan shall cover all water outlets in the plant.  2. Whether the items and methods meet the requirements of the *Standards for Drinking Water Quality* (GB5749).  3. Hygiene control procedures shall be formulated and implemented for the secondary water supply facilities, and appropriate food protection measures shall be in place.  4. Boiler additives used in the production of steam in direct contact with food shall meet the requirements of food production and processing. | □ Yes  □ No  □ N/A |  |
| **5. Raw and Auxiliary Materials and Packaging Materials** | | | | | | |
| 5.1 Acceptance of Raw and Auxiliary Materials | | 1. Article 7 of the *General Hygienic Regulation for Food Production* (GB14881).  2. Article 7 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 5.1 Provide acceptance measures for raw materials and additives, including acceptance standards and methods. | 1. Acceptance standards for raw materials and additives, and their compliance with the requirements of Chinese laws and standards. | □ Yes  □ No |  |
| 5.2 Source of Raw Materials | | 1. Article 7.2 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941).  2. Raw materials of aquatic products, such as viscera, eggs, skin, fins, scales, bones, shells and other non-muscle tissues of aquatic animals, shall conform to the *Fresh and Frozen Aquatic Products of Animal Origin* (GB 2733).  3. Raw materials of aquatic products of animal origin shall conform to the *Fresh and Frozen Aquatic Products of Animal Origin* (GB 2733).  4. Raw materials of algae products shall conform to the *Algae and Algae Products* (GB 19643).  5. Table 1 of the *Maximum Levels of Pathogenic Bacteria in Food* (GB29921)  6. Articles 3.6 and 3.7 of the *Aquatic Products of Animal Origin* (GB10136) | 5.2.1 If the raw materials are those for aquatic products with biological toxins or raw aquatic products, please provide the latest inspection report. (where applicable)  5.2.2 If a fishing vessel is used, provide the official license documents for the fishing vessel's operation area, operation time, fishing varieties and the description of fishing methods. (where applicable)  5.2.3 If they are breeding raw materials, provide the qualification of the farm. (where applicable) | 1. Toxin detection shall be carried out on raw materials of aquatic products with biological toxins, such as bivalve molluscs and globefish, and acceptance and treatment shall be carried out in accordance with relevant regulations to ensure the safety of raw materials.  2. Raw materials used shall meet the requirements of relevant agreements, protocols, memorandums on inspection and quarantine of aquatic products exported to China. | □ Yes  □ No  □ N/A |  |
| 5.3 Raw Materials of Bivalve Molluscs (Where Applicable) | | 1. Article 7.2 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941).  2. Table 1 of the *Maximum Levels of Pathogenic Bacteria in Food* (GB29921).  3. Articles 3.6 and 3.7 of the *Aquatic Products of Animal Origin* (GB10136-2015). | 5.3.1 Provide a description of the sea area location where shellfish raw materials come from and the official license certificate of bivalve molluscs catchers.  5.3.2 Provide purification and treatment methods of shellfish raw materials.  5.3.2 Provide monitoring measures for shellfish toxins from shellfish raw materials. | 1. Bivalve molluscs should come from officially allowed aquaculture or fishing waters and be purified when necessary. Farmers or catchers of shellfish raw materials should have a license from an official competent authority.  2. Shellfish toxin detection shall be conducted on shellfish raw materials on a regular basis to verify the safety of raw materials. | □ Yes  □ No  □ N/A |  |
| 5.4 Food Additives (Where Applicable) | | 1. Article 7.3 of the *General Hygienic Regulation for Food Production* (GB14881).  2. Article 7.3 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941).  3. National Food Safety Standard - Standards for Uses of Food Additives (GB 2760) | 5.4 List of food additives used in production and processing (including the name, purpose and added amount, etc.). | 1. The food additives used in the production conform to China's regulations on the use of food additives. | □ Yes  □ No  □ N/A |  |
| 5.5 Packaging Materials | | 1. Article 8.5 of the *General Hygienic Regulation for Food Production* (GB14881).  2. Article 8.5 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941).  3. Relevant bilateral inspection and quarantine agreements, memorandums and protocols | 5.5.1 Provide proof that the inner and outer packaging materials are suitable for dairy packaging.  5.5.2 Provide label styles for finished products to be exported to China. | 1. Packaging materials do not affect food safety and product characteristics under specific storage and use conditions.  2. Packaging labels shall meet the requirements of bilateral inspection and quarantine agreements, memorandums and protocols. | □ Yes  □ No |  |
| **6 Production and Processing Control** | | | | | | |
| 6.1 Establishment and Operation of HACCP System | | 1. Article 8.1 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941).  2. *Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Processing Plant* (GB/T 27341). | 6.1.1 Provide the production and processing flow chart, hazard analysis work sheet and HACCP schedule of all products to be exported to China.  6.1.2 Provide sample tables of CCP monitoring records, correction records and verification records. | 1. Biological, physical and chemical hazards should be analyzed and effectively controlled in the HACCP program.  2. The production process flow should be reasonable to avoid cross contamination.  3. The setting of CCPs should be scientific and feasible, and corrective and verification measures should be appropriate. | □ Yes  □ No  □ N/A |  |
| 6.2 Temperature Control | | 1. Articles 8.2.2.1.4 and 8.2.2.1.6 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941).  2. Article 8.2.2.2.1 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941) (applicable to refrigerated aquatic products). | 6.2.1 Provide the thawing method, thawing time and temperature control requirements of raw materials (if applicable).  6.2.2 Provide temperature control requirements and temperature monitoring equipment for processing workshops and storage warehouses. (applicable to refrigerated aquatic products). | 1. Control the thawing time and temperature of raw materials.  2. Temperature control measures shall be in place in the processing workshop for refrigerated aquatic products, and the processed aquatic products shall be moved to the refrigerated environment as soon as possible. The refrigerating chamber shall be equipped with temperature indicators. | □ Yes  □ No  □ N/A |  |
| 6.3 Frozen Aquatic Products | | 1. Article 8.2.2.2.2 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 6.3.1 Provide the freezing method, time and freezing temperature control requirements of frozen aquatic products and their determination bases.  6.3.2 Provide cold treatment temperature and time of raw aquatic products. | 1. Based on the thickness, shape and production of aquatic products, the freezing time and temperature are determined to ensure that they pass the maximum ice crystal generation zone as soon as possible.  1. Raw aquatic products should go through sufficient cold treatment to kill parasites harmful to humans. Cryopreservation for 7 days at an ambient temperature below -20°C;  Frozen to solid state at an ambient temperature of -35°C or below and preserved for 15 hours at an ambient temperature of -35°C or below;  Frozen to solid state at an ambient temperature of -35°C or below and preserved for 24 hours at an ambient temperature of -20°C or below; | □ Yes  □ No  □ N/A |  |
| 6.4 Dried Aquatic Products (Where Applicable) | | 1. Article 8.2.2.2.3 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 6.4 Provide drying time and temperature, ambient humidity, water activity of finished products and packaging and storage methods of dried aquatic products. | 1. The water activity of dried products should be within a safe range. | □ Yes  □ No  □ N/A |  |
| 6.5 Salted Aquatic Products (Where Applicable) | | 1. Article 8.2.2.2.4 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 6.5 Provide the sugar/salt ratio of salted aquatic products. | 1. Proper salinity should be adopted in the production of salted products to prevent the reproduction of non-halophilic bacteria. | □ Yes  □ No  □ N/A |  |
| 6.6 Canned Aquatic Products (Where Applicable) | | 1. Article 8.2.2.2.5 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 6.6.1 Provide sterilization temperature and time requirements for canned aquatic products of different specifications, and the latest sterilization/temperature records.  6.6.2 Provide reports on heat penetration and distribution of sterilization containers for canned aquatic products of different specifications. | 1. Sufficient sterilization temperature and time shall be provided for canned aquatic products. | □ Yes  □ No |  |
| **7. Cleaning and Disinfection** | | | | | | |
| 7.1 Cleaning and Disinfection | | 1. Article 8.2.1 of the *General Hygienic Regulation for Food Production* (GB14881).  2. Article 8.2.1 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 7.1 Provide cleaning and disinfection measures, including cleaning and disinfection methods and frequency, and verification of cleaning and disinfection effects. | 1. Cleaning and disinfection measures should be able to eliminate cross contamination and meet hygiene requirements. | □ Yes  □ No |  |
| 7.2 Environmental Microbiological Monitoring | | 1. Articles 8.2.2.1.2 and 8.2.2.1.3 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 7.2 Provide a monitoring plan for product microorganisms in the environment and production process, including monitoring items, frequency, judgment criteria and corrective measures for positive results. | 1. The focus of monitoring should cover areas where microorganisms are easy to hide and breed.  2. Sampling points are set. Add necessary sampling points to the monitoring plan in case of major maintenance, construction activities or worse sanitary conditions.  3. Whether the implementation frequency of the environmental monitoring plan is adjusted in accordance with the inspection results and the severity of pollution risks.  4. Corrective measures for positive results. | □ Yes  □ No |  |
| **8. Control of Chemicals, Waste and Damage by Insects and Rats** | | | | | | |
| 8.1 Control of Chemicals | | 1. Article 8.3 of the *General Hygienic Regulation for Food Production* (GB14881-2013).  2. Article 8.3 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 8.1 Describe the requirements for the use and storage of chemicals in a brief manner. | 1. Prevent the chemicals used from polluting the products. | □ Yes  □ No  □ N/A |  |
| 8.2 Waste Management | | 1. Article 8.1.4 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 8.2.1 Provide pictures of identifications distinguishing edible product containers and waste storage containers in the workshop.  8.2.2 Describe the requirements of waste disposal procedures in a brief manner. | 1. Edible product containers and waste storage containers in the workshop shall be clearly marked and distinguished.  2. Waste should be stored separately and disposed of in time to avoid pollution to production. | □ Yes  □ No |  |
| 8.3 Control of Damage by Insects and Rats | | 1. Article 6.4 of the *General Hygienic Regulation for Food Production* (GB14881). | 8.3 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. | □ Yes  □ No |  |
| **9. Product Traceability** | | | | | | |
| 9 Traceability and Recall | | 1. Article 11 of the *General Hygienic Regulation for Food Production* (GB14881).  2. Article 11 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 9. Describe the product traceability procedure in a brief manner and take the batch number of a batch of finished products as an example to illustrate how to trace raw materials from finished products. | 1. Traceability procedures should be established to realize the two-way traceability of the whole chain from raw materials, production and processing processes to finished products. | □ Yes  □ No |  |
| **10. Personnel Management and Training** | | | | | | |
| 10.1 Personnel Health and Hygiene Management | | 1. Article 6.3 of the *General Hygienic Regulation for Food Production* (GB14881).  2. Article 6.3 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 10.1 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. | □ Yes  □ No |  |
| 10.2 Personnel Training | | 1. Article 12 of the *General Hygienic Regulation for Food Production* (GB14881).  2. Article 12 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941). | 10.2 Provide annual training plans, contents, assessments and records for employees. | 1. The training content should cover memorandums, agreements and protocols on inspection and quarantine of aquatic products exported to China, Chinese laws and standards, etc. | □ Yes  □ No |  |
| **11. Self-inspection and Self-control** | | | | | |  |
| 11. Finished Product Inspection | | 1. Article 9 of the *General Hygienic Regulation for Food Production* (GB14881).  2. Article 9 of the *Hygienic Regulation for Aquatic Products Production* (GB 20941).  3. *National Food Safety Standard - Fresh and Frozen Aquatic Products of Animal Origin* (GB 2733)  4. *National Food Safety Standard - Aquatic Products of Animal Origin* (GB 10136)  5. *National Food Safety Standard - Aquatic Flavouring* (GB 10133)  6. *National Food Safety Standard - Algae and Algae Product*s (GB 19643)  7. *National Food Safety Standard - Standards for Uses of Food Additives* (GB 2760)  8. *National Food Safety Standard - Maximum Levels of Mycotoxins in Foods* (GB 2761)  9. *National Food Safety Standard - Maximum Levels of Contaminants in Foods* [(GB 2762)](javascript:void(0);)  10. *National Food Safety Standard - Maximum Residue Limits for Pesticides in Food* (GB 2763)  *Limited Concentrations of Radioactive Materials in Foods* (GB 14882)  *National Food Safety Standard - Dried Sea Cucumber* (GB 31602) | 11.1 Provide items, indicators, methods and frequency of finished product inspection.  11.2 If the enterprise has its own laboratory, please submit the laboratory capability and qualification certificates; if the enterprise entrusts a third-party laboratory, please provide the qualification certificates of the entrusted laboratory. | 1. The items of finished product inspection meet the requirements of Chinese standards. | □ Yes  □ No |  |
| **12. Declaration** | | | | | | |
| 11.1 Corporate Declaration | | 1. Articles 6 and 7 of the Regulations on the Registration Administration of Overseas Manufacturers of Imported Food |  | Signature of legal person and company seal | □ Yes  □ No |  |
| 11.2 Confirmation by Competent Authority | | 1. Articles 6 and 7 of the Regulations on the Registration Administration of Overseas Manufacturers of Imported Food |  | Signature of principal and seal of competent authority | □ Yes  □ No |  |