

Annex 5-4-1

Conditions and Compliance Checklist for Registration of Overseas Manufacturers of Imported Aquatic Product

Registration number:

Enterprise's name:

Enterprise's address:

Date of filling out the form:

Instructions for filling out the form:

1. According to the "Regulations of the People's Republic of China on the Registration of Overseas Manufacturers of Imported Food" (General Administration of Customs Order No. 248), the sanitation conditions of overseas manufacturers of aquatic products applying for registration in China shall conform to the relevant provisions of Chinese laws, regulations, standards and norms and to the requirements of the Protocol on Inspection and Quarantine of Aquatic Product to be Exported to China. This form is provided for the overseas competent authorities of imported aquatic products to carry out official inspection on aquatic product

manufacturers according to the listed main conditions and basis and in accordance with the key points of inspection; meanwhile, the overseas manufacturers of aquatic products shall fill in and submit the supporting materials based on the listed main conditions and basis, and self-inspection should also be carried out according to the key points of the inspection for the self-assessment before the application for registration of enterprises.

2. Overseas competent authorities and overseas manufacturers of aquatic products should determine the conformity based on the actual situation of the inspection.

3. The submitted materials shall be filled out in Chinese or English, and the contents shall be true and complete. The annexes should be numbered, and the number and contents of the annexes shall correspond to the item number and contents in the column of "Filling-in Requirements and Supporting Materials". Besides, the directory of annexes to supporting materials should also be submitted.

4. "Aquatic products" refers to aquatic animal and plant products and their products made thereof edible for humans, including aquatic animal products and their products made such as jellyfish, molluscs, crustaceans, echinoderms, cephalopods, fish, amphibians, reptiles, aquatic mammals, as well as marine plant products and their products made such as algae, excluding living aquatic animals and propagating materials of aquatic animal and plant.

Item	Conditions and Basis	Filling-in Requirements and Supporting Materials	Key Points of Review and Audit	Conformity determination	Remarks
1. Basic information of the enterprise					
1. Basic information of the enterprise	<p>1. Article V, Article VI, Article VII, Article VIII of the "Regulations of the People's Republic of China on the Registration of Overseas Manufacturers of Imported Food" (General Administration of Customs Order No. 248)</p> <p>2. The "Measures of the People's Republic of China for the Administration of Import and Export Food Safety" (General Administration of Customs</p>	1.1 Fill in the basic information form for foreign producers of imported aquatic products	<p>1. Enterprises shall fill in the true basic information, which shall be in line with the information provided by the competent authority of exporting country and the situation of their actual production and processing.</p> <p>2. Aquatic products to be exported to China must fall within the</p>	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	

	<p>Order No. 249).</p> <p>3. Protocol on Inspection and Quarantine of Aquatic Products to Be Exported to China signed between the competent authority of the applicant state and the General Administration of Customs of China (GACC).</p>		<p>scope of products specified in the relevant agreement, protocol, memoranda and others on inspection and quarantine of aquatic products exported to China.</p> <p>3. Human resources (enterprises and official veterinarians) shall be able to meet the requirements of enterprise' s production and processing and official inspection supervision.</p> <p>4. Cooling and storage capacity should meet the</p>		
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			capacity of continuous production and storage of frozen / chilled aquatic products.		
2. Enterprise location and workshop layout					
2.1 Site selection and plant surroundings	<p>1. Articles 3.1 and 3.2 of the "National Food Safety Standards - General Hygiene Practice for Food Production" (GB14881).</p> <p>2. Articles 3.1 and 3.2 of the "Hygienic Practice for the Production of Aquatic Products" (GB 20941).</p>	<p>2.1.1 Provide the floor plan of plant and indicate clearly the names of different work areas.</p> <p>2.1.2 Provide pictures of the plant location and environment, indicating clearly the surrounding environment</p>	<p>1. Plant layout shall meet the needs of production and processing.</p> <p>2. No pollution sources around the plant.</p>	<p><input type="checkbox"/> Conform</p> <p><input type="checkbox"/> Does not conform</p>	<p>Remark supporting material:</p>

		information (urban, suburban, industrial, agricultural and residential areas).			
2.2 Workshop layout	1. Article 4.1 of the "National Food Safety Standards - General Hygienic Practice for Food Production" (GB14881). 2. Article 4.1 of the "Hygienic Practice for the Production of Aquatic Products" (GB 20941).	2.2 Provide the floor plan of workshop, labelling flow direction of personnel, products and water, processing flow and different cleaning areas.	1. The workshop layout should be reasonable to meet the production and processing requirements and avoid cross-contamination.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	Remark supporting material:
3. Facilities and equipment					
3.1 Production and processing equipment	1. Article 5.2.1 of the "National Food Safety Standards - General Hygiene Practice for Food Production" (GB14881).	3.1 Provide a list of major equipment and facilities, as well as design and processing	1. Enterprises shall be equipped with production equipment in line with its production	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	Remark supporting material:

	2. Article 5.2.1 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941).	capabilities.	capacity.		
3.2 Storage facilities	1. Article 10 of the "National Food Safety Standards - General Hygienic Practice for Food Production" (GB14881). 2. Article 10.2 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941).	3.2 If cold storage is used, please describe the temperature control requirements and monitoring methods. (If applicable).	1. Storage facilities can meet the temperature requirements of product storage.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	Remark supporting material:
4. Water/ice/steam					

<p>4.1 Production and processing of water/stea m/ice (if applicable)</p>	<p>1. "Standards for Drinking Water Quality" (GB 5749) 2. Article 5.1.1 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941). 3. Article 5.1.1 of the "National Food Safety Standards - General Hygiene Practice for Food Production" (GB14881).</p>	<p>4.1.1 Provide photos of self-provided water source or secondary water supply facilities, and indicate whether there are food protection measures such as special person in charge, locking, etc. (if applicable) 4.1.2 Provide monitoring plan of the water for production and of the ice / steam that is in direct contact with food (if applicable), including items,</p>	<p>1. The monitoring plan of production water should cover all water outlets in the plant. 2. Whether the items and methods are in line with the "Standards for Drinking Water Quality" (GB5749) requirements. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs and Regulation concerning water supply and water intended for human</p>	<p><input type="checkbox"/> Conform <input type="checkbox"/> Does not conform <input type="checkbox"/> Not applicable</p>	<p>Remark supporting material:</p>
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		<p>methods, frequency, records, test results of the bacteriological inspection and the latest 2 test reports.</p> <p>4.1.3 Provide the boiler additives used in the production of steam that is in direct contact with food and indicate whether it meets the requirements of food production and processing.</p>	<p>consumption.</p> <p>3. The secondary water supply facilities shall formulate and implement hygiene control procedures and has appropriate food protection measures.</p> <p>4. Boiler additives used in the production of steam that is in direct contact with food shall meet the requirements of food production and processing.</p>		
5. Raw and auxiliary materials and packaging materials					

<p>5.1 Acceptance of raw and auxiliary materials</p>	<p>1. Article 7 of the "National Food Safety Standards - General Hygienic Practice for Food Production" (GB14881). 2. Article 7 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941).</p>	<p>5.1 Provide measures for acceptance of raw materials and additives, including standards and methods for acceptance.</p>	<p>1. The acceptance standards of raw materials and additives meet the requirements of Chinese EU regulations and standards.</p>	<p><input type="checkbox"/> Conform <input type="checkbox"/> Does not conform</p>	<p>Remark supporting material:</p>
<p>5.2 Source of raw materials</p>	<p>1. Article 7.2 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941). 2. The raw materials of aquatic products made of non-muscle tissues such as viscera, egg, skin, fin,</p>	<p>5.2.1 If the raw material is the raw material of aquatic products with biological toxin or raw aquatic products, please provide the latest test report. (When applicable)</p>	<p>1. The raw materials of aquatic products which have their own biological toxins such as bivalves and puffer fish shall be tested for toxins and accepted and treated according to relevant regulations to ensure</p>	<p><input type="checkbox"/> Conform <input type="checkbox"/> Does not conform <input type="checkbox"/> Not applicable</p>	<p>Remark supporting material:</p>

	<p>scale, bone and shell of aquatic animals shall conform to the "National Food Safety Standard - Fresh or Frozen Aquatic Products of Animal Origin" (GB 2733).</p> <p>3. Raw materials of animal aquatic products shall conform to the "National Food Safety Standards - Fresh and Frozen Aquatic Products of Animal Origin" (GB 2733)</p> <p>4. Raw materials of algal products shall conform to the "National Food Safety Standards - Algae and their products" (GB 19643).</p>	<p>5.2.2 If a fishing vessel is used, provide official license documents of the fishing vessel's operation area, operation time and fishing species as well as fishing method descriptions. (When applicable)</p> <p>5.2.3 In case of raw materials from aquaculture, provide qualification certificate of the farm. (When applicable)</p>	<p>the safety of raw materials.</p> <p>2. The raw materials used shall conform to the requirements of relevant agreements, protocols, memoranda and others on inspection and quarantine of aquatic products exported to China.</p>		
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	<p>5. Table 1 of the "National Food Safety Standards - Limits of Pathogenic Bacteria in Food" (GB29921).</p> <p>6. Articles 3.6 and 3.7 of the "National Food Safety Standards - Animal Aquatic Products" (GB10136).</p>				
5.3 Raw materials of bivalve shellfish (when applicable)	<p>1. Article 7.2 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941).</p> <p>2. Table 1 of "National Food Safety Standards - Limits of Pathogenic Bacteria in Food" (GB29921).</p> <p>3. Articles 3.6 and 3.7 of</p>	<p>5.3.1 Provide a description of the sea area location where the raw material of shellfish comes from and the official license of the bivalve shellfish catcher.</p> <p>5.3.2 Provide purification treatment methods</p>	<p>1. Bivalve shellfish should come from officially permitted aquaculture or fishing waters and be purified when necessary. Farmers or fishermen of shellfish should have a license from the necessary official authority.</p> <p>2. Test shellfish raw</p>	<p><input type="checkbox"/> Conform</p> <p><input type="checkbox"/> Does not conform</p> <p><input type="checkbox"/> Not applicable</p>	<p>Remark supporting material:</p>

	the "National Food Safety Standards - Animal Aquatic Products" (GB10136- 2015).	for shellfish raw material. 5.3.3 Provide shellfish toxin monitoring measures for shellfish raw material.	materials regularly for shellfish toxins to verify the safety of raw materials.		
5.4 Food additives (when applicable)	1. Article 7.3 of the "National Food Safety Standards - General Hygiene Practice for Food Production" (GB14881). 2. Article 7.3 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941). 3. "National Food Safety Standards - Standard for	5.4 List of food additives used in production and processing (including the name, use, amount added, etc.).	1. Food additives used in production in line with China's EU' s regulations regarding the use of food additives.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform <input type="checkbox"/> Not applicable	Remark supporting material:

	Uses of Food Additives" (GB 2760).				
5.5 Packaging materials	<p>1. Article 8.5 of the "National Food Safety Standards - General Hygienic Practice for Food Production" (GB14881).</p> <p>2. Article 8.5 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941).</p> <p>3. Relevant bilateral inspection and quarantine agreements, memoranda and protocols.</p>	<p>5.5.1 Provide certification materials that the internal and external packaging materials are suitable for product packaging.</p> <p>5.5.2 Provide the label style of finished product to be exported to China.</p>	<p>1. Packaging materials do not affect the safety of food and product properties under specific storage and use conditions.</p> <p>2. Packaging markings should be consistent with the requirements of bilateral inspection and quarantine agreements, memoranda and protocol.</p>	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	Remark supporting material:
6 Production and processing control					
6.1 Establishme	1. Article 8.1 of the "National Food Safety	6.1.1 Provide the production and	1. HACCP plan should analyse and	<input type="checkbox"/> Conform <input type="checkbox"/> Does not	Remark supporting material:

<p>nt and operation of HACCP system</p>	<p>Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941). 2. "Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Production Enterprises" (GB/T 27341).</p>	<p>processing process flow chart, hazard analysis worksheet and HACCP planning sheet for all products to be exported to China. 6.1.2 Provide sample forms of CCP monitoring records, correction records, and verification records.</p>	<p>effectively control all biological, physical and chemical hazards. 2. The production process should be reasonable to avoid cross-contamination. 3. CCP points should be set scientifically and feasibly, and corrective and verification measures should be appropriate.</p>	<p>conform <input type="checkbox"/> Not applicable</p>	
<p>6.2 Temperature control</p>	<p>1. Articles 8.2.2.1.4 and 8.2.2.1.6 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941). 2. Article 8.2.2.2.1 of the "National Food Safety</p>	<p>6.2.1 Provide the method used to thaw raw materials, and requirements of thawing time and temperature control (if applicable).</p>	<p>1. Control the thawing time and temperature of raw materials. 2. There should be temperature control measures in the processing location of refrigerated aquatic</p>	<p><input type="checkbox"/> Conform <input type="checkbox"/> Does not conform <input type="checkbox"/> Not applicable</p>	<p>Remark supporting material:</p>

	Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941) (Frozen aquatic products are applicable).	6.2.2 Provide temperature control requirements and temperature monitoring equipment in processing location and storage. (Applicable to refrigerated aquatic products).	products. The processed aquatic products shall be moved to the refrigerated environment as soon as possible, and the refrigerated room should be equipped with temperature indicators.		
6.3 Frozen aquatic products	1. Article 8.2.2.2.2 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941).	6.3.1 Provide freezing methods, time and freezing temperature control requirements of frozen aquatic products and its determination	1. Determine the freezing time and temperature of aquatic products according to their thickness, shape and production to ensure that they pass through the	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform <input type="checkbox"/> Not applicable	Remark supporting material:

		<p>basis.</p> <p>6.3.2 In the case of raw aquatic products, provide cold processing temperature and time.</p>	<p>maximum ice crystal production zone as soon as possible.</p> <p>2. Raw aquatic products should undergo sufficient cold treatment to ensure the killing of parasites that are harmful to humans. Frozen storage for 7 days under -20°C (ambient temperatures).</p> <p>3. Freeze to solid at -35°C or below and store for 15 hours at -35°C or below.</p> <p>4. Freeze to solid at -35°C or below and store for 24 hours at -20°C or below.</p>		
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6.4 Dried aquatic products (when applicable)	1. Article 8.2.2.2.3 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941).	6.4 Provide the drying time, drying temperature, environmental humidity and finished product's water activity and packaging and storage methods of processing dry aquatic products.	1. It should be ensured that the water activity of the dry product is within the range deemed safe.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform <input type="checkbox"/> Not applicable	Remark supporting material:
6.5 Pickled aquatic products (when applicable)	1. Article 8.2.2.2.4 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941).	6.5 Provide sugar / salinity for pickled aquatic products.	1. The production of pickled products should use the appropriate salinity to prevent the propagation of non-halophilic bacteria.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform <input type="checkbox"/> Not applicable	Remark supporting material:
6.6 Canned aquatic products	1. Article 8.2.2.2.5 of the "National Food Safety Standards - Hygienic	6.6.1 Provide sterilization temperature and	1. Canned aquatic products should ensure enough	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	Remark supporting material:

(when applicable)	Practice for the Production of Aquatic Products" (GB 20941).	time requirements of different specifications of canned aquatic products, and the latest sterilization / temperature records. 6.6.2 Provide heat penetration and heat distribution reports for sterilization containers of different specifications of canned aquatic products.	sterilization temperature and time.		
7. Cleaning and disinfection					
7.1 Cleaning	1. Article 8.2.1 of the "National Food Safety	7.1 Provide cleaning and	1. Cleaning and disinfection measures	<input type="checkbox"/> Conform <input type="checkbox"/> Does not	Remark supporting material:

and disinfection	Standards - General Hygiene Practice for Food Production" (GB14881). 2. Article 8.2.1 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941).	disinfection measures, including methods and frequency of cleaning and disinfection, as well as validation of cleaning and disinfection effect.	should be able to eliminate cross-contamination and be in line with health requirements.	conform	
7.2 Environmen tal microbiolo gical monitoring	1. Articles 8.2.2.1.2 and 8.2.2.1.3 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941).	7.2 Provide product microorganism monitoring plan of environmental and production process, including monitoring items, frequency, determination criteria, and corrective measures for positive results.	1. The focus of monitoring should cover areas where microorganisms can easily hide and breed. 2. Sampling point setting. Add necessary sampling points to the monitoring plan in case of major maintenance, construction activities	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	Remark supporting material:

			<p>or poor sanitation.</p> <p>3. Whether to adjust the frequency of implementation of the environmental monitoring plan based on the test results and pollution risks severity.</p> <p>4. Corrective measures of positive results.</p>		
8. Control of chemicals, wastes, pests and rodents					
8.1 Control of chemicals	<p>1. Article 8.3 of the "National Food Safety Standards - General Hygienic Practice for Food Production" (GB14881-2013).</p> <p>2. Article 8.3 of the "Hygienic Practice for the</p>	8.1 Briefly describe the use and storage requirements for chemicals.	1. Prevent the used chemicals from contaminating the product.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform <input type="checkbox"/> Not applicable	Remark supporting material:

	Production of Aquatic Products" (GB 20941).				
8.2 Waste Management	1. Article 8.1.4 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB 20941).	8.2.1 Provide distinguishing identification pictures of edible product containers and waste storage containers in the workshop. 8.2.2 Briefly describe the requirements of waste disposal procedures.	1. The edible product containers, waste storage containers of the workshop should be clearly marked and distinguished. 2. Waste should be stored separately and disposed of timely to avoid pollution to production.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	Remark supporting material:
8.3 Control of pests and rodents	1. Article 6.4 of the "National Food Safety Standards - General Hygienic Practice for Food Production"	8.3 Provide pest control methods and distribution layout plan. If this is undertaken by	1. Shall avoid pests and rodents from affecting safety and health of the production.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	Remark supporting material:

	(GB14881)	third party, please provide qualification of the third party.			process and/or official controls.
9. Product traceability					
9 Traceability and recall of products	1. Article 11 of the "National Food Safety Standards - General Hygienic Practice for Food Production" (GB14881). 2. Article 11 of the "Hygienic Practice for the Production of Aquatic Products" (GB 20941).	9. Briefly describe the product traceability procedure and take the lot numbers of a batch of finished product as an example to explain how to trace finished product to raw material.	1. Traceability procedures should be established to achieve bidirectional traceability of the whole chain of raw materials, production and processing processes, as well as finished products.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	Remark supporting material:
10. Management and training of personnel					
10.1 Personnel health and hygiene	1. Article 6.3 of the "National Food Safety Standards - General Hygienic Practice for	10.1 Provide pre-employment health management and medical	1. The employees must have medical examination and be certified to be fit for	<input type="checkbox"/> Conform <input checked="" type="checkbox"/> Does not conform	Remark supporting material:

managem ent	Food Production" (GB14881). 2. Article 6.3 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB20941).	examination requirements for employees.	the work in food processing enterprise prior to employment. 2. Employees should take regular medical examination and the records shall be kept		
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10.2 Personnel training	<p>1. Article 12 of the "National Food Safety Standards - General Hygienic Practice for Food Production" (GB14881).</p> <p>2. Article 12 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB20941).</p>	10.2 Provide annual training plan, contents, assessment and records of employees.	1. The training should cover the memoranda, agreements and protocols on the inspection and quarantine of aquatic products exported to China, Chinese regulations and standards, etc.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	Remark supporting material:
11. Self-checking and self-control					
11.	1. Article 9 of the	11.1 Provide items,	1. The items of	<input type="checkbox"/> Conform	

<p>Inspection for finished product</p>	<p>"National Food Safety Standards - General Hygienic Practice for Food Production" (GB14881). 2. Article 9 of the "National Food Safety Standards - Hygienic Practice for the Production of Aquatic Products" (GB20941). 3. "National Food Safety Standards - Fresh and Frozen Animal Aquatic Products" (GB 2733). 4. "National Food Safety Standards - Animal Aquatic Products" (GB 10136). 5. "National Food Safety Standards - Aquatic Condiments" (GB 10133).</p>	<p>indicators, inspection methods and frequency of finished product inspection. 11.2 Enterprise has its own laboratory and shall submit certificate of its laboratory capacity and qualification; enterprise entrusts to third-party for the laboratory and shall provide entrusted laboratory qualifications.</p>	<p>finished product inspection meet the requirements of Chinese Chinese standards.</p>	<p><input type="checkbox"/> Does not conform</p>	
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	<p>6. "National Food Safety Standards - Algae and their products" (GB 19643).</p> <p>7. "National Food Safety Standards - Standard for Uses of Food Additives" (GB 2760).</p> <p>8. "National Food Safety Standards - Limits for Mycotoxins in Food" (GB 2761).</p> <p>9. "National Food Safety Standards - Limits for Contaminants in Food" (GB 2762).</p> <p>10. National Food Safety Standards - Maximum Residue Limits for Pesticides in Food (GB 2763).</p> <p>"National Food Safety</p>				
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	Standards - Standard for Limited Concentration of Radioactive Materials in Food" (GB 14882). "National Food Safety Standards - Dried Sea Cucumber" (GB 31602).				
12. Statement					
12.1 Enterprise Statement	1. Article VIII, Article IX of the "Regulations of the People's Republic of China on the Registration of Overseas Manufacturers of Imported Food".	12.1 Fill out the "Application for Registration of Overseas Manufacturers of Imported Aquatic Products".	It should be signed by legal representative and stamped with seal of the enterprise.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	
12.2 Confirmation from competent authority	1. Article VIII, Article IX of the "Regulations of the People's Republic of China on the Registration of Overseas Manufacturers of Imported Food".	12.2 Fill out the "Application for Registration of Overseas Manufacturers of Imported Aquatic	The signature and official stamp of the competent authority should be provided.	<input type="checkbox"/> Conform <input type="checkbox"/> Does not conform	

		Products".			
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Signed by enterprise:

(Signature of legal representative)

Stamp

Signed by competent authority –

(Signature of Norwegian Food Safety Authority)

Stamp