



# EU ASIA COOPERATION

on (PHYTO-) SANITARY (SPS) and  
FOOD SAFETY REGULATION



## COMPARATIVE ANALYSIS OF CHINESE RULES FOR FISHERY PRODUCTS

Overview of EU LAW versus  
CHINESE LAW concerning the  
export of fish and fishery products to  
the People's Republic of China

EuropeAid 139908/DH/SER/MULTI Contract: PI/2019/409-971/	EU-Asia Cooperation on (Phyto-) Sanitary (SPS) and Food Safety Regulation in China, India, Indonesia, Malaysia, Philippines, South Korea, Thailand, Vietnam
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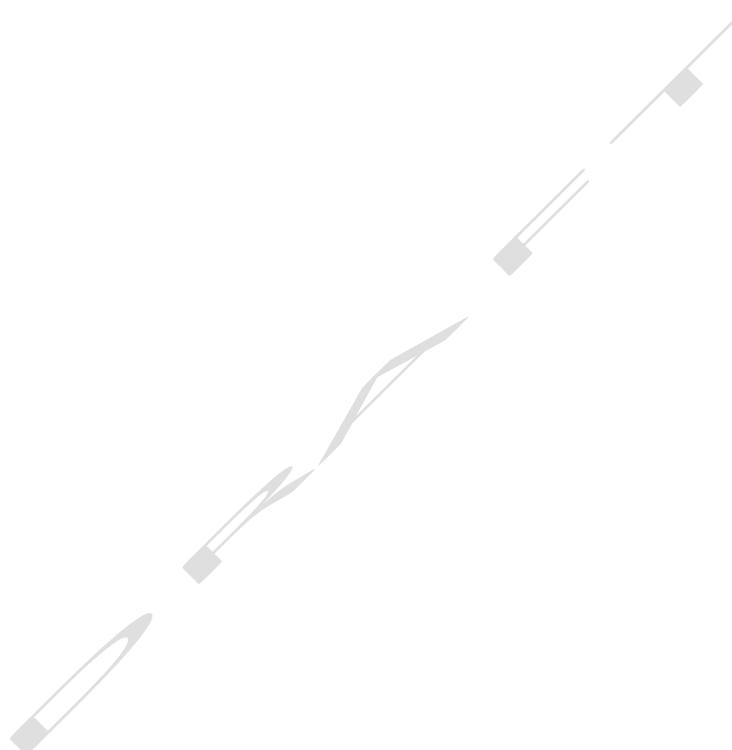
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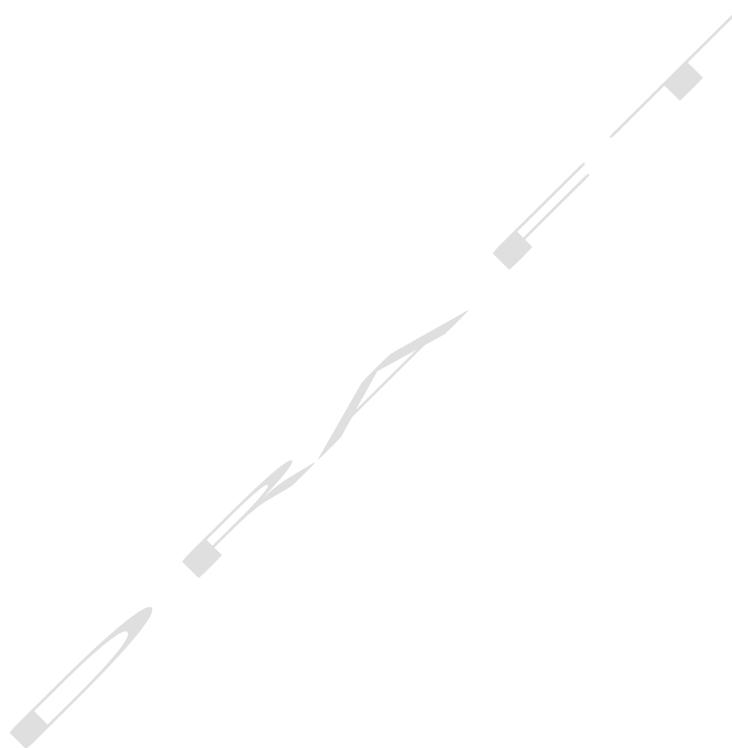
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## LIST OF ACRONYMS

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ALARA	As Low As Reasonably Achievable
EC	European Commission
EU	European Union
GACC	General Administration of Customs of the People's Republic of China
HACCP	Hasard Analysis Critical Control Point
OM	Overseas Manufacturers (of food imported to China)



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## EXECUTIVE SUMMARY

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### Project Background and Introduction

The objective of the study is to contribute to the facilitation of trade in fish and fishery products between the European Union and the People's Republic of China by a systematic comparison of applicable hygiene and food safety standards in the production of these products.

By identifying matching provisions – or any discrepancies in legal requirements – the work is hoped to contribute to the streamlining and simplification of approval and verification procedures in the trade of these products.

European Union (EU) Regulations pertinent to food hygiene in general and the hygiene of products of animal origin including fishery products are laid down in the General Food Law (Regulation (EC) No 178/2002), the Hygiene Legislation (Regulations (EC) No 852, No 853 and Regulation (EU)), Regulation 2017/625 on official controls and other official activities, and the respective implementing rules. In addition, various guidelines were published as Commission notices (such as Commission Notice 2016/C 278/01 and Commission Notice 2020/C 199/01) to assist food business operators with implementing the legislative requirements.

The implementing rules of China pertinent to food hygiene in general and hygiene of fishery products in particular are laid down in a range of National Food Safety Standards. In addition, Compliance Checklists were published by the General Customs Administration GACC for the Registration of Overseas Establishments intending to export to the People's Republic of China.

For the purpose of this study a detailed evaluation of 14 Chinese National Food Safety Standards applicable to fish and fishery products was made and compared to the requirements laid down in the legislation of the European Union, which are legally binding for all food business operators in the EU.

### Results and conclusions

In general, the EU food law and Chinese food safety standards pursue the same objective and identify very similar end points and limit values for biotic and abiotic contaminants with only minor differences. Process controls based on HACCP principles are mandatory for all food business operators and provide the core element of food safety controls in both regulatory systems.

Chinese national standards were sometimes found to be overlapping and frequently contain technical details, such as analytical methods that in the EU are rather described in Guides to Good Practice or other Guidance documents (such as the "Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs" produced by the European Commission in 2018).

The comparison of the microbiological analysis of fish products shows few differences between the Chinese and the European requirements. While in the EU separate criteria were defined for process controls and market surveillance (process hygiene criteria and food safety criteria), in China only one set of criteria exists. However, in both systems similar indicators of microbial contamination must be monitored and very similar limits must be observed. Also the list of environmental contaminants for which limit values were defined in fishery products or the water used in processing is not totally

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identical and specific National Standards exist for condiments, algae and sea urchins while in the EU these products fall under general rules applicable to fishery products. However, the discrepancies identified are considered minor and not relevant in practice as products sourced and processed in accordance with EU standards are expected to meet the criteria laid down in Chinese standards.

Some food additives mentioned in the Chinese National Standard are not approved in the EU while some EU approved additives are not mentioned in the Chinese National Standards. EU food business operators must ensure that only additives approved by Chinese Standards are used in products exported to China.

Overall, based on our analysis the conclusion is established that the objectives, aims and end points of EU and Chinese hygiene rules applicable to fishery products are largely identical. EU legislation, as implemented by all food business operators and enforced by Member States and the EU Commission is consistent with applicable Chinese Food Safety Standards. Adherence to EU legal requirements will ensure that fish and fishery products produced in the European Union fulfil the eligibility criteria of the People's Republic of China.

## List of Chinese National Food Safety Standards assessed:

National standard GB 14881-2013 – General hygiene practice for food production

National standard GB 4789.1-2016 – Food microbiological examination- general rules

National standard GB 29921-2013 – Limit of pathogens in food products

National standard GB/T 27341-2009 – Hazard Analysis and Critical Control Point (HACCP) System - General requirements for food processing plant

National standard GB 2762-2017 – Maximum levels of contaminants in foods

National standard GB 2763-2021 – Maximum residue limits for pesticides in food

National standard GB 2760-2014 – Uses of food additives

National standard GB 5749 - Drinking water quality

National standard GB 20941-2016 – Hygienic practice of aquatic products

National standard GB 10136-2015 - Aquatic products of animal origin

National standard GB 2733-2015 – Fresh, frozen aquatic products of animal origin

National standard GB 10133-2014 – Aquatic product condiments

National standard GB 31602-2015 – Dried sea cucumbers

National standard GB 19643-2016 – Algae and algae products

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## Tabulated comparison of main elements of Chinese and EU standards

Subject	Evaluation result
<b>Chinese Food Safety Standards applicable to all food products</b>	
<b>National standard 14881-2013</b> specifies basic requirements and management rules for locations, facilities and personnel of material purchasing, processing, packaging, storage and transportation in the process of food production.	In EU legislation the implementation of HACCP-based self-controls is mandatory for all food business operators (except primary producers), while in the National Standard GB 14881-2013 as well as in National Standard GB 12694-2016 (point 11.1.2) it is “encouraged” to be adopted (i.e. not mandatory). According to EU legislation inspection activities shall be done by both the food business operator and by the official food inspection agencies.
<b>National standard GB 4789.1-2016</b> defines the basic principles and requirements of microbiological testing of food.	The Chinese National Standard provides sampling methods of different kinds of foods such as pre-packaged food, liquid food, bulk food. The general rules are consistent with the requirements laid down in EU legislation.
<b>National standard 29921-2013</b> specifies limit values for specific microbial contaminants in food, including sampling and testing methods.	EU legislation defines food safety criteria that are applicable to products placed on the market and process hygiene criteria for the monitoring of food processing. In the Chinese National standard such a distinction is not made. Few differences were identified in the end points and testing methods (e.g. Chinese National Standards set limits for <i>Vibrio parahaemolyticus</i> , while in the EU <i>E.coli</i> is used as an indicator of faecal contamination; Chinese National Standard require testing for <i>Staphylococcus aureus</i> , while in the EU legislation coagulase positive <i>staphylococcae</i> are used as indicator) but overall the applicable food safety criteria are consistent.
<b>National standard GB/T 27341-2009 – Hazard Analysis and Critical Control Point (HACCP) System - General requirements for food processing plant</b> specifies the general requirements of HACCP for food processing (catering) plant, including the purchasing, processing,	EU legislation provides that all establishments carrying out any stage of processing and distribution of food shall operate under HACCP principles.

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packaging, storing and transporting of raw material and food packaging material.	
<b>National standard GB 2762-2017</b> sets limits for lead, cadmium, mercury, arsenic, tin, nickel, chromium, nitrite, nitrate, Benzo[a]pyrene, N-nitrosodimethylamine, polychlorinated biphenyl, 3-chloro-1, 2-propanediol in foods.	In the Chinese National Standard limit values are defined for contamination with arsenic and chromium in aquatic animals and their products while in EU legislation no limits are set. The ‘ALARA’ Principle applies (as low as reasonably achievable). Likewise, the Chinese National Standard defines limits for N-Nitrosodimethylamine in aquatic products (excluding canned aquatic products) and dried aquatic products while no such limits are laid down in EU legislation.  These discrepancies are considered formal rather than substantial and will not affect consumer risk.
<b>National standard GB 2763-2021</b> regulates 10,092 maximum residue limits of 564 pesticides (including 2,4-DB) in food. The standard applies to foods related to residue limits. The food categories and testing parts (Appendix A) are used to define the application scope of the pesticides’ maximum residue limits, which applies only to this standard. The list of pesticides that are exempted from developing MRL standards in food (Appendix B) is used to define scope of pesticides that do not need to have MRL developed.	According to the Chinese National standard, aquatic products must be tested for the presence of DDT and HCH, while no specific requirements are laid down in EU legislation because the environmental contamination is generally very low.  These discrepancies are not considered relevant and will not affect consumer risk.
<b>National standard GB 2760-2014</b> specifies the principles for application of food additives, allowed food additive varieties, scope of application, and maximum levels.	Some food additives mentioned in the Chinese National Standard are not approved in the EU while some EU approved additives are not mentioned in the Chinese National Standards.  <i>EU food business operators must ensure that only additives approved by Chinese Standards are used in products exported to China.</i>
<b>National standard GB 5749</b> applies to drinking water from all water supplies in urban and rural areas.	Chinese Standards and EU Legislation pursue the same objectives and limit values are largely identical. Under harmonized EU law there are fewer contaminants listed for obligatory monitoring by all Member States. However, all authorities must monitor potential hazards that might be relevant under local

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	conditions. Water used in processing of food products must be monitored and fulfil the quality criteria established.
<b>Chinese Food Safety Standards specifically applicable to fishery products</b>	
<b>National standard 20941-2016</b> specifies the basic requirements and management guidelines for sites, facilities and personnel for handling of raw materials, purchasing, accepting, processing, packaging, storage and transportation in the production process of aquatic products.	<p>In EU food hygiene legislation aquatic products are subdivided in wild caught fishery products and aquaculture products including bivalve molluscs.</p> <p>For bivalve molluscs, in EU legislation production areas and relaying areas are defined. General requirements are laid down in EU legislation (Regulation 853/2004), detailed procedures such as drying and pickling procedures (as mentioned in the Chinese national Standard) are laid down in guides to good practice developed by the sector in the form of national guides or EU wide community guides. In the Chinese national standard the suggested frequency for environmental microbial monitoring is fixed (every two weeks or every month to test for aerobic bacteria count and coliform bacteria) while in the EU the frequency of testing must be determined by the food business operator as part of the HACCP and prerequisite programs put in place in the food production establishment, which are controlled by competent authorities.</p> <p>Sampling plans, testing methods and criteria for microbial testing of fishery products (Salmonella, E; coli, staphylococci, , histamine) are laid down in EU legislation as process hygiene and food safety criteria for live bivalve molluscs, live echinoderms, tunicates and gastropods and for fishery products associated with a high amount of histidine and other fishery products (Annex I, Chapter 1 of Regulation (EC) No 2073/2004).</p>
<b>National standard GB 10136-2015</b> applies to aquatic products of animal origin and provides limit values for histamine, volatile nitrogen, peroxides, microorganisms and environmental contaminants.	EU limits for microbial contamination, parasites, histamine, environmental contaminants and food additives are provided in different pieces of legislation but values are consistent with Chinese standards.
<b>National standard GB 2733-2015</b> applies to fresh, frozen aquatic products of animal origin, including marine products and freshwater products. It provides organoleptic criteria and limit values for volatile nitrogen, histamine and shellfish toxins.	<p>EU limits are consistent with Chinese standards.</p> <p>Diarrhetic shellfish poison (DSP) is mentioned in the Chinese National Standard but not in the EU legislation, while amnesic shellfish poison (ASP),</p>

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	okadaic acid and dinophysistoxins, yessotoxins and azaspiracids are mentioned in the EU legislation and not in the Chinese National Standard. Prescribed analytical techniques for shellfish toxins differ but are considered to be of comparable sensitivity.
<b>National standard GB 10133-2014</b> applies to aquatic products condiments and provides organoleptic criteria as well as limit values for microbial and environmental contaminants and food additives.	EU criteria and limit values are provided in different pieces of legislation but are consistent with Chinese standards.
<b>National standard GB 31602-2015</b> applies to dried sea cucumbers. It defines organoleptic and quality criteria such as moisture or protein content and provides that Chinese standards related to residues and contaminants are applicable.	No specific legislation has been laid down in the EU concerning sea cucumbers. However, all fishery products must comply with general organoleptic requirements and with applicable criteria related to biotic and abiotic contamination. Applicable standards related to protein or moisture content must be fulfilled but have no relevance for food safety.
<b>National standard GB 19643-2016</b> is applicable to the edible algae and algae products. It defines organoleptic criteria and provides that Chinese standards related to residues and contaminants are applicable. In addition the standard defines limit values for coliform microbial contamination in instant (dried) algae products.	No specific legislation has been laid down in the EU concerning algae. However, all fishery products must comply with general organoleptic requirements and with applicable criteria related to biotic and abiotic contamination. The Chinese National Standard sets microbial limits for instant algae (limited to instant algae dry products). Commission Regulation (EC) No 2073/2005, foresees no specific microbiological criteria applicable to seaweeds or algae. It appears unlikely that these products are exported from the EU to China.

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## 1 DETAILED ANALYSIS

### 1.1 General requirements for all food products

#### 1.1.1 National standard GB 14881-2013 – General hygiene practice for food production

Chinese National standard GB 14881	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
<p><b>Scope</b> This standard specifies basic requirements and management rules for locations, facilities and personnel of material purchasing, processing, packaging, storage and transportation in the process of food production. This standard applies to production of various kinds of food.</p>	<p><b>Article 1<sup>1</sup> Scope</b> This Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles: (a) primary responsibility for food safety rests with the food business operator; (b) it is necessary to ensure food safety throughout the food chain, starting with primary production; (c) it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain; (d) general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility; <sup>1</sup> <b>unless specified otherwise, Articles in this table refer to Regulation 852/2004</b></p>	
	<p><b>Article 1 Scope (cont.)</b> (e) guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance</p>	

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Chinese National standard GB 14881	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
	with food hygiene rules and with the application of the HACCP principles; (f) it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment; (g) it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard. This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.	
<b>2. Terms and Definitions</b> Various terms are defined such as: Contamination, monitoring, contact surface, food processing location, etc.	<b>Article 2 Definitions</b> Various terms are defined such as: Food hygiene, establishment, contamination, processing, processed products, unprocessed products, etc.	
<b>3. Site selection and plant surroundings</b> 3.1.1 The areas that have large contamination on foods shall not be selected for the plant. If a place has obviously adverse effect which can't be improved by taking measures on food safety and edibility, the plant shall not be built there. 3.1.2 Sites where hazardous waste, dust, harmful gas, radioactive substance and other diffusive contaminants cannot be eliminated effectively shall not be selected for the plant. 3.1.3 Regions where flood disaster can usually occur should not be selected for the plant. If it's difficult to keep it away, necessary precaution measures shall be taken.	<b>Regulation (EC) No 853/2004, Article 4</b> states that establishments handling products of animal origin shall not operate unless the competent authority has approved them following an on-site visit.  <b>Article 4, 1.</b> Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I. Annex I, II, 3 a) states:	<b>Guidance document Commission Notice 2016/C 278/01, Annex I, Examples of PRPs 2.1 Infrastructure:</b> a) When assessing the risk from the location and surrounding areas, the proximity of potential sources of contamination, water supply, wastewater removal, power supply, access for transport, climate, possible flooding, ... should be taken into account.  <i>In the EU Guidance Document on the implementation of certain provisions of</i>

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Chinese National standard GB 14881	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
<p>3.1.4 There should not be potential locations with a large number of insect pest breeding around the plant. If it's difficult to keep it away, necessary precaution measures shall be taken.</p> <p>3.2 Plant surroundings</p> <p>3.2.1 Potential contamination risk of the surroundings to food production shall be considered and appropriate measures shall be taken to reduce it to the minimum level.</p> <p>3.2.2 The plant shall be arranged reasonably; each functional area shall be obviously divided with proper separation or partition measures to prevent cross contamination.</p> <p>3.2.3 The roads in the plant shall be paved with concrete, tar or other hard materials. Necessary measures shall be taken for vacant land, e.g. cement, floor tile or lawn shall be paved to maintain clean surrounding and prevent raising dust and accumulated water under normal weather.</p> <p>3.2.4 Plant greening shall be kept an appropriate distance from the production workshop, and vegetation shall be maintained on regular basis to prevent insect pest from breeding.</p> <p>3.2.5 The plant shall be equipped with proper drainage system.</p> <p>3.2.6 Living area such as dormitory, canteen or recreation facilities of employees shall be kept an appropriate distance or partitioned from the production areas.</p>	<p>a) measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste;</p> <p><b>Article 4, 2.</b> Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies (see Article 4.1.) shall comply with the general hygiene requirements laid down in Annex II. Chapter I of Annex II states: Food premises are to be kept clean and maintained in good repair and condition.</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I, 8 states: Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.</p>	<p><i>Regulation (EC) No 852/2004 on the hygiene of foodstuffs (Brussels 2018) it is stated that: "Food premises" is not limited to the rooms where foodstuffs are handled or processed. It includes, additionally, and where applicable, the immediately surrounding area within the perimeter of the food business operation site.</i></p> <p><i>The requirements for approval are explained in detail in the EU Guidance Document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin (SANCO/10098/2009 Rev. 3 (POOL/G4/2009/10098/10098R3-EN.doc of 2018).</i></p>

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<b>Chinese National standard GB 14881</b>	<b>EU Regulation (EC) No 852/2004</b>	<b>Implementing rules, other remarks</b>
<p><b>4. Plant and workshop</b></p> <p><b>4.1 Design and layout</b></p> <p>4.1.1 Internal design and layout of plant and workshop shall meet the operation requirements on the food hygiene to avoid cross contamination during the process of food production.</p> <p>4.1.2 Design of plant and workshop shall be arranged reasonably according to production process to prevent and reduce the risk of contamination on products.</p> <p>4.1.3 Operating areas in the plant and workshop shall be divided reasonably based on product characteristics, production process, production characteristics and the requirements of cleanliness in production process and shall be effectively separated or partitioned. For example, operating areas are generally divided into clean operating area, quasi-clean operating area and general operating area, or clean operating area and general operating area, etc. General operating area shall be partitioned from other operating areas.</p> <p>4.1.4 Inspection room in the plant shall be partitioned from the production area.</p> <p>4.1.5 Area and space of the plant shall correspond to the productivity so that it can be convenient for equipment arrangement, cleaning and disinfection, material storage and personnel operation.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I, 2. states: The layout, design, construction and size of food premises are to:</p> <p>(a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise airborne contamination, and provide adequate working space to allow for the hygienic performance of all operations;</p> <p>(b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;</p> <p>(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control; and</p> <p>(d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.</p>	

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Chinese National standard GB 14881	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
<p><b>4.2 Internal structure and materials of the building</b></p> <p>4.2.1 Internal structure The building's internal structure shall be easy for maintenance, cleaning or disinfection and shall be constructed with appropriate durable materials.</p> <p>4.2.2 Ceiling</p> <p>4.2.1.1 Ceiling shall be constructed with nontoxic, odorless materials to meet the production demand and easy for observing cleaning condition. If it is directly coated on the inner-layer of the roof as ceiling, nontoxic, odorless and mold-proof coatings which are difficult for shedding and easy for cleaning shall be used.</p> <p>4.2.1.2 Ceiling shall be easy for cleaning and disinfection, but difficult for condensed water to vertically drip so that insects and mold can be prevented from breeding.</p> <p>4.2.1.3 Pipelines of accessories for steam, water and electricity shall not be arranged above the exposed food. If it's unavoidable, device or measure to prevent dust from scattering and water drop from dripping shall be provided.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter II, 1</p> <p>In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations.</p> <p>(c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mold and the shedding of particles;</p>	<p><i>For establishments producing food of animal origin additional requirements for internal structure and materials of the building are specified in more detail in <b>Regulation (EC) No 853/2004</b>.</i></p>
<p>4.2.3 Wall</p> <p>4.2.3.1 Wall surface and partition shall be constructed with nontoxic, odorless and anti-seepage materials. Wall surface within the range of operation height shall be smooth, difficult for accumulating dirt and easy for cleaning. If coatings are necessary, they shall</p>	<p>(b) wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business</p>	

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<p>be nontoxic, odorless, mold-proof, difficult for shedding and easy for cleaning.</p> <p>4.2.3.2 Wall, partition and ground junctions shall be reasonable in structure, easy for cleaning and effectively avoid the accumulation of dirt, for example, the arrangement of smooth and accessible surfaces.</p>	<p>operators can satisfy the competent authority that other materials used are appropriate;</p>	
<p>4.2.4 Doors and windows</p> <p>4.2.4.1 Doors and windows shall be closed firmly. Door surface shall be smooth, adsorption-proof, anti-seepage and easy for cleaning and disinfection. They shall be made of water-proof, solid, and non-deformable materials.</p> <p>4.2.4.2 Doors of clean operating area, quasi-cleaning operation area and other areas shall be able to timely be shut down.</p> <p>4.2.4.3 Window glass shall be made of breakage-proof materials. If simple glass is used, necessary measures shall be taken to prevent contamination on materials, packaging materials and foods after glass breakage.</p> <p>4.2.4.4 If windows are arranged with sills, their structure shall be able to avoid dust accumulation and be easy for cleaning. Windows able to open shall be equipped with insect pest prevention window screen which is easy for cleaning.</p>	<p>(d) windows and other openings are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;</p> <p>(e) doors are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and nonabsorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate;</p>	
<p>4.2.5 Ground</p> <p>4.2.5.1 Ground shall be made of nontoxic, odorless, anti-seepage and corrosion-</p>	<p>(a) floor surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require</p>	<p><i>More detailed requirements on this subject (ground) are mentioned in the Guidance</i></p>

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resistant materials. The ground structure shall contribute to sewage discharge and cleaning. 4.2.5.2 Ground shall be flat, anti-skid, crack-free and easy for cleaning and disinfection and shall be provided with appropriate measures to prevent accumulated water.	the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;	<i>document Commission Notice 2016/C 278/01, Annex I, 2.3:</i> e) The presence of an indoor pool of water should be immediately addressed.
<b>5 Facilities and Equipment</b> <b>5.1 Facilities</b> 5.1.1 Water supply facilities 5.1.1.1 Water supply facilities shall ensure that the quality, pressure and amount of water meet the production requirements. 5.1.1.2 The quality of food processing water shall meet the requirements of GB 5749. For food with special requirements of processing water quality, corresponding requirements shall be met. The quality of food production water such as indirect cooling water and boiler water shall meet the production requirements. 5.1.1.3 Food processing water and other water such as indirect cooling water, sewage or waste water with no contact with food shall be transported with completely separated pipelines to prevent cross contamination. Each pipeline system shall be marked explicitly for distinction. 5.1.1.4 Self-provided water source and water supply facilities shall meet related requirements. Products used in water supply facilities involving hygienic security of drinking water shall also meet relevant national requirements.	<b>Regulation (EC) No 852/2004</b> , Annex II, Chapter VII: 1. (a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated; 2. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with, or allow reflux into, potable water systems. 3. Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form. 4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination. 5. Steam used directly in contact with food is not to contain any substance that presents a	<i>Potable water, clean seawater and clean water are defined in Regulation (EC) No 852/2004, Article 2.</i> (Article 2, 1, (g) 'potable water' means water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption).

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<p>5.1.2 Drainage facilities</p> <p>5.1.2.1 Drainage system shall be designed and constructed to ensure unblocked drainage and convenient cleaning and maintenance. It shall be adapted to the demand of food production and ensure that food, production and clean water be free from contamination.</p> <p>5.1.2.2 The inlet of drainage system shall be installed with a device such as a floor drain with water seal to prevent solid waste from entering and discharged air from emitting.</p> <p>5.1.2.3 Outlet of drainage system shall be provided with appropriate measures to lower the risk of insect attack.</p> <p>5.1.2.4 Indoor drainage shall flow from areas with high cleanliness to those with low cleanliness and shall be designed to prevent backflow.</p> <p>5.1.2.5 Sewage shall be disposed of properly before discharge on order to meet relevant national requirements on sewage discharge.</p>	<p>hazard to health or is likely to contaminate the food.</p> <p>6. Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I, 8: Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.</p>	
<p>5.1.3 Cleaning and disinfection facilities</p> <p>Sufficient specialized cleaning facilities for food, tools and instruments and equipment shall be provided; where necessary,</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I, 10: Cleaning agents and disinfectants are not to be stored in areas where food is handled.</p>	

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appropriate disinfection facilities shall be provided. Measures shall be taken to avoid cross contamination caused by tools and instruments for cleaning and disinfection.	<b>Regulation (EC) No 852/2004</b> , Annex II, Chapter II, 2: Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.	
5.1.4 Waste storage facilities Specialized facilities for storing waste which are reasonably designed, anti-seepage and easy for cleaning shall be provided. Facilities and containers for storing waste in the workshop shall be marked clearly. Where necessary, facilities for storing waste temporarily shall be arranged in appropriate site and waste shall be stored in classes according to characteristics.	<b>Regulation (EC) No 852/2004</b> , Annex II, Chapter VI: 1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation. 2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect. 3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests. 4. All waste is to be eliminated in a hygienic and environmentally friendly way in	

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	accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.	
<p>5.1.5 Personal hygienic facilities</p> <p>5.1.5.1 Changing room shall be arranged at the entrance of production location or production workshop. Where necessary, changing room may be arranged at the entrance of the specific operating area as needed. The changing room shall be designed to ensure that work clothes, personal clothes and other articles can be kept apart.</p> <p>5.1.5.2 Facilities for changing shoes (putting on shoe covers) or disinfection facilities for work shoes or boots shall be arranged as needed at the entrance and necessary places of the production workshop. If disinfection facilities for work shoes or boots are needed, their specification and size shall meet the requirements of disinfection. 5.1.5.3 Restroom shall be arranged as needed. Its structure, facilities and internal materials shall be easy to keep clean. Facilities for washing hand shall be arranged at proper place in the rest room. The restroom shall not be directly connected with areas for food production, packaging or storage.</p> <p>5.1.5.4 Facilities for washing and drying hand and disinfection shall be arranged at the entrance of clean operating area. If necessary, facilities for washing hand and (or) disinfection shall be arranged in the operating area. For</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I, 9. Where necessary, adequate changing facilities for personnel are to be provided.</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter VIII, Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I, 3. An adequate number of flush lavatories are to be available and connected to an effective</p>	<p><i>More detailed requirements on this subject (changing room) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.1:</b></i></p> <p>g) The specific clothes changing room(s) should be clean and ordered, not used as a refectory or a smoking room, and should facilitate a separation between normal clothing, clean work clothing and used work clothing.</p>

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<p>the faucets that are matched with disinfection facilities, their switches shall be non-manual.</p> <p>5.1.5.5 Quantity of the faucets for hand washing facilities shall be matched with the number of food processing personnel of the same shift. Where necessary, mixer of cold and hot water shall be arranged. Wash basins shall be made of smooth, water-proof and easy-to-clean materials and shall be designed and constructed to be easy for cleaning and disinfection. Simple and clear hand washing method shall be marked at visible position near the hand washing facilities.</p> <p>5.1.5.6 In accordance with the cleanliness of food processing personnel, where necessary, facilities such as air shower and shower room can be arranged.</p>	<p>drainage system. Lavatories are not to open directly into rooms in which food is handled.</p> <p>4. An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.</p> <p>Regulation 853/2004, Annex III, Section 1, Chapter 2 provides: Slaughterhouses must: ...</p> <ul style="list-style-type: none"> <li>• They must have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.</li> <li>• The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.</li> </ul>	
<p>5.1.6 Ventilation facilities</p> <p>5.1.6.1 Appropriate natural ventilation or artificial ventilation measures shall be taken; where necessary, natural ventilation or mechanical facilities shall be made to effectively control temperature and humidity of production environment. For ventilation facilities, air shall not flow from operating areas with low requirements on cleanliness to those with high requirements on cleanliness.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I,</p> <p>5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.</p>	<p><i>More detailed requirements on this subject (ventilation) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.8:</b></i></p> <p>d) Ventilation systems are kept clean, so that they do not become a source of contamination. For high risk/care areas requiring air control, the implementation of positive air pressure systems and appropriate air filtering systems should be considered.</p>

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<p>5.1.6.2 Air inlet position shall be arranged reasonably, and contamination source such as air inlet, air outlet and device for storing outdoor garbage shall be kept an appropriate distance and angle. Air inlet and outlet shall be provided with facilities such as mesh enclosure to prevent insect pest from intruding. Ventilation facilities shall be easy for cleaning, maintenance or replacement.</p> <p>5.1.6.3 If filtration and purification treatment for air is needed in the production process, air filtration device shall be added and cleaned on regular basis.</p> <p>5.1.6.4 According to production requirements, where necessary, de-dusting facilities shall be installed.</p>	<p>6. Sanitary conveniences are to have adequate natural or mechanical ventilation</p>	
<p>5.1.7 Lighting facilities</p> <p>5.1.7.1 Sufficient natural lighting or artificial lighting shall be provided in the plant. Luster and luminance shall meet production and operation requirements. Light source shall make it possible that food takes on its actual color.</p> <p>5.1.7.2 If lighting facilities are necessary to be installed above the exposed food and materials, safe lighting facilities shall be adopted or protection measures shall be taken.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I,</p> <p>7. Food premises are to have adequate natural and/or artificial lighting.</p>	<p><i>More detailed requirements on this subject (lighting) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.1:</b></i></p> <p>e) There should be sufficient lighting in all areas, with special attention paid to provision of suitable lighting to food preparation and inspection areas. Lighting should be easy to clean, with protective covers to prevent contamination of food in the event of lights breaking.</p>
<p>5.1.8 Storage facilities</p> <p>5.1.8.1 Storage facilities corresponding to quantity, storage requirements of products shall be provided.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter IX,</p> <p>2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful</p>	

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<p>5.1.8.2 Warehouse shall be made of nontoxic and solid materials; warehouse ground shall be flat and convenient for ventilation. Warehouse shall be designed to be easy for maintenance and cleaning to prevent insect pest from hiding and shall be equipped with device for preventing insect pest from intruding.</p> <p>5.1.8.3 Materials, semi-finished products, finished products and packaging materials shall be arranged with different storage sites or placed in different areas based on different properties and shall be marked explicitly to prevent cross contamination. Where necessary, warehouse shall be provided with control facilities of temperature and humidity.</p> <p>5.1.8.4 Storing articles shall be kept a proper distance from wall and ground to contribute to ventilation and articles handling.</p> <p>5.1.8.5 Detergent, disinfectant, pesticide, lubricant or fuel shall be packaged safely and marked explicitly and shall be kept apart from materials, semi-finished products, finished products and packaging materials.</p>	<p>deterioration and protect them from contamination.</p> <p>3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter X,</p> <p>1. Material used for wrapping and packaging are not to be a source of contamination.</p> <p>2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.</p> <p>3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products.</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I</p> <p>10. Cleaning agents and disinfectants are not to be stored in areas where food is handled.</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter II</p> <p>2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.</p>	

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<p>5.1.9 Temperature control facilities</p> <p>5.1.9.1 Appropriate heating, cooling and freezing facilities and facilities for monitoring temperature shall be equipped in accordance with the characteristics of food production.</p> <p>5.1.9.2 According to production requirements, facilities for controlling room temperature may be arranged.</p>	<p><b>Regulation (EC) No 852/2004, Article 4</b></p> <p>3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:</p> <p>(c) compliance with temperature control requirements for foodstuffs;</p> <p>(d) maintenance of the cold chain;</p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter I</b></p> <p>2, (d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.</p>	
<p>5.2 Equipment</p> <p>5.2.1 Production equipment</p> <p>5.2.1.1 General requirements</p> <p>Production equipment corresponding to productivity shall be provided and kept in order according to process flow to avoid cross contamination.</p> <p>5.2.1.2 Materials</p> <p>5.2.1.2.1 Equipment and instruments contacting with materials, semi-finished products and finished products shall be made of nontoxic, odorless, corrosion-resistant materials which are difficult for shedding and shall be easy for cleaning and maintenance.</p> <p>5.2.1.2.2 Surface of equipment and tools and instruments contacting with food shall be made of smooth, nonabsorbent materials</p>	<p><b>Regulation (EC) No 852/2004, Annex II, Chapter V</b></p> <p>1. All articles, fittings and equipment with which food comes into contact are to:</p> <p>(a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;</p> <p>(b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;</p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter II</b></p> <p>1. In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including</p>	

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easy for cleaning, curing and disinfection, and will not react with food, detergent and disinfectant under normal production and shall be kept in perfect condition	rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations. In particular: (f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials... 2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.	
5.2.1.3 Design 5.2.1.3.1 All production equipment shall make it possible in design and structure to prevent parts, metal chip, lubricating oil or other contamination factors being mixed into food and shall be easy for cleaning, disinfection, inspection and maintenance. 5.2.1.3.2 Equipment shall be fixed on the wall or floor without any gap or a sufficient distance shall be remained between the equipment and ground or wall during the installation to be convenient for cleaning and maintenance.	<b>Regulation (EC) No 852/2004</b> , Annex II, Chapter I 2. The layout, design, construction, siting and size of food premises are to: (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise airborne contamination, and provide adequate working space to allow for the hygienic performance of all operations; (b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;	<i>More detailed requirements on this subject (equipment) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.1:</b></i>

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	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter V:</p> <p>1. All articles, fittings and equipment with which food comes into contact are to:</p> <p>(b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;</p>	<p>k) Attention should be paid to the different possibilities whereby the use of equipment can result in (cross-) contamination of food:</p> <p>i. Prevention of contamination of the equipment by the environment e.g. condensation dripping from ceilings;</p> <p>ii. Prevention of contamination within the food handling equipment e.g. accumulation of food residues in slicing devices;</p> <p>iii. Prevention of contamination by raw materials: separate equipment (or cleaning and disinfection between use) for raw products and cooked products (chopping boards, knives, dishes, ...).</p> <p>and <b>Annex I, 2.10:</b></p> <p>d) Storage conditions at the establishment itself should take into account any instructions provided by the supplier, ‘first in, first out’ or ‘first expire, first out’ principles, accessibility for inspection from all sides (e.g. not placed directly on the ground, against walls, ...).</p>
<p>5.2.2 Monitoring equipment</p> <p>The equipment used for monitoring, controlling and recording such as pressure gauge, thermometer and recorder shall be calibrated and maintained on regular basis.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I</p> <p>2, (d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter V</p>	<p><i>More detailed requirements on this subject (calibration) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.4 Technical maintenance and calibration:</b></i></p> <p>c) Calibration of monitoring devices (e.g. weighing scales, thermometers, flow meters) is of importance in controlling food safety and hygiene.</p>

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	2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation’s objectives.	
5.2.3 Equipment maintenance and repair Equipment maintenance and repair system shall be established to enhance the routine maintenance and curing of equipment. The equipment shall be inspected on regular basis and the result shall be recorded timely.	<b>Regulation (EC) No 852/2004</b> , Annex II, Chapter V, Equipment requirements: 1. All articles, fittings and equipment with which food comes into contact are to: ...(b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;	Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRPs, 2.4 Technical maintenance and calibration:</b> a) The maintenance plan should be considered with a technical specialist. The plan should include ‘emergency’ procedures when equipment is defective and instructions for preventive replacement of seals, gaskets, ... b) Attention should be paid to hygiene during maintenance operations and to proper operation of equipment e.g. avoidance of overloading or exceeding the equipment’s capacity, leading to cracks, (too) hot food in cooling systems preventing a quick cooling, too low (re)heating capacity for the amount of food put in warming tables of food service establishments, ...
<b>Hygiene Management</b> <b>6.1 Hygiene management system</b> 6.1.1 Hygiene management system for food processing personnel, food production and corresponding assessment standard shall be established. Post responsibilities shall be determined to carry out post responsibility system. 6.1.2 Monitoring system for key control link significant to ensure food safety shall be	<b>Regulation (EC) No 852/2004, Article 4</b> 1. Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I 2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the	

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<p>issued according to the characteristics of food and hygienic requirements in the production and storage process to be implemented well and inspected periodically. If any problem is found, it shall be corrected at once.</p> <p>6.1.3 Hygienic monitoring system for production environment, food processing personnel, equipment and facilities shall be established to determine the range, object and frequency of internal monitoring. The monitoring results shall be recorded and filed, and executive condition and effect shall be inspected periodically so that any problem can be corrected at once if it's found.</p> <p>6.1.4 Cleaning and disinfection system and management system for cleaning and disinfection instruments shall be built up. Equipment and tools and instruments before and after cleaning and disinfection shall be kept apart and safely kept to avoid cross-contamination.</p>	<p>general hygiene requirements laid down in Annex II...</p> <p>3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:</p> <p>(a) compliance with microbiological criteria for foodstuffs;</p> <p>(b) procedures necessary to meet targets set to achieve the objectives of this Regulation;</p> <p>(c) compliance with temperature control requirements for foodstuffs;</p> <p>(d) maintenance of the cold chain;</p> <p>(e) sampling and analysis.</p> <p>6. Food business operators may use the guides provided for in Articles 7, 8 and 9 as an aid to compliance with their obligations under this Regulation.</p> <p><b>Regulation (EC) No 852/2004, Article 5</b></p> <p>1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</p> <p>2. The HACCP principles referred to in paragraph 1 consist of the following:</p> <p>(a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;</p> <p>(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;</p> <p>(c) establishing critical limits at critical control points which separate acceptability from</p>	<p><i>Many guides to good practice have been developed both as Community guides as well as National guides by each Member State. These have been developed for all sectors (for example for monitoring of bivalve mollusc production and relaying areas, for self-checking in the fish sector, for retail, for wholesale markets, etc.)</i></p> <p><i>In these guides requirements are explained in detail to enable application in that sector using simplified language and examples.</i></p>

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	<p>unacceptability for the prevention, elimination or reduction of identified hazards;</p> <p>(d) establishing and implementing effective monitoring procedures at critical control points;</p> <p>(e) establishing corrective actions when monitoring indicates that a critical control point is not under control; 4</p> <p>(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively;</p> <p>and</p> <p>(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).</p> <p>When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.</p> <p><b>See also</b> <i>EU requirements equivalent to points 5.2.1.3, 5.2.2, 5.2.3 and in addition:</i>  <b>Regulation (EC) No 852/2004</b>, Annex II, Chapter II</p> <p>2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials,</p>	

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	be easy to clean and have an adequate supply of hot and cold water.	
<p><b>6.2 Hygiene management of plant and facilities</b></p> <p>6.2.1 Facilities in the plant shall be kept clean and repaired or renewed timely in case of any problem. If there is any damage of plant ground, roof, ceiling and wall, it shall be repaired timely.</p> <p>6.2.2 Equipment and tools and instruments for production, packaging and storage, pipeline for production, and exposed food contact surface shall be cleaned and disinfected on regular basis.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I</p> <p>1. Food premises are to be kept clean and maintained in good repair and condition.</p> <p>2. The layout, design, construction, siting and size of food premises are to:</p> <p>(a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter V</p> <p>1. All articles, fittings and equipment with which food comes into contact are to:</p> <p>(a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;</p> <p>(b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;</p>	
<p><b>6.3 Health management and hygienic requirement for food processing personnel</b></p> <p>6.3.1 Health management for food processing personnel</p> <p>6.3.1.1 Health management system for food processing personnel shall be established and implemented.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter VIII</p> <p>1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.</p> <p>2. No person suffering from, or being a carrier of a disease likely to be transmitted through</p>	<p><i>More detailed requirements on this subject (personnel, health status) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.9:</b></i></p> <p>a) Personnel should be aware of hazards from gastro-intestinal infections, hepatitis and wounds with appropriate exclusion from food handling or suitable protection; relevant health</p>

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<p>6.3.1.2 Personnel involved in food processing shall take an annual physical examination and obtain a health certificate. They shall accept hygienic training before taking posts.</p> <p>6.3.1.3 Food processing personnel who suffer from infectious disease of digestive tract such as dysentery, typhoid, viral hepatitis A and viral hepatitis E, diseases affecting food safety such as active pulmonary tuberculosis and suppurative or exudative dermatosis, or the personnel whose skin injury has not been healed shall be transferred to other posts without affecting food safety.</p> <p>6.3.2 Hygiene requirements for food processing personnel</p> <p>6.3.2.1 The personnel shall handle personal hygiene before entering food production site to avoid food contamination.</p> <p>6.3.2.2 The personnel shall wear clean work clothes, wash hand and disinfect oneself as needed when entering the operating area. Hair shall be hidden in work cap or restraint by hairnet.</p> <p>6.3.2.3 The personnel shall not wear jewelry or watch, and shall not make up, dye fingernails and spray perfume. They shall not carry or store personal articles which are irrelevant to food production.</p> <p>6.3.2.4 After going to the rest room, contacting articles which may contaminate food or engaging in other activities irrelevant to food production, the personnel shall wash hand and disinfect themselves before being</p>	<p>food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.</p>	<p>problems should be reported to the manager. Special consideration should be given to temporary workers who might be less familiar with potential hazards.</p> <p><i>More detailed requirements on this subject (personnel, hygiene) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.9:</b></i></p> <p>c) Hands should be washed (+ disinfected) regularly, as a minimum, before starting to work, after using the lavatory, after breaks, after rubbish disposal, after coughing or sneezing, after handling of raw materials, ...</p> <p>d) Hair covers (and beard snoods) should be considered and appropriate clothing with high degree of cleanliness, minimum of pockets, absence of jewelry and watches.</p> <p>e) Eating, drinking and/or smoking rooms should be separated and clean.</p> <p><i>More detailed requirements on this subject (visitors) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.9:</b></i></p>

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<p>engaged in activities related to food production contacting food, tools and instruments or food equipment again.</p> <p>6.3.3 Visitors Those who are not food processing personnel shall not enter food production site. If they enter the food production site under special circumstances, they shall observe the same hygienic requirements as food processing personnel.</p>		<p>g) The number of visitors should be minimized. Visitors should wear appropriate protective clothing, provided by the Food Business Operator.</p>
<p><b>6.4 Insect pest control</b></p> <p>6.4.1 The building shall be kept in perfect condition and tidy to prevent insect attack from intruding and breeding.</p> <p>6.4.2 Insect pest control measures shall be prepared and carried out for regular inspection. Effective measures such as yarn curtain, gauze, rat guard, fly prevention lamp or wind screen shall be taken in production workshop and warehouse to prevent rodent or insects from intruding. If trail of insects or rodent is found, its source shall be traced to eradicate hidden danger.</p> <p>6.4.3 Plan drawing for insect pest control shall be exactly drawn to mark the positions of mousetrap, glue board, fly-killing lamp, outdoor bait and killing device of biochemical pheromone. 6.4.4 Pest control shall be carried out on regular basis in the plant.</p> <p>6.4.5 During the treatment by physical, chemical or biological agent, food safety and the proper food quality shall not be affected and food contact surface, equipment, tools</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter I General requirements for food premises:</p> <p>1. Food premises are to be kept clean and maintained in good repair and condition.</p> <p>2. The layout, design, construction, siting and size of food premises are to:</p> <p>(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control;</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter IX</p> <p>4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).</p>	<p><i>More detailed requirements on this subject (pest control) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.3 Pest control: focus on prevention:</b></i></p> <p>a) External walls should be free of cracks or chinks, surroundings neat and clean and areas for cleaning accessible.</p> <p>b) Insect screen should be placed at windows.</p> <p>c) Doors should be kept closed except when loading and or unloading.</p> <p>d) Unused equipment and rooms should be clean.</p> <p>e) The presence of an indoor pool of water should be immediately addressed.</p>

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<p>and instruments and packaging material shall not be contaminated. Pest control shall be recorded correspondingly.</p> <p>6.4.6 Before using various kinds of pesticides or other drugs, preventive measures shall be taken to avoid contamination on persons, food, equipment and tools. In case of contamination carelessly, contaminated equipment or tools shall be cleaned thoroughly in time to eradicate contamination.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter IX</p> <p>3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.</p> <p>2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.</p>	
<p><b>6.5 Waste disposal</b></p> <p>6.5.1 System for waste storage and elimination shall be published; for waste with special requirements, its disposal shall meet the relevant requirements. Waste shall be eliminated periodically; corruptible waste shall be eliminated as soon as possible; where necessary, waste shall be eliminated in time.</p> <p>6.5.2 Waste location outside the workshop shall be kept from food processing site to prevent contamination; smelly or harmful, toxic gas shall be prevented from escaping; insect pest shall be prevented from breeding.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter VI</p> <p>1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.</p> <p>2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.</p> <p>3. Adequate provision is to be made for the storage and disposal of food waste, non-</p>	

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	<p>edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.</p> <p>4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.</p>	
<p><b>6.6 Work clothes management</b></p> <p>6.6.1 The personnel shall wear work clothes when entering the operating areas.</p> <p>6.6.2 Specialized clothes such as coats, pants, shoes, caps and hairnet shall be equipped in accordance with the food characteristics and the requirements of production process; where necessary, mask, apron, sleeve or glove may be provided.</p> <p>6.6.3 Cleaning system for work clothes shall be prepared, where necessary, work clothes shall be replaced timely. During the process of food production, work clothes shall be kept clean and in perfect condition.</p> <p>6.6.4 Work clothes shall be designed and made to meet to the requirements of different operating areas to lower the risk of cross contamination. Position of work clothes pocket and connection fastening shall be reasonably selected to reduce the contamination risk brought by content or fastening dropping.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter VIII</p> <p>1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.</p>	<p><i>More detailed requirements on this subject (work clothes management) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.9:</b></i></p> <p>d) Hair covers (and beard snoods) should be considered and appropriate clothing with high degree of cleanliness, minimum of pockets, absence of jewelry and watches.</p>

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<p><b>7 Food Raw Materials, Food Additives and Food Related Products</b></p> <p><b>7.1 General requirements</b></p> <p>Purchasing, acceptance, transportation and storage management system for food raw materials, food additives and food related products shall be established to ensure that food raw materials, food additives and food related products meet relevant national requirements. Any substance which harm to human health and life safety may do shall not be added to foods.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter IX</p> <p>A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.</p>	
<p><b>7.2 Food raw materials</b></p> <p>7.2.1 Licenses and qualified certificates of the suppliers for the purchased food raw materials shall be checked. Food raw materials without qualified certificate shall be inspected based on food safety standard.</p> <p>7.2.2 Food raw materials can be used only when they are approved. Food raw materials without being approved shall be kept from the qualified materials in designated areas with obvious marks and shall be returned and replaced timely.</p> <p>7.2.3 Sensory inspection should be conducted before processing and where necessary, laboratory inspection shall be conducted. Once the item indexes involving food safety</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter IX</p> <p>2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.</p> <p>3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.</p>	

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<p>are found to be abnormal, the food raw materials shall not be used and only the verified applicable ones shall be used.</p> <p>7.2.4 During transportation and storage, the food raw materials shall be kept away from direct sunlight and shall be equipped with rainproof and dustproof facilities. According to the characteristics and hygiene requirements of food raw materials, they shall also be equipped with facilities for insulation, cold storage and preservation.</p> <p>7.2.5 Transportation tools and vessels of food raw materials shall be kept clean and in good condition and be disinfected where necessary. The food raw materials shall not be shipped together with toxic and harmful substances to avoid contamination on food raw materials.</p> <p>7.2.6 For warehouse of food raw materials, management system shall be built up and it shall be managed by specific personnel who are responsible for periodical inspection on the quality and hygienic condition and timely cleaning for bad food raw materials or those exceeding quality guarantee period. The distribution order of warehouse shall comply with the principle of "first in first out"; where necessary, it shall be determined according to the characteristics of different food raw materials.</p>	<p>4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter IV</p> <p>1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection. 2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination.</p> <p>3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.</p>	<p><i>More detailed requirements on this subject (first in, first out) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.10.</b></i></p> <p>d) Storage conditions at the establishment itself should take into account any instructions provided by the supplier, 'first in, first out' or 'first expire, first out' principles, accessibility for inspection from all sides (e.g. not placed directly on the ground, against walls, ...).</p>

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<p><b>7.3 Food additives</b></p> <p>7.3.1 Licenses of the suppliers and qualified certificates of products shall be inspected where food additives are purchased. Food additives can only be used after being approved.</p> <p>7.3.2 The transportation tools and containers of food additives shall be kept clean and in good condition and shall be provided with necessary protective measures to avoid contamination on food additives.</p> <p>7.3.3 Storage of food additives shall be managed by specific personnel who are responsible for periodical inspection on the quality and hygienic condition and timely cleaning for the bad food materials or those exceeding quality guarantee period. The distribution order of warehouse shall comply with the principle of "first in first out"; where necessary, it shall be determined according to the characteristics of food additives.</p>	<p><b>Regulation (EC) No 1333/2008, Article 4</b></p> <p>1. Only food additives included in the Community list in Annex II may be placed on the market as such and used in foods under the conditions of use specified therein.</p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter IV</b></p> <p>5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.</p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter IX</b></p> <p>2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.</p>	<p><b>Regulation (EC) No 1333/2008 on food additives provides general principles of safety and application for all food additives and sets out harmonised rules on food additives: definitions, conditions of use, labelling and procedures.</b></p> <p><i>In addition, Regulation (EU) No 1130/2011 establishes a Union list of additives approved for use in food additives, food enzymes, food flavourings and nutrients.</i></p> <p><i>More detailed requirements on this subject (first in, first out) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.10.:</b></i></p> <p>d) Storage conditions at the establishment itself should take into account any instructions provided by the supplier, 'first in, first out' or 'first expire, first out' principles, accessibility for inspection from all sides (e.g. not placed directly on the ground, against walls, ...).</p>
<p><b>7.4 Food related products</b></p> <p>7.4.1 Food related products including purchased food packaging materials, containers, detergents and disinfectants shall be inspected for qualified certificates. Those which are carried out with license management shall also be inspected for the licenses of the suppliers and those such as food packaging materials can only be used after being approved.</p>	<p><b>Regulation (EC) No 852/2004, Annex II, Chapter IX</b></p> <p>1. A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or</p>	

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<p>7.4.2 The transportation means and vessels of food related products shall be kept clean and be maintained in good condition and shall be provided with necessary protective measures to prevent contamination on food raw materials and cross contamination.</p> <p>7.4.3 Storage of food related products shall be managed by specific personnel who are responsible for periodical inspection on the quality and hygienic condition and timely cleaning for the bad food materials or those exceeding quality guarantee period. The distribution order of warehouse shall abide by the principle of "first in first out".</p>	<p>foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter IV</p> <p>1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter IX</p> <p>2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.</p>	<p><i>More detailed requirements on this subject (first in, first out) are mentioned in the Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2.10.</b></i></p> <p>d) Storage conditions at the establishment itself should take into account any instructions provided by the supplier, 'first in, first out' or 'first expire, first out' principles, accessibility for inspection from all sides (e.g. not placed directly on the ground, against walls, ...).</p>
<p><b>7.5 Others</b> For packaging or containers of food materials, food additives and packaging materials directly contacting food, their materials shall be stable, nontoxic, harmless, and difficult to be contaminated and meet hygienic requirements. Food materials, food additives and food packaging materials shall be provided with a certain buffer or cleaning</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter II</p> <p>1. (f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth,</p>	<p><b>Commission Regulation (EC) No 1935/2004</b> provides general principles of safety and quality of all Food Contact Materials and sets out a harmonised legal EU framework.</p>

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<b>Chinese National standard GB 14881</b>	<b>EU Regulation (EC) No 852/2004</b>	<b>Implementing rules, other remarks</b>
measures for external packaging to lower the contamination risk.	washable corrosion-resistant and non-toxic materials... <b>Regulation (EC) No 852/2004</b> , Annex II, Chapter X 1. Material used for wrapping and packaging are not to be a source of contamination. 2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination. 3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products.	
<b>8 Food Safety Control in Production Process</b> <b>8.1 Contamination risk control of product</b> 8.1.1 Hazard analysis method shall be used to affirm the key link of food safety during production process, and control measures for the key link of food safety shall be taken. In the key link, relevant documents such as list of ingredients (feeding) and post operating procedures shall be provided to implement control measures. 8.1.2 Hazard Analysis and Critical Control Point system is encouraged to be adopted for the food safety control during the process of production.	<b>Regulation (EC) No 852/2004, Article 5</b> 1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.	<i>In EU legislation the implementation of HACCP-based self-controls is mandatory for all food business operators (except primary producers), while in the National Standard GB 14881-2013 as well as in National Standard GB 12694-2016 (point 11.1.2) it is encouraged to be adopted (i.e. not mandatory). However, overall, the objective and aim of the provisions are the same. A detailed assessment of National Standard GB 27341-2009 in comparison with EU legislation is provided below.</i>
<b>8.2 Control of biological contamination</b> <b>8.3 Control of chemical contamination</b> <b>8.4 Control of physical contamination</b>	<b>Regulation (EC) No 852/2004, Articles 4 and 5.</b> <b>Guidance document (Commission Notice 2016/C 278/01) Annex I and Annex II.</b>	<i>A detailed assessment of the requirements for the implementation of HACCP in EU legislation is provided below.</i>

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<p><b>8.5 Packaging</b></p> <p>8.5.1 The food packaging shall be able to protect the food safety and quality to the maximum extent under normal storage, transportation and marketing conditions.</p> <p>8.5.2 Identification shall be checked to avoid misuse where packaging materials are used. The use condition of packaging materials shall be recorded faithfully.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter X</p> <p>1. Material used for wrapping and packaging are not to be a source of contamination.</p> <p>2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.</p> <p>3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products.</p> <p>4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.</p>	
<p><b>9 Inspection</b></p> <p>9.1 The raw materials and products shall be inspected by the enterprise itself or by consigning food inspection agencies with corresponding qualifications. The recording system for delivery inspection of food shall be established.</p> <p>9.2 There shall be corresponding inspection room and inspection capability for self-inspection. The inspection shall be implemented by the inspection personnel with corresponding qualifications based on required inspection method. The inspection instruments and equipment shall be inspected on regular basis.</p> <p>9.3 The inspection room shall be equipped with sound management system to properly preserve the original record and inspection</p>	<p><b>Regulation (EC) No 852/2004, Article 5</b> (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively;</p> <p>The verification of effective self-controls is a key objective of official controls in food establishments:</p> <p><b>Regulation (EU) 2017/625, Article 14</b> Official control methods and techniques shall include the following as appropriate: (a) an examination of the controls that operators have put in place and of the results obtained; (b) an inspection of:</p>	<p><i>Guidance document <b>Commission Notice 2016/C 278/01</b> provides that adequate infrastructure and resources must be provided to develop, organise and execute efficient self-controls.</i></p> <p>3.1 Assembly of a multidisciplinary HACCP team This team, which involves all parts of the food business concerned with the product, should include the whole range of specific knowledge and expertise appropriate to the product under consideration, its production (manufacture, storage, and distribution), its consumption and the associated potential hazards and should also involve as much as possible the higher management levels. The team should get the full support of the</p>

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<p>report of each inspection. Products sampling system shall be built up to timely keep sample.</p> <p>9.4 Comprehensive consideration shall be taken for factors such as product characteristics, process characteristics, and material control condition to reasonably determine inspection items and frequency so that control measures can be effectively verified during production process. The inspection frequency of net content, sensory requirements and other inspection items easy to change due to effect of production process shall be greater than that of other inspection items.</p> <p>9.5 For the same variety of product with different packaging, inspection items free from effect of packaging specification and packaging type may be inspected together.</p>	<p>(i) equipment, means of transport, premises and other places under their control and their surroundings;</p> <p>(ii) animals and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals;</p> <p>(iii) cleaning and maintenance products and processes;</p> <p>(iv) traceability, labelling, presentation, advertising and relevant packaging materials including materials intended to come into contact with food;</p> <p>(c) controls on the hygiene conditions in the operators’ premises;</p> <p>(d) an assessment of procedures on good manufacturing practices, good hygiene practices, good farming practices, and of procedures based on the principles of hazard analysis critical control points (HACCP);</p> <p>(e) an examination of documents, traceability records and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2), including, where appropriate, documents accompanying food, feed and any substance or material entering or leaving an establishment;</p> <p>(f) interviews with operators and with their staff; (g) the verification of measurements taken by the operator and other test results;</p> <p>(h) sampling, analysis, diagnosis and tests;</p> <p>(i) audits of operators;</p>	<p>management who should consider itself owner of the HACCP plan and overall Food Safety Monitoring System.</p>

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	(j) any other activity required to identify cases of non-compliance.	
<p><b>10 Storage and Transportation of Foods</b></p> <p>10.1 Proper storage and transportation conditions are selected in accordance with requirements of food characteristics and hygienic requirements. Where necessary, the facilities shall be provided for thermal insulation, cold storage and preservation. Foods shall not be stored and transported together with toxic, harmful or smelly goods.</p> <p>10.2 Suitable warehousing system shall be established and carried out. In case of any abnormality, it shall be timely handled.</p> <p>10.3 The containers, tools and instruments and equipment to store, transport and load and unload foods shall be safe, harmless and clean to lower the risk of food contamination.</p> <p>10.4 During the storage and transportation, direct sunlight, rain, notable temperature and humidity change and violent impact shall be avoided to prevent the adverse effect on foods.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter IX</p> <p>5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted.</p> <p>8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.</p> <p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter IV</p> <p>1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.</p> <p>7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored.</p>	

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<p><b>11 Product Recall Management</b></p> <p>11.1 The product recall system shall be established based on relevant national regulations.</p> <p>11.2 Where the produced food is not up to the food safety standard or other inedible conditions are found, the production shall be stopped immediately and the food already sold in market shall be recalled. Relevant production operators and consumers shall be notified and the recall and notification condition shall be recorded.</p> <p>11.3 The recalled food shall be safely disposed of or destroyed to prevent them from flowing into the market again. For foods that are recalled due to improper labeling, identification, or directions for use not in conformity with food safety standards, corrective measures shall be taken to ensure the safety of the products and explain the situation to consumers once the products are re-launched for sale.</p> <p>11.4 Production batch shall be reasonably divided and recorded and it shall be labeled with product batch number for the convenience of product tracing.</p>	<p><b>Regulation (EC) No 178/2002, Article 19</b></p> <p>1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.</p> <p>2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.</p>	

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<b>Chinese National standard GB 14881</b>	<b>EU Regulation (EC) No 852/2004</b>	<b>Implementing rules, other remarks</b>
<p><b>12 Training</b></p> <p>12.1 Training system for relevant posts of food production shall be established and the corresponding training on food safety knowledge shall be carried out for food processing personnel and practitioners.</p> <p>12.2 The awareness and responsibility of the practitioners to comply with relevant laws, regulations and standards of food safety and implement management system of food safety shall be improved and the corresponding knowledge level shall be improved through the process of training.</p> <p>12.3 The annual training plan of food safety shall be developed and implemented according to the actual demand of different posts of food production. The training plan should be evaluated, and the training should be recorded.</p> <p>12.4 Where the relevant laws, regulations and standards of food safety are updated, training shall be developed in time.</p> <p>12.5 The training plan shall be examined and revised on regular basis and the training effect shall be evaluated. The routine inspection is carried out to guarantee the effective implementation of the training plan.</p>	<p><b>Regulation (EC) No 852/2004</b>, Annex II, Chapter XII</p> <p>Food business operators are to ensure:</p> <ol style="list-style-type: none"> <li>1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;</li> <li>2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation (= <i>HACCP programme</i>) or for the operation of relevant guides have received adequate training in the application of the HACCP principles; and</li> <li>3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.</li> </ol>	
<p><b>13 Management System and Personnel</b></p> <p>13.1 The professional technical personnel and management personnel of food safety shall be allocated and the management system to ensure food safety shall be established.</p> <p>13.2 The management system of food safety shall correspond to the production scale,</p>	<p><b>Regulation 178/2002</b></p> <p>Article 17 Responsibilities</p> <ol style="list-style-type: none"> <li>1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy</li> </ol>	<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex II, Heading 3: Preliminary activities</b></p> <p><b>3.1 Assembly of a multidisciplinary HACCP team</b></p> <p>This team, which involves all parts of the food business concerned with the product, should</p>

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<p>process level and variety characteristics of food and shall be constantly improved based on practical production and implementation experience.</p> <p>13.3 The management personnel shall master the basic principles and operation procedures of food safety and shall have the ability to judge the potential risks and take appropriate preventive and corrective measures to guarantee the effective management.</p>	<p>the requirements of food law which are relevant to their activities and shall verify that such requirements are met.</p>	<p>include the whole range of specific knowledge and expertise appropriate to the product under consideration, its production (manufacture, storage, and distribution), its consumption and the associated potential hazards and should also involve as much as possible the higher management levels. The team should get the full support of the management who should consider itself owner of the HACCP plan and overall Food Safety Monitoring System.</p>
<p><b>14 Record and Document Management</b></p> <p><b>14.1 Record management</b></p> <p>14.1.1 The recording system shall be established to record links of food production including purchasing, processing, storage, inspection and marketing in details. The record contents shall be complete and true to ensure that all links from material purchasing to production, to marketing of the products can be traced effectively.</p> <p>14.1.1.1 The contents including name, specification, quantity, supplier’ name and contact information and purchase date of food related products including food raw materials, food additives and food packaging materials shall be recorded faithfully.</p> <p>14.1.1.2 The contents including food processing (process parameters and environmental monitoring included), storage condition of food and inspection batch No., inspection date, inspection personnel, inspection method and inspection result of the products shall be recorded truthfully.</p>		<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex II, Heading 10: Documentation and record keeping</b></p> <p>Efficient and accurate record keeping is essential to the application of HACCP-based procedures. HACCP-based procedures should be documented in the HACCP-plan and continuously supplemented by records on findings. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP-based procedures are in place and being maintained. Documents and records should be kept for a sufficient period of time beyond the shelf life of the product for traceability purposes, for the regular revision of the procedures by the FBO and to allow the competent authority to audit the HACCP-based procedures. Documents should be signed by a responsible reviewing official of the company. Recommended documentation includes:</p>

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<p>14.1.1.3 The contents such as name, specification, quantity, production date, production batch No., purchaser's name and contact information, quality certificate and selling date of delivery product shall be recorded truthfully.</p> <p>14.1.1.4 The contents including name, batch, specification, quantity, recall reason and subsequent rectification program of recalled food shall be recorded truthfully.</p> <p>14.1.2 The purchasing inspection record of food related products including food raw materials, food additives and food packaging materials as well as delivery inspection record of foods shall be rechecked and signed by the recorders and examiner. The record contents shall be integral, which shall be kept not less than 2 years.</p> <p>14.1.3 The customer complaint handling mechanism shall be built up. As for the written or verbal advice and complaint put forward by customers, the related management departments of the enterprise shall make records, find out the reasons and handle them carefully.</p> <p>14.2 The document management system shall be established for effective document management to ensure that documents at each relevant location are valid.</p> <p>14.3 The advanced technology and means (electronic computer information system included) are encouraged to be adopted to</p>		<ul style="list-style-type: none"> <li>— PRPs applied, working instructions, standard operational procedures, control instructions;</li> <li>— Description of the preparatory stages (before 7 principles);</li> <li>— Hazard analysis;</li> <li>— CCP (+/- PRPs) identification;</li> <li>— Critical limit determination;</li> <li>— Validation activities;</li> <li>— Corrective actions anticipated;</li> <li>— Description of planned monitoring and verification activities (what, who, when);</li> <li>— Record forms;</li> <li>— Modifications to the HACCP-based procedures;</li> <li>— Supporting documents (generic guides, scientific evidence, ...).</li> </ul> <p>Record examples are:</p> <ul style="list-style-type: none"> <li>— Outcome of CCP monitoring activities;</li> <li>— Observed deviations and executed corrective actions;</li> <li>— Outcome of verification activities. Records should be kept for an appropriate period of time. That period should be long enough to ensure information to be available in case of an alert that can be traced back to the food in question. For certain foods the date of consumption is certain. For instance, in food catering, consumption takes place shortly after the time of production. For food for which the date of consumption is uncertain, records should be kept for a reasonably short period after the expiry date of the food. Records are</li> </ul>

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implement record and document management.		an important tool for the competent authorities to allow verification of the proper functioning of the food businesses' FSMS. A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.

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## 1.1.2 National standard GB 4789.1-2016 – Food microbiological examination- general rules

Chinese National standard GB 4789.1	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
<p><b>1. Scope</b> This standard sets out the basic principles and requirements of microbiological test of food. This standard is applicable to microbiological test of food</p>	<p><b>Article 1 Subject-matter and scope</b> This Regulation lays down the microbiological criteria for certain microorganisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004.</p>	
<p><b>2. Basic Laboratory Requirements</b> <b>2.1 Inspectors</b> 2.1.1 The inspectors shall have the corresponding professional education or training experience of microbiology and related qualification, and be able to understand and implement the examination correctly. 2.1.2 The inspectors shall master the knowledge of safety operation and disinfection for biological examination in laboratory. 2.1.3 Personal cleanliness and hygiene shall be maintained during the examination to prevent the sample from man-made contaminant. 2.1.4 The inspectors shall comply with the provisions of relevant security measures during the examination to ensure his/her own security. 2.1.5 The inspectors with color vision disorder are prohibited from carrying out</p>	<p><b>Directive 2004/10/EC, Article 1</b> 1. Member States shall take all measures necessary to ensure that laboratories carrying out tests on chemical products, in accordance with Directive 67/548/EEC, comply with the principles of good laboratory practice (GLP) as laid down in Annex I to this Directive. <b>Directive 2004/10/EC, Annex I, Section II Good laboratory practice principles</b> 1.1. Test facility management's responsibilities 2. At a minimum it should: (b) ensure that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study; c) ensure the maintenance of a record of the qualifications, training, experience and job description for each professional and technical individual; (d) ensure that personnel clearly understand the functions they are to perform and, where</p>	<p><b>Directive 2004/9/EC on the inspection and verification of good laboratory practice (GLP), Annex I Part A Revised guides for compliance monitoring procedures for GLP</b> Personnel and training (National) GLP Monitoring Authorities should: — ensure that an adequate number of inspectors is available. — ensure that inspectors are adequately qualified and trained.</p> <p><i>In addition, EU guidance documents are available for GLP:</i> - Guidance Document for GLP inspectors and GLP test facilities. - Guidance for GLP facilities on the implementation and maintenance of a risk-based quality assurance programme.</p>

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<p>any color discrimination-involving examination.</p> <p><b>2.2 Environment and facilities</b></p> <p>2.2.1 The laboratory environment shall not affect the accuracy of the test results.</p> <p>2.2.2 The laboratory area shall be clearly separated from the office area.</p> <p>2.2.3 The working area and general layout of the laboratory shall meet the examination requirements. The laboratory layout shall apply single-direction workflow to avoid cross-contamination.</p> <p>2.2.4 The temperature, humidity, cleanliness, and illumination as well as noise level in laboratory shall meet the working requirements.</p> <p>2.2.5 Food sample examination shall be conducted in clean area where shall be indicated with obvious signs.</p>	<p>necessary, provide training for these functions;</p> <p>(f) ensure that there is a quality assurance programme with designated personnel and assure that the quality assurance responsibility is being performed in accordance with these principles of good laboratory practice;</p> <p>(g) ensure that for each study an individual with the appropriate qualifications, training, and experience is designated by the management as the study director before the study is initiated. Replacement of a study director should be done according to established procedures, and should be documented.</p> <p>3. Facilities</p> <p>3.1. General</p> <p>1. The test facility should be of suitable size, construction and location to meet the requirements of the study and to minimise disturbance that would interfere with the validity of the study.</p> <p>2. The design of the test facility should provide an adequate degree of separation of the different activities to assure the proper conduct of each study.</p> <p>3.2. Test system facilities</p> <p>1. The test facility should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects, involving substances or</p>	

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<p>2.2.6 The separation and identification of pathogenic micro-organism shall be carried out in Biosafety laboratory at Level II or higher level.</p> <p><b>2.3 Laboratory equipment</b></p> <p>2.3.1 The laboratory equipment shall meet the requirements of the examination. See A.1 for common equipment.</p> <p>2.3.2 The laboratory equipment shall be placed under appropriate environmental conditions so as to make its maintenance, cleaning, disinfection and calibration easy, keep it neat and make it work in good condition.</p> <p>2.3.3 The laboratory equipment shall be inspected and/or calibrated (labeled with mark), repaired and maintained regularly to ensure working performance and operational security.</p>	<p>organisms known to be or suspected of being biohazardous.</p> <p>2. Suitable rooms or areas should be available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems.</p> <p>3.3. Facilities for handling test and reference items</p> <p>1. To prevent contamination or mix-ups, there should be separate rooms or areas for receipt and storage of the test and reference items, and mixing of the test items with a vehicle.</p> <p>2. Storage rooms or areas for the test items should be separate from rooms or areas containing the test systems. They should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.</p> <p>4. Apparatus, material, and reagents</p> <p>1. Apparatus, including validated computerised systems, used for the generation, storage and retrieval of data, and for controlling environmental factors relevant to the study should be suitably located and of appropriate design and adequate capacity.</p> <p>2. Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to standard operating procedures. Records of these</p>	

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<p>2.3.4 The laboratory equipment shall be provided with daily monitoring or using records.</p> <p><b>2.4 Examination supplies</b></p> <p>2.4.1 The examination supplies shall meet the requirements of the microbiological examination. The commonly used examination supplies are shown in A.2.</p> <p>2.4.2 All examination supplies shall be kept clean and/or sterile before use.</p> <p>2.4.3 The examination supplies requiring sterilizing shall be placed in specific containers or packaged/plugged with suitable materials (such as special packaging paper or aluminum-foil paper) to ensure the sterilization effect.</p> <p>2.4.4 The storage condition of examination supplies shall be kept dry and clean. And the sterilized and unsterilized supplies shall be stored separately and clearly marked.</p> <p>2.4.5 The temperature, duration and effective life of sterilization for the sterilized examination supplies shall be recorded.</p>	<p>activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of measurement.</p> <p>3. Apparatus and materials used in a study should not interfere adversely with the test systems.</p> <p>4. Chemicals, reagents, and solutions should be labelled to indicate identity (with concentration if appropriate), expiry date and specific storage instructions. Information concerning source, preparation date and stability should be available. The expiry date may be extended on the basis of documented evaluation or analysis.</p> <p>5.2. Biological</p> <p>1. Proper conditions should be established and maintained for the storage, housing, handling and care of biological test systems, in order to ensure the quality of the data.</p> <p>2. Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, this lot should not be used in studies and, when appropriate, should be humanely destroyed. At the experimental starting date of a study, test systems should be free of any disease or condition that might interfere with the purpose or conduct of the study. Test systems that become diseased or injured during the course of a study should be isolated and treated, if necessary to</p>	

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<p><b>2.5 Culture media and reagents</b> The preparation and quality requirements of the culture media and reagents shall be in accordance with the provision specified in GB 4789.28.</p> <p><b>2.6 Quality control strains</b> 2.6.1 The laboratory shall keep standard strains that can meet the requirements of the experiment. 2.6.2 Only traceable standard strains stored in special institutions of microbial culture preservation or professional authority institutes shall be used.</p>	<p>maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded.</p> <p>3. Records of source, date of arrival, and arrival condition of test systems should be maintained.</p> <p>4. Biological test systems should be acclimatised to the test environment for an adequate period before the first administration/application of the test or reference item.</p> <p>5. All information needed to properly identify the test systems should appear on their housing or containers. Individual test systems that are to be removed from their housing or containers during the conduct of the study should bear appropriate identification, wherever possible.</p> <p>6. During use, housing or containers for test systems should be cleaned and sanitised at appropriate intervals. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the study. Bedding for animals should be changed as required by sound husbandry practice. Use of pest control agents should be documented.</p> <p>6. Test and reference items</p>	

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<p>2.6.3 The preservation and transferring of standard strains shall be in accordance with the provision in GB 4789.28.</p> <p>2.6.4 The strains separated in laboratory (wild strains) shall be regarded as the internal quality control strains in laboratory after identification.</p>	<p>6.1. Receipt, handling, sampling and storage</p> <p>1. Records including test item and reference item characterisation, date of receipt, expiry date, quantities received and used in studies should be maintained.</p> <p>2. Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured to the degree possible and contamination or mix-up are precluded.</p> <p>3. Storage container(s) should carry identification information, expiry date, and specific storage instructions.</p>	
<p><b>3. Sample Collections</b></p> <p><b>3.1 Sampling principles</b></p> <p>3.1.1 Sampling should follow the principle of randomness and representativeness.</p> <p>3.1.2 Sterile operation procedure shall be followed during sampling, so as to prevent all potential foreign contamination.</p> <p><b>3.2 Sampling plan</b></p> <p>3.2.1 Determine the sampling plan according to the examination objective, product characteristics, lot size, examination method and harmful levels of microorganisms, etc.</p>	<p><b>Regulation (EC)No 2073/2005, Annex I, Chapter 3. Rules for sampling and preparation of test samples</b></p> <p>3.1 General rules for sampling and preparation of test samples</p> <p>In the absence of more specific rules on sampling and preparation of test samples, the relevant standards of the ISO (International Organisation for Standardisation) and the guidelines of the Codex Alimentarius shall be used as reference methods.</p> <p><b>Regulation (EC)No 2073/2005, Article 4</b></p> <p>2. Food business operators shall decide the appropriate sampling frequencies, except where Annex I provides for specific sampling frequencies, in which case the sampling frequency shall be at least that provided for in Annex I. Food business operators shall</p>	

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<p>3.2.2 The sampling plan can be classified into Grade II and Grade III. There are n, c and m values set in Grade II sampling plan; while n, c, m and M values set in Grade III sampling plan.</p> <p>n: the number of the samples collected from one batch;  c: the maximum number of the sample allowed to excess m value;  m: the limit value of the acceptance level of microbiological indicator (Grade III Sampling plan) or maximum safety limit value (Grade II sampling plan);  M: the maximum safety limit value of microbiological indicator.</p> <p>Note 1: According to the indicators set in Grade II sampling plan, it is allowed to have not more than c samples whose examination value of the corresponding microbiological indicator exceed m among n samples.</p> <p>Note 2: According to the indicators set in Grade III sampling plan, the examination value of the corresponding microbiological indicator for all the samples are allowed to</p>	<p>make this decision in the context of their procedures based on HACCP principles and good hygiene practice, taking into account the instructions for use of the foodstuff.</p> <p>The frequency of sampling may be adapted to the nature and size of the food businesses, provided that the safety of foodstuffs will not be endangered.</p> <p><b>Regulation (EC) No 2073/2005, Annex I, Chapter 1. Food safety criteria</b>  n = number of units comprising the sample;  c = number of sample units giving values between m and M.</p> <p><b>Chapter 2. Process hygiene criteria</b>  <b>2.4 Fishery products</b>  Interpretation of the test results  The limits given refer to each sample unit tested.  The test results demonstrate the microbiological quality of the process tested.  <i>E. coli</i> in shelled and shucked products of cooked crustaceans and molluscan shellfish:  — satisfactory, if all the values observed are <math>\leq m</math>,  — acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are <math>\leq m</math>,  — unsatisfactory, if one or more of the values observed are <math>&gt; M</math> or more than c/n values are between m and M.</p>	<p><b>Regulation (EC) No 2073/2005, Annex I, Chapter 1. Food safety criteria</b></p> <p>Interpretation of the test results</p> <p>Histamine in fishery products: Histamine in fishery products from fish species associated with a high amount of histidine except fish sauce produced by fermentation of fishery products:</p> <p>— satisfactory, if the following requirements are fulfilled:</p> <ol style="list-style-type: none"> <li>1. the mean value observed is <math>\leq m</math></li> <li>2. a maximum of c/n values observed are between m and M</li> <li>3. no values observed excess the limit of M.</li> </ol> <p>— unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or one or more of the values observed are <math>&gt; M</math>.</p> <p>Histamine in fish sauce produced by fermentation of fishery products:</p> <p>— satisfactory, if the value observed is <math>\leq</math> the limit,  — unsatisfactory, if the value observed is <math>&gt;</math> the limit.</p>

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<p>be not more than m; that for not more than c samples are allowed to be between m and M; while that for no sample is allowed to be more than M among n samples. For example: n=5, c=2, m=100 CFU/g, M=1000 CFU/g. It means as follows, 5 samples are collected from one batch. If the test results of all the 5 samples are less than or equal to m (<math>\leq 100</math> CFU/g), the result is acceptable; if the test results (X) of not more than two samples are between m and M (100 CFU/g1000 CFU/g), then the result is unacceptable, either.</p> <p>3.2.3 Sampling plan for different kinds of foods shall be implemented in accordance with the provisions of relevant food safety standards.</p> <p>3.2.4 Collection of food sample during food safety incidents: a) For food safety incidents caused by food contamination in batch production, the collection and determination of food samples shall be conducted in accordance with the principle of Section 3.2.2 and 3.2.3. The collection shall be focused on the food samples of the same batch.</p>	<p>Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish: — satisfactory, if all the values observed are <math>\leq m</math>, — acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are <math>\leq m</math>, — unsatisfactory, if one or more of the values observed are <math>&gt; M</math> or more than c/n values are between m and M</p> <p><b>Regulation (EC)No 2073/2005, Article 5</b> 1. The analytical methods and the sampling plans and methods in Annex I shall be applied as reference methods. 2. Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method.</p>	<p><b>Guidance document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs</b> of 13 November 2006</p> <p>5.3.4. Food-borne outbreaks In case of food-borne outbreaks the investigations should reveal suspect batches and should identify the establishment in which the product was manufactured/processed. In such cases the competent authority assesses the situation and can decide to take samples for microbiological analysis. The competent authority</p>

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<p>b) For food safety incidents caused by restaurants or family cooked food, the collection shall be focused on the rest food samples on the spot, so as to meet the requirements of cause determination and pathogen confirmation of food safety incidents.</p> <p>3.3 Sampling methods of different kinds of food</p> <p>3.3.1 Prepackaged food</p> <p>3.3.1.1 The collected food samples shall be of the same batch, packaged individually and with appropriate number of packages. The sampling size of each sample shall meet the requirements of microbiological indicator examination.</p> <p>3.3.1.2 For the solid food or liquid food with individual package size of no more than 1000 g or 1000 mL, samples of the same batch should be collected.</p> <p>3.3.1.3 The liquid food packaged individually, which is more than 1000 mL, shall be shaken or stirred with sterile rod before sampling so as to homogenize the liquid, then collect appropriate amount of the sample , and transfer it to a sterile sampling container as one food sample; for solid food with individual package size of more than 1000 g, respectively collect</p>		<p>should choose the necessary sampling procedures according to the situation and should also take account of the operator’s records from the food safety management systems. The sampling plan may include environmental samples and samples of different raw materials, products and batches. Account could also be taken of measures taken by food business operators to prevent, reduce or eliminate the risk in concern according to Article 19 of Regulation (EC) No 178/2002.</p> <p><b>Guidance document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs</b> of 13 November 2006</p> <p>The competent authority should establish a sampling strategy taking into account the sampling procedures proposed by EUROSTAT. The following definitions for these three identified sampling strategies in the context of control and monitoring activities have been proposed by EUROSTAT:</p> <p>Objective sampling</p> <p>A planned strategy based on the selection of a random sample, which is statistically representative of the population to be analysed. Each unit, within the framework population, has a specified probability of being selected. This strategy provides data from which statistical inference can be implemented. That means that the results inferred are comparable.</p> <p>Selective sampling</p>

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<p>appropriate amount of sample with a sterile sampler from different positions of the same package, then transfer into one sterile sampling container as one sample.</p> <p>3.3.2 Bulk food or on-site produced food Samples were collected from n different parts of the site with the sterile sampler and put into n sterile sampling containers as n food samples. The sampling amount of each sample shall meet the requirements of microbiological indicator examination unit.</p> <p>3.4 Mark of collected sample The collected sample shall be recorded and marked correctly and timely. The content includes sampler, sampling site, time, sample name, source, batch number, quantity, storage condition and so on.</p> <p>3.5 Storage and transport of collected sample 3.5.1 The sample shall be sent to the laboratory for examination as soon as possible. 3.5.2 The sample shall be kept intact during transportation. 3.5.3 The sample shall be stored at a similar temperature to the original, or necessary measures shall be taken to</p>		<p>A planned strategy where the selection of the sample is from previously defined “high-risk” population groups. Samples are normally selected to either illustrate or document unsatisfactory conditions or suspected adulteration of a product. The sampling is deliberately biased and is directed at the particular products or manufacturers. The sampling procedure can be random or not. The specification of the “high-risk” population comes from either scientific studies or previous analysis and information of other regions or countries. The comparability of the results lies on both the definition of the population to be analysed and the way the samples have been drawn. If the sample is drawn randomly to be representative of the population analysed, the results can be applied to the whole of this population.</p> <p>Suspect sampling A selection of samples, where the units are selected based on the judgement and experience regarding the population, lot, or sampling frame. The samples obtained from this procedure are not randomly extracted.</p> <p><b>Guidance document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs</b> of 13 November 2006</p> <p>5.7. Transport of samples, storage and starting of the analysis Standardized procedures for the transport of samples to the laboratory, the storage and the starting of the analysis are presented in ISO/DIS 7218: Microbiology of food and animal</p>

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prevent the change of microorganism amount in sample.		feeding stuffs – General rules for microbiological examinations.
<p><b>4. Examinations</b></p> <p><b>4.1 Sample treatment</b></p> <p>4.1.1 After receiving the submitted sample the laboratory shall check and register it carefully to ensure that the relevant information of the sample is complete and meets the examination requirements.</p> <p>4.1.2 The examination shall be carried out as required as soon as possible. If not, necessary measures shall be taken to keep the original state of the sample and prevent the change of original microorganisms in sample caused by the interference of objective conditions.</p> <p>4.1.3 The treatment of different food samples shall be in accordance with the provisions of examination methods in corresponding food safety standards.</p> <p><b>4.2 Sample examination</b></p> <p>Examination shall comply with the provisions of corresponding food safety standards.</p>	<p><b>Directive 2004/10/EC, Annex I, Section II</b></p> <p><b>Good laboratory practice principles</b></p> <p><b>5.2. Biological</b></p> <p>1. Proper conditions should be established and maintained for the storage, housing, handling and care of biological test systems, in order to ensure the quality of the data.</p> <p>2. Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, this lot should not be used in studies and, when appropriate, should be humanely destroyed.</p> <p>At the experimental starting date of a study, test systems should be free of any disease or condition that might interfere with the purpose or conduct of the study. Test systems that become diseased or injured during the course of a study should be isolated and treated, if necessary to maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded.</p> <p>3. Records of source, date of arrival, and arrival condition of test systems should be maintained.</p> <p>4. Biological test systems should be acclimatised to the test environment for an adequate period before the first administration/application of the test or reference item.</p>	

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	<p>5. All information needed to properly identify the test systems should appear on their housing or containers. Individual test systems that are to be removed from their housing or containers during the conduct of the study should bear appropriate identification, wherever possible.</p> <p>6. During use, housing or containers for test systems should be cleaned and sanitised at appropriate intervals. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the study. Bedding for animals should be changed as required by sound husbandry practice. Use of pest control agents should be documented.</p>	
<p><b>5. Biosafety and Quality Control</b>  <b>5.1 Laboratory biosafety requirement</b>  It shall comply with the provisions in GB 19489.  <b>5.2 Quality control</b>  5.2.1 The laboratory shall set up positive control, negative control and blank control as required, and perform quality control for the examination process periodically.  5.2.2 The laboratory shall conduct technical examination periodically for the laboratory personnel.</p>	<p><b>Directive 2004/10/EC, Annex I, Section II</b>  <b>Good laboratory practice principles</b>  <b>2. Quality assurance programme</b>  2.1. General 1. The test facility should have a documented quality assurance programme to assure that studies performed are in compliance with these principles of good laboratory practice.</p>	
<p><b>6. Records and Reports</b>  <b>6.1 Records</b>  All information such as phenomena, results and data observed during</p>	<p><b>Directive 2004/10/EC, Annex I, Section II</b>  <b>Good laboratory practice principles</b>  <b>3.4. Archive facilities</b>  Archive facilities should be provided for the secure storage and retrieval of study plans,</p>	

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<p>examination shall be recorded instantaneously and objectively.</p> <p><b>6.2 Reports</b> The laboratory shall report the examination results accurately and objectively in accordance with the requirements specified in examination methods.</p>	<p>raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.</p> <p>10. Storage and retention of records and materials</p> <p>10.1. The following should be retained in the archives for the period specified by the appropriate authorities: (a) the study plan, raw data, samples of test and reference items, specimens, and the final report of each study; (b) records of all inspections performed by the quality assurance programme, as well as master schedules; (c) records of qualifications, training, experience and job descriptions of personnel; (d) records and reports of the maintenance and calibration of apparatus; (e) validation documentation for computerised systems; (f) the historical file of all standard operating procedures; (g) environmental monitoring records.</p>	
<p><b>7. Sample Disposal after Examination</b></p> <p>7.1 The test sample can be disposed only when the examination results have been reported.</p> <p>7.2 Bio-safety disposal shall be necessary for the sample detected with pathogens.</p> <p>7.3 After the examination results have been reported, the rest samples or samples of the same batch shall not be used for the re-examination of microbiological items</p>	<p><b>Directive 2004/10/EC, Annex I, Section II Good laboratory practice principles</b></p> <p><b>3.5. Waste disposal</b> Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.</p>	

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<b>Chinese National standard GB 4789.1</b>	<b>EU Regulation (EC) No 2073/2005</b>	<b>Implementing rules and remarks</b>
<b>Annex A</b> <b>Conventional Examination Supplies and Equipment of Microbiological Laboratory</b> <b>A.1 Equipment</b> <b>A.2 Examination supplies</b>	<b>Regulation (EU) 2015/1375 (laying down specific rules on official controls for <i>Trichinella</i> in meat), Annex I, Chapter I and II</b> provide details of equipment and examination supplies for the detection of <i>Trichinella</i> .	

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### 1.1.3 National standard GB 29921-2013 – Limit of pathogens in food products

Chinese National standard GB 29921	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
<p><b>1. Scope</b> This standard specifies pathogen indexes, limit requirements and testing methods for food products. This standard is applicable to pre-packed food products. This standard is not applicable to canned food products.</p>	<p><b>Article 1 Subject-matter and scope</b> This Regulation lays down the microbiological criteria for certain microorganisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004.</p>	
<p><b>2. Application principles</b> 2.1. Whether or not there are provisions of pathogen limits, food products manufacturers, processors, and operators should, to the best of their ability, take control measures to reduce the level of pathogens in food products and possibility of risks.  2.2. Samples should be taken in accordance with provisions of GB4789.1 and should be tested with methods listed in table one.</p>	<p><b>Article 3 General requirements</b> 1. Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I. To this end the food business operators at each stage of food production, processing and distribution, including retail, shall take measures, as part of their procedures based on HACCP principles together with the implementation of good hygiene practice, to ensure the following: (a) that the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the process hygiene criteria are met, (b) that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.</p> <p><b>Article 5 Specific rules for testing and sampling</b></p>	See above for GB 4789.1

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Chinese National standard GB 29921	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
	<p>1. The analytical methods and the sampling plans and methods in Annex I shall be applied as reference methods.</p> <p>2. Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method.</p>	
<p><b>3. Index requirements</b> Limit of Pathogens in food products is listed in table 1.</p>	<p><b>Annex I, Chapter 1. Food safety criteria</b> <b>Annex I, Chapter 2. Process hygiene criteria</b> <b>2.4. Fishery products</b></p>	
<p><b>Table 1</b> <b>Aquatic Products</b> - cooked aquatic products - ready to eat raw aquatic products - ready to eat algae products <i>Salmonella</i>: n = 5, c = 0, m = 0</p> <p><i>Vibrio parahaemolyticus</i>: n=5, c =1, m = 100 MPN/g, M = 1000 MPN/g</p>	<p><b>Annex I, Chapter 1. Food safety criteria</b> 1.16 Cooked crustaceans and molluscan shellfish: <i>Salmonella</i>: n = 5, c = 0, m = absence in 25 g (Products placed on the market during their shelf-life) 1.17 Live bivalve molluscs and live echinoderms, tunicates and gastropods: <i>Salmonella</i>: n = 5, c = 0, m = absence in 25 g (Products placed on the market during their shelf-life) 1.25 Live bivalve molluscs and live echinoderms, tunicates and marine gastropods: <i>E. coli</i> (used as an indicator of faecal contamination): n = 1, c = 0, m = 230 MPN/100g of flesh and intra-valvular liquid</p>	<p><i>Microbiological criteria for algae products are not mentioned in EU legislation.</i></p> <p><i>In EU legislation no specific criteria are set for Vibrio parahaemolyticus. E.coli is used as an indicator organism of faecal contamination.</i></p>

Chinese National standard GB 29921	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
<p><i>Staphylococcus aureus</i>: n=5, c =1, m = 100 CFU/g, M = 1000 CFU/g</p>	<p>(Products placed on the market during their shelf-life) <b>Annex I, Chapter 2. Process hygiene criteria</b> <b>2.4. Fishery products</b> 2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish: <i>E. coli</i>: n = 5, c = 2, m = 1 cfu/g and M = 10 cfu/g (End of the manufacturing process) 2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish: Coagulase-positive staphylococci: n = 5, c = 2, m = 100 cfu/g and M = 1000 cfu/g (End of the manufacturing process) Interpretation of the test results The limits given refer to each sample unit tested. The test results demonstrate the microbiological quality of the process tested. <i>E. coli</i> in shelled and shucked products of cooked crustaceans and molluscan shellfish: — satisfactory, if all the values observed are <math>\leq m</math>, — acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are <math>\leq m</math>, — unsatisfactory, if one or more of the values observed are <math>&gt; M</math> or more than c/n values are between m and M.</p>	<p><i>Staphylococcus aureus</i> is a coagulase-positive staphylococcus</p>

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Chinese National standard GB 29921	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
<p>Note 1: Food category is used to define applicable scope of pathogen limit; it applies to this standard only.</p> <p>Note 2: n is the number of samples collected from the same batch of products; c is the maximum allowable number of samples exceeding m level; m is the acceptable limit level for pathogen index; M is the highest safety limit for pathogen index.</p>	<p>Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:</p> <ul style="list-style-type: none"> <li>— satisfactory, if all the values observed are <math>\leq m</math>,</li> <li>— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are <math>\leq m</math>,</li> <li>— unsatisfactory, if one or more of the values observed are <math>&gt; M</math> or more than c/n values are between m and M.</li> </ul>	

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1.1.4 National standard GB/T 27341-2009 – Hazard Analysis and Critical Control Point (HACCP) System - General requirements for food processing plant

Chinese National standard GB-27341	EU Regulation (EC) No 852/2004	Implementing rules and remarks
<p><b>1 Scope</b> This standard specifies the general requirements of HACCP for food processing (catering) plant, including the purchasing, processing, packaging, storing and transporting of raw material and food packaging material.</p> <p><b>2 Normative References</b></p>	<p><b>Article 1 Scope</b> This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.</p>	<p><b>Article 5 of the EU law</b> requires the implementation and maintenance of HACCP mandatory for <b>all food business operators except primary producers</b> (some additional exceptions are: primary production for private domestic use; the domestic preparation, handling or storage of food for private domestic consumption; the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer; collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen).</p> <p><i>The Chinese legislation refers to processing plants.</i></p> <p><b>Three more Chinese standards</b> apply and have been studied: GB/T 19538 (Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application), GB/T 22000 (Food Safety Management Systems - Requirements for Any Organization in the Food Chain) and GB 31621-2014 (National Food Safety Standard-Hygienic norms of food production).</p>

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Chinese National standard GB-27341	EU Regulation (EC) No 852/2004	Implementing rules and remarks
		<i>A guidance document on the implementation of HACCP principles was published by the EU on 16 November 2005 to facilitate the implementation and cover all principles in more detail. The guidance document was extended in 2016 in order to provide a more integrated approach within a Food Safety Management System (Commission Notice 2016/C 278/01).</i>
<p><b>3 Terms and Definitions</b></p> <p><b>3.1 Raw material</b> All intended products articles or substances constituting food constituent or composition. Note: including materials, auxiliary materials and additives contained in foods or all intended substances of other source.</p> <p><b>3.2 Potential hazard</b> Food safety hazard which may occur in case of no precaution.</p> <p><b>3.3 Significant hazard</b> Potential hazard which is much more likely to occur and may result in disease or injury in case of no control. Note: "much more likely to occur" and "result in disease or injury" mean that the hazard has "probability" and "severity".</p> <p><b>3.4 Operation limit</b> The operation index established in order to avoid deviation of monitoring index from critical limit.</p> <p><b>3.5 Food defense plan</b> Measures established and implemented to protect food supply from deliberate biological,</p>	<p><b>Definitions</b> In Regulation (EC) No 178/2002 definitions are listed in Article 2 for food and in Article 3 for:</p> <p>'hazard' means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;</p> <p>'risk' means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;</p> <p>'retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;</p> <p>'primary production' means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also</p>	<p><i>In EU legislation there is no definition for raw material. The various components of raw material (food, animal by-products, residues, additives, etc.) are defined and dealt with in specific Regulations.</i></p> <p>In the guidance document (Commission Notice 2016/C 278/01) <b>Annex II, heading 5</b> deals with identification of critical control points (CCP) and identifies different levels of risk: lower risk levels, intermediate levels of risks and high level of risks. This is equivalent to the notion of potential hazard and significant hazard used in GB 27341.</p> <p><i>Operation limit is an additional tool to assess the deviation noticed while monitoring the Critical limit.</i></p> <p>In the guidance document (Commission Notice 2016/C 278/01) <b>heading 3</b> deals with <b>links between FSMS, PRPS, GHP, GMP and HACCP</b>.</p> <p>FSMS = food safety management system; PRPs = prerequisite programs; GHP = good</p>

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Chinese National standard GB-27341	EU Regulation (EC) No 852/2004	Implementing rules and remarks
chemical or physical contamination or artificial damage.	includes hunting and fishing and the harvesting of wild products; In Regulation (EC) No 852/2004 several definitions are listed (in Article 2) such as for food hygiene, establishment, potable water, clean water, wrapping, packaging, processing, processed products and unprocessed products.	hygiene practices; GMP = good manufacturing practices <i>These measures are equivalent to the food defense plan and have the same objective.</i>
<p><b>4 HACCP System of Plant</b> <b>4.1 General Requirements</b> The plant shall:</p> <p>a) Plan, implement, inspect and improve the HACCP system process, and provide the required resource.</p> <p>b) Determine the scope of HACCP system, and define the relationship between the step involved in this scope and other steps of the food chain.</p> <p>c) Guarantee to control all operations (including the outsourced process) which may affect the food safety requirements, and to carry out identification and verification in HACCP system. During verification, main attention shall be paid to the conformance of product safety with relevant laws, regulations, and standards.</p> <p>d) Guarantee that the HACCP system is effectively implemented so as to effectively control the product safety. Where systematic deviation occurs to product safety, HACCP plan shall be reconfirmed to continuously improve the HACCP system.</p>	<p><b>Article 5</b> <b>Hazard analysis and critical control points</b></p> <p>1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</p> <p>2. The HACCP principles referred to in paragraph 1 consist of the following:</p> <p>(a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;</p> <p>(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;</p> <p>(c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;</p>	<p><i>While the Chinese standard is directed to the plant, the EU Regulation is directed to the food business operator, allocating clear accountability and liability to the management of the establishment.</i></p> <p>In the guidance document (Commission Notice 2016/C 278/01) <b>Annex II, heading 2</b> deals with: <b>General principles</b> The HACCP-based procedures should be science/risk-based and systematic, identifying specific hazards, and measures for control of those hazards, to ensure the safety of food. HACCP-based procedures are tools to identify and assess hazards and establish control systems that focus on prevention, as opposed to older systems that relied mainly on end product testing. All HACCP-based procedures are capable of accommodating changes, such as advances in equipment design, processing procedures or technological developments as they include a requirement to review the procedures to ensure that new hazards have not</p>

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<p><b>4.2 Document Requirements</b>  <b>4.2.1 HACCP system documents</b> shall include:  a) Documented food safety guideline;  b) HACCP manual;  c) Documented procedure required in this standard;  d) Documents required to guarantee the effective planning, operation and control of HACCP system process;  e) Record required in this standard.  <b>4.2.2 HACCP manual</b>  The plant shall prepare and maintain HACCP manual, at least covering:</p>	<p>(d) establishing and implementing effective monitoring procedures at critical control points;  (e) establishing corrective actions when monitoring indicates that a critical control point is not under control;  (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs to (e) are working effectively; and  (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).</p> <p>When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.</p> <p>3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production.</p> <p>4. Food business operators shall:  (a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking</p>	<p>been introduced when such changes are made.  ...  The intent of HACCP-based procedures is to focus on control at CCPs. They should be applied to each specific operation separately. The application of the HACCP-based procedures should be reviewed and necessary changes made when any modification is made in the product, process, or any step. It is important when applying the HACCP-based procedures to be flexible where appropriate, given the context of the application taking into account the nature and the size of the operation.</p> <p>In the guidance document (Commission Notice 2016/C 278/01) <b>Annex II, heading 10</b> deals with:  <b>Documentation and record keeping</b>  Efficient and accurate record keeping is essential to the application of HACCP-based procedures. HACCP-based procedures should be documented in the HACCP-plan and continuously supplemented by records on findings. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP-based procedures are in place and being maintained.</p>

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<p>a) Scope of HACCP system, including the covered product or product category, operation step, site, and the relationship with other steps of food chain;</p> <p>b) Procedure document of HACCP system or the quotation of such document;</p> <p>c) Expression for HACCP system process and its interaction.</p> <p><b>4.2.3 Document control</b></p> <p>Documents required for HACCP system shall be controlled. The documented procedure shall be prepared to specify the control on the following aspects:</p> <p>a) The document is approved prior to issuance so as to guarantee that it is sufficient, proper and effective;</p> <p>b) Where necessary, review and update the document and re-approve it;</p> <p>c) Ensure that changes and the current revision status of the document are identified;</p> <p>d) Ensure that relevant effective version of applicable document is available at application location;</p> <p>e) Ensure that the document is clear and easy for identification;</p> <p>f) Ensure that documents related to HACCP system are identified, with their distribution controlled;</p> <p>g) Prevent the unintended use of obsolete documents, properly mark the obsolete documents which shall be reserved.</p> <p><b>4.2.4 Record control</b></p>	<p>account of the nature and size of the food business;</p> <p>(b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;</p> <p>(c) retain any other documents and records for an appropriate period.</p>	<p>Documents and records should be kept for a sufficient period of time beyond the shelf life of the product for traceability purposes, for the regular revision of the procedures by the FBO and to allow the competent authority to audit the HACCP-based procedures. Expert developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilized as part of the documentation, provided that those materials reflect the specific food operations of the business. Documents should be signed by a responsible reviewing official of the company.</p>

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<p>Record shall be established and maintained to provide effective operation evidence meeting relevant requirements and HACCP system. Documented procedure shall be prepared, specifying the control required for mark, storage, protection, retrieval, storage life and disposal of the record.</p> <p>The record shall be maintained clear and easy for identification and retrieval.</p>		<p>Records should be kept for an appropriate period of time. That period should be long enough to ensure information to be available in case of an alert that can be traced back to the food in question. For certain foods the date of consumption is certain. For food for which the date of consumption is uncertain, records should be kept for a reasonably short period after the expiry date of the food. Records are an important tool for the competent authorities to allow verification of the proper functioning of the food businesses' FSMS.</p>
<p><b>5 Management Responsibilities</b>  <b>5.1 Management Commitment</b>  Top management shall, through the following activities, provide evidence for the commitment made to establish and implement HACCP system: a) Transmit the importance to meet the requirements of the customer and laws and regulations to plants;  b) Establish food safety guideline;  c) Ensure the establishment of food safety objective;  d) Conduct management review;  e) Ensure the obtaining of resource.</p> <p><b>5.2 Food Safety Guideline</b>  Top management shall focus on the consumer's edible safety, establish food safety guideline and food safety objective, and ensure food safety.</p> <p><b>5.3 Responsibility, Authority and Communication</b></p>	<p><i>Regulation (EC) No 178/2002 (General Food Law) as well as Regulation (EC) No 852/2004 and 853/2004 are directed to the food business operator (= management).</i></p> <p><i>For example Regulation 178/2002 provides in Article 17: Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law.</i></p> <p><b>Regulation 852/2005 Article 5</b> (on HACCP):  1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</p>	<p>In the guidance document (Commission Notice 2016/C 278/01) <b>Annex II, heading 3</b> states:  <b>Preliminary activities</b>  <b>Assembly of a multidisciplinary HACCP team</b></p> <p>This team, which involves all parts of the food business concerned with the product, should include the whole range of specific knowledge and expertise appropriate to the product under consideration, its production (manufacture, storage, and distribution), its consumption and the associated potential hazards and should also involve as much as possible the higher management levels. The team should get the full support of the management who should consider itself owner of the HACCP plan and overall FSMS.</p> <p>Where necessary, the team should be assisted by specialists who will help it to solve its</p>

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<p><b>5.3.1 Responsibility and authority</b> Top management shall appoint a leader for HACCP working team, and confirm his responsibility and authority; meanwhile, it shall specify the responsibilities and authorities of all departments in a plant.</p> <p><b>5.3.2 Communication</b> In order to obtain necessary food safety information and guarantee the effectiveness of HACCP system, top management shall ensure that the plant has established, implemented and maintained the required internal communication, and has carried out necessary external communication with other suppliers, customers, food safety competent departments and other interested parties. Communication personnel shall accept proper training, sufficiently learn about the product, relevant hazard and HACCP system of the plant, and reasonably authorized. Communication record shall be maintained.</p> <p><b>5.4 Internal Review</b> The plant shall carry out internal review according to planned time interval to determine whether the HACCP system meets relevant requirements or not, and whether it is effectively implemented, maintained and updated or not. Consider the proposed review process, the regional condition and importance and the previous review results; plan the review scheme; specify the accuracy, scope, frequency and method of review. The</p>	<p><b>Annex II, Chapter XII to Reg 852/2004 Training</b> Food business operators are to ensure:</p> <ol style="list-style-type: none"> <li>1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;</li> <li>2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received</li> </ol>	<p>difficulties as regards assessment and control of critical points.</p> <p>In the guidance document (Commission Notice 2016/C 278/01) <b>heading 7. Training</b> states: Staff should be supervised and instructed and/or trained in food hygiene matters appropriate to their role, and those responsible for developing and maintaining the food safety management system should be suitably trained in the application of PRPs and HACCP principles.</p> <p>In the guidance document (Commission Notice 2016/C 278/01) <b>Annex II, heading 9</b> states: <b>Verification (and validation) procedures</b> The HACCP team should specify the methods and procedures to be used for determining if the HACCP-based procedures are working correctly.</p>

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<p>selection and review by the internal reviewer shall ensure the objectivity and impartiality of review process; internal reviewer shall not review his own work. Manager responsible for the reviewed region shall timely take measures to eliminate the discovered non-conformance item and its cause. Tracing activity shall include the verification for measures taken and the report for the verification result. Internal review procedure for the documented shall be prepared, the review shall be specified, planned and implemented, the result shall be reported, and the record shall be maintained.</p> <p><b>5.5 Management Review</b> Top management shall review HACCP system according to the planned time interval to ensure its continuous suitability, sufficiency and effectiveness; the review shall include the improvement and updating demand of HACCP system; record of management review shall be maintained.</p>	<p>adequate training in the application of the HACCP principles;</p> <p>Article 5(2)(f) provides that food business operators must establish ‘procedures, which shall be carried out regularly, to verify that the [control] measures outlined ... are working effectively</p>	<p>The frequency of verification should be sufficient to confirm that HACCP-based procedures are working effectively. The frequency of verification shall depend on the characteristics of the business (output, number of employees, nature of the food handled), the monitoring frequency, the accuracies of the employees, the number of deviations detected over time and the hazards involved.</p> <p>Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.</p> <p>Where necessary, such a review must result in the amendment of the procedures laid down. The changes should be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is available.</p>
<p><b>6 Prerequisite Plan</b> <b>6.1 General</b> Plant shall establish, implement, verify and maintain the prerequisite plan, and update and improve it where necessary, so as to continuously meet the sanitation condition required for HACCP system; prerequisite plan shall include human resource security plan, good manufacture practice (GMP), sanitation</p>	<p><b>Article 4 states:</b> <b>General and specific hygiene requirements</b> 1. Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I and any specific requirements provided for in Regulation (EC) No 853/2004.</p>	<p>In the guidance document (Commission Notice 2016/C 278/01) <b>Annex I</b> states: <b>Prerequisite programs (PRPs)</b> Each FBO should implement prerequisite programs as part of the Food Safety Management System (FSMS). They include good hygiene practices (GHP) and good manufacturing practices (GMP) among other</p>

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<p>standard operation procedure (SSOP), safety and sanitation security system of packaging material of raw material or that directly contacting foods, recall and tracing system, equipment and facility maintenance plan and emergency plan. Plant prerequisite plan shall be approved and recorded.</p> <p><b>6.2 Human Resource Security Plan</b> Plant shall establish and implement human resource security plan, so as to ensure that all personnel engaged in food safety work are competent. The plan shall meet the following requirements: a) Provide continuous training on HACCP system, relevant professional technology knowledge, operating skills, laws and regulations, or take other measures to ensure that all managers and staff are equipped with necessary capacity; b) Assess the effectiveness of training provide or other</p>	<p>2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No 853/2004.</p> <p>3. Food business operators shall, as appropriate, adopt the following specific hygiene measures: (a) compliance with microbiological criteria for foodstuffs; (b) procedures necessary to meet targets set to achieve the objectives of this Regulation; (c) compliance with temperature control requirements for foodstuffs; (d) maintenance of the cold chain; (e) sampling and analysis.</p> <p><b>Annex II, Chapter XII stipulates:</b> <b>Training</b> Food business operators are to ensure:</p> <ol style="list-style-type: none"> <li>1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;</li> <li>2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received</li> </ol>	<p>good practices. Food hygiene and safety is the result of the implementation by food businesses of prerequisite programs (PRPs) and procedures based on the HACCP principles. The PRPs provide the foundation for effective HACCP implementation and should be in place before any HACCP-based procedures are established.</p> <p>PRPs must always be in place in any food business, including at primary production.</p> <p>The FBO should describe the applied PRPs, proportionate to the size and nature of the establishment, including a list of responsible person(s).</p> <p>Guidance document (Commission Notice 2016/C 278/01) <b>Annex I, 2 Examples of PRPs, 2.2 Cleaning and disinfection:</b></p> <p>Cleaning and sanitation procedures are part of PRPs, including a description</p> <ol style="list-style-type: none"> <li>a) What, when and how cleaning and disinfection should be considered.</li> <li>b) Typical steps should be removal of visible dirt → cleaning → rinsing → disinfection → rinsing.</li> <li>c) Materials and approach for cleaning equipment should be different between low and highly contaminated areas.</li> </ol>

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measures taken; c) Maintain proper records of personnel education, training, skill and experience.	adequate training in the application of the HACCP principles; and 3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.	d) Hot water should be used as much as possible for cleaning. e) Technical information should be available regarding detergents, disinfection agents (e.g. active component, contact time, concentration). f) Visual checks on cleaning and sampling for analysis (e.g. hygienogram) should be used to control disinfection activities. <b>2.12 Working methodology</b> Work instructions should be kept clear and simple, visible or easily accessible. They may include instructions to clean and remove broken glass immediately and report it, not to leave inspection places unmanned, put finished products in cooled room as soon as possible if cooled storage is required, fill in records correctly as soon as possible, ... <b>Appendix I Glossary</b> Provides definitions for: FSMS, GHP, GMP, PRPs
<b>6.3 Good Manufacture Practice (GMP)</b> Plant shall establish and implement GMP according to food regulations and corresponding sanitary regulations.		In the guidance document (Commission Notice 2016/C 278/01) <b>Annex I</b> states: <b>Prerequisite programs (PRPs)</b> Each FBO should implement prerequisite programs as part of the FSMS. They include good hygiene practices (GHP) and good manufacturing practices (GMP) among other good practices.

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<p><b>6.4 Sanitation Standard Operation Procedure (SSOP)</b> Plant shall at least meet the following requirements when establishing and implementing SSOP:</p> <p>a) Water and ice contacting foods (including raw material, semi-finished product and finished product) or those in articles contacting foods shall meet the safety and sanitation requirements;</p> <p>b) Instruments, gloves or interior and exterior packaging materials contacting foods shall be clean, sanitary and safe;</p>	<p><b>Annex II</b> to the Regulation provides detailed requirements under the heading: <b>General hygiene requirements for all food business operators, Chapter VII deals with water supply:</b></p> <p>1. a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;</p> <p>4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water.</p> <p><b>Chapter V deals with equipment requirements</b> All articles, fittings and equipment with which food comes into contact are to:</p> <p>(a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;</p> <p>(b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;</p> <p>(c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected;</p>	<p>In addition, the guidance document (Commission Notice 2016/C 278/01) <b>Annex I</b> lays down the: <b>Prerequisite programs (PRPs)</b> <b>2.8 Water and air control</b></p> <p>a) Regular own microbiological and chemical analysis of water directly in contact with food (unless community potable water) should be carried out. Factors such as the source, intended use of the water, etc. will determine the frequency of analysis.</p> <p><b>2.1 Infrastructure (building, equipment)</b> j) Equipment and monitoring/recording devices (e.g. thermometers) should be clean and the equipment suitable for contact with food products.</p>

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<p>c) Protect foods free from cross contamination;</p> <p>d) Ensure that hands of operators are cleaned and disinfected and the toilet facilities are clean;</p> <p>e) Protect food safety free of hazard by lubricants, fuels, articles for cleaning and</p>	<p>(d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.</p> <p><b>Chapter IX Provisions applicable to foodstuffs</b></p> <p>3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.</p> <p><b>Chapter VIII Personal hygiene</b></p> <p>1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.</p> <p><b>Chapter I General requirements for food premises</b></p> <p>3. An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.</p> <p>2. b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;</p>	<p>k) Attention should be paid to the different possibilities whereby the use of equipment can result in (cross-) contamination of food:</p> <p>i. Prevention of contamination of the equipment by the environment e.g. condensation dripping from ceilings;</p> <p>ii. Prevention of contamination within the food handling equipment e.g. accumulation of food residues in slicing devices;</p> <p>iii. Prevention of contamination by raw materials: separate equipment (or cleaning and disinfection between use) for raw products and cooked products (chopping boards, knives, dishes, ...).</p> <p><b>2.9 Personnel (hygiene, health status)</b></p> <p>c) Hands should be washed (+ disinfected) regularly, as a minimum, before starting to work, after using the lavatory, after breaks, after rubbish disposal, after coughing or sneezing, after handling of raw materials, ...</p> <p><b>2.1 Infrastructure (building, equipment)</b></p> <p>h) Toilets should not open directly to food handling areas. Preferably water flushing with use of foot/arm pedals should be present and reminders to wash hands strategically placed.</p> <p><b>2.5 Physical and chemical contaminations from production environment</b></p> <p>a) The frequency of the control of physical hazards (glass, plastic, metal, ...) should be determined using a risk-based analysis (how big</p>

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<p>disinfecting, condensate and other chemical, physical and biological contaminants;</p> <p>f) Correctly label, store and use various toxic chemicals;</p> <p>g) Ensure the physical health and sanitation of the personnel contacting foods;</p> <p>h) Prevent and eliminate damage caused by rats and insects.</p>	<p><b>Chapter IX Provisions applicable to foodstuffs</b></p> <p>3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.</p> <p><b>Chapter I General requirements for food premises</b></p> <p>10. Cleaning agents and disinfectants are not to be stored in areas where food is handled.</p> <p><b>Chapter VIII Personal hygiene</b></p> <p>2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.</p>	<p>is the likelihood of occurrence in an establishment in question?).</p> <p>b) A procedure should be available explaining what to do in case of breakage of glass, hard plastic, knives, ...</p> <p>c) Only cleaning products suitable for food contact surfaces should be used in food processing environments where there is some possibility of incidental food contact. Other cleaning products should be only used outside periods of production.</p> <p>d) Possible chemical hazards should only be dealt with by specialized, trained staff. Weighing scales for additives should be automatic.</p> <p><b>2.9 Personnel (hygiene, health status)</b></p> <p>a) Personnel should be aware of hazards from gastro-intestinal infections, hepatitis and wounds with appropriate exclusion from food handling or suitable protection; relevant health problems should be reported to the manager. Special consideration should be given to temporary workers who might be less familiar with potential hazards.</p> <p><b>2.3 Pest control: focus on prevention</b></p> <p>a) External walls should be free of cracks or chinks, surroundings neat and clean and areas for cleaning accessible.</p>

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SSOP record shall be preserved.	<p><b>Chapter IX Provisions applicable to foodstuffs</b></p> <p>4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).</p> <p><b>Article 5, point 4:</b> Food business operators shall:</p> <p>(a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;</p> <p>(b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;</p> <p>(c) retain any other documents and records for an appropriate period.</p>	<p>b) Insect screen should be placed at windows. c) Doors should be kept closed except when loading and or unloading. d) Unused equipment and rooms should be clean. e) The presence of an indoor pool of water should be immediately addressed. f) A pest control program should be available</p> <p><i>In the guidance document (Commission Notice 2016/C 278/01) <b>Annex II, point 10</b> specifies</i> <b>Documentation and record keeping:</b> Recommended documentation includes: — PRPs applied, working instructions, standard operational procedures, control instructions.</p> <p><b>Annex II, point 10</b> concludes: Records should be kept for an appropriate period of time. That period should be long enough to ensure information to be available in case of an alert that can be traced back to the food in question. Cleaning and sanitation procedures are part of PRPs and fall under these requirements of record keeping.</p>
<p><b>6.5 Safety and Sanitation Security System of Raw Material and Food Packaging Material</b> Plant shall protect raw material and food packaging material free of food safety hazard, and shall establish and implement its safety</p>	<p>Reg 178/2002 provides in Art 18:</p> <p>2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance</p>	<p>The guidance document (Commission Notice 2016/C 278/01) <b>Annex I, 2.10 Raw materials</b> states: a) Consideration should be given not only to the supply of raw materials themselves but also to</p>

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<p>and sanitation security system so as to meet the following requirements:</p> <p>a) Establish valid qualification conditions for raw material and food packaging material suppliers, and determine the supplier name list;</p> <p>b) Assess the capacity of raw material and food packaging material suppliers to provide product safety and sanitation, and carry out document review or site review for the supplier's food safety management system;</p> <p>c) Establish acceptance requirements and procedure for raw material and food packaging material, including checking for inspection and quarantine, sanitation qualification and tracing mark of raw material and food packaging material; carry out targeted inspection and verification for the health and sanitation of raw material and food packaging material where necessary;</p> <p>d) Establish control measures for food additives where necessary;</p> <p>e) Establish the supplier's assessment system, including elimination system for rejected suppliers.</p>	<p>intended to be, or expected to be, incorporated into a food or feed.</p> <p><b>Commission Regulation (EC) No 1935/2004</b> provides general principles of safety and inertness for all Food Contact Materials and sets out a harmonised legal EU framework.</p> <p>Art. 11 of Reg 178/2002 and Art 10 of Reg 852/2004 provide that any supplies from Third countries must comply with the EU food law. As EU food business operators, importers must verify that these conditions are met.</p>	<p>the supply of additives, processing aids, packaging material and food contact material.</p> <p>b) A strict supply policy, containing agreement on specifications (e.g. microbiological) and hygiene assurance and/or requesting a certified quality management system can be taken into account in the extent of details on the PRPs and HACCP plan of the establishment itself</p> <p>c) Apart from agreements with and possible auditing of the supplier, a number of issues might give a good indication on the reliability of the supplier such as homogeneity of delivered goods, compliance with agreed delivery period, accuracy of information added, sufficient shelf life or freshness, use of clean and suitably equipped transportation, hygiene awareness of the driver and other food handlers transporting the food, correct temperature during transport, long term satisfaction, etc. Most of these issues should be part of a reception control. It may be necessary to be aware of previous cargoes of a transport vehicle in order to implement adequate cleaning procedures to reduce the likelihood of cross contamination.</p> <p>d) Storage conditions at the establishment itself should take into account any instructions provided by the supplier, 'first in, first out' or 'first expire, first out' principles, accessibility for inspection from all sides (e.g. not placed directly on the ground, against walls, ...).</p>

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<p><b>6.6 Maintenance Plan</b> Plant shall establish and implement maintenance plans for plant area, plant, facility and equipment, maintain them in good conditions and protect them free from contamination.</p>	<p>Annex II, Chapter I to Reg 852/2004 provides: 1. Food premises are to be kept clean and maintained in good repair and condition. 2. The layout, design, construction, siting and size of food premises are to: (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise airborne contamination, and provide adequate working space to allow for the hygienic performance of all operations;</p>	
<p><b>6.7 Marking and Tracing Plan and Product Recall Plan</b> <b>6.7.1 Marking and tracing plan</b> Plant shall ensure that it has capacity to identify products and trace their states. It shall establish and implement product marking and tracing plan, which shall at least meet the following requirements: a) Identify product with proper method, and ensure its traceability during the whole food production process; b) Mark the product state in allusion to monitoring and verification requirements; c) Maintain product shipment record, including all distributors, retailers, customers and the consumers.</p>	<p><b>Regulation (EC) No 178/2002, Article 18</b> states: 1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution. 2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand. 3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information</p>	<p>In addition, detailed requirements for the traceability of food of animal origin has been laid down in implementing Regulation (EU) No 931/2011, Article 3: 1. Food business operators shall ensure that the following information concerning consignments of food of animal origin is made available to the food business operator to whom the food is supplied and, upon request, to the competent authority: (a) an accurate description of the food; (b) the volume or quantity of the food; (c) the name and address of the food business operator from which the food has been dispatched; (d) the name and address of the consignor (owner) if different from the food business operator from which the food has been dispatched;</p>

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<p><b>6.7.2 Product recall plan</b> Plant shall establish product recall plan, and ensure that all released products under safety hazard effect are recalled. This plan shall at least cover the following requirements:</p> <ul style="list-style-type: none"> <li>a) Ensure the responsibilities and rights of personnel starting and implementing product recall plan;</li> <li>b) Ensure relevant laws and regulations and related requirements which shall be complied with;</li> <li>c) Establish and implement recall measures for products under safety hazard effect;</li> <li>d) Establish analysis and disposal measures for recalled products;</li> <li>e) Periodic drill and verify its effectiveness.</li> </ul> <p>Implementation record for product recall plan shall be maintained.</p>	<p>shall be made available to the competent authorities on demand.</p> <p>4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.</p> <p><b>Regulation (EC) No 178/2002, Article 19</b> states:</p> <p>1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.</p>	<ul style="list-style-type: none"> <li>(e) the name and address of the food business operator to whom the food is dispatched;</li> <li>(f) the name and address of the consignee (owner), if different from the food business operator to whom the food is dispatched;</li> <li>(g) a reference identifying the lot, batch or consignment, as appropriate; and</li> <li>(h) the date of dispatch.</li> </ul> <p>2. The information referred to in paragraph 1 shall be made available in addition to any information required under relevant provisions of Union legislation concerning the traceability of food of animal origin.</p> <p>3. The information referred to in paragraph 1 shall be updated on a daily basis and kept at least available until it can be reasonably assumed that the food has been consumed.</p>

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	<p>2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.</p> <p>3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.</p> <p>4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.</p>	
<p><b>6.8 Emergency Plan</b> Plant shall identify and determine potential food safety accident or emergency situation,</p>	<p><b>Regulation (EC) No 178/2002, Article 17</b> states:</p>	<p><i>Emergency plans are not part of food hygiene rules in the EU. If the safety of food products becomes compromised in a situation of</i></p>

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<p>preestablish response plan and measure, and make response where necessary to reduce the effect of potential safety hazard. Where necessary, especially in or after accident or emergency situation, plant shall review and improve the emergency plan. Implementation record for emergency plan shall be maintained. Periodic drill shall be conducted and its effectiveness shall be verified. Note: emergency situations include conditions put the plant's products under effect of force majeure, like natural disaster, epidemic situation and biohazard.</p>	<p>Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.</p>	<p><i>disaster or emergency, food must not be placed on the market.</i></p>
<p><b>7 Establishment and Implementation of HACCP Plan</b> <b>7.1 General</b> HACCP team shall establish and implement food HACCP plan according to the following 7 principles and systematically control the significant hazard, so as to prevent and eliminate such hazard, or reduce it to an acceptable level, and further to guarantee food safety. a) Carry out hazard analysis and establish control measures; b) Determine critical control point; c) Determine critical limit; d) Establish monitoring system of critical control point; e) Establish correction measures; f) Establish verification procedure;</p>	<p><b>Regulation (EC) No 852/2004, Article 5</b> <b>Hazard analysis and critical control points</b> 1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. 2. The HACCP principles referred to in paragraph 1 consist of the following: (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels; (b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels; (c) establishing critical limits at critical control points which separate</p>	

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<p>g) Establish maintenance system for documents and records. Any change in factors affecting the effectiveness of HACCP plan, like the change in product formula, process and processing condition, may affect the change of HACCP plan. Thus, the HACCP plan shall be confirmed and verified, and updated where necessary.</p>	<p>acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;</p> <p>(d) establishing and implementing effective monitoring procedures at critical control points;</p> <p>(e) establishing corrective actions when monitoring indicates that a critical control point is not under control;</p> <p>(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs to (e) are working effectively; and</p> <p>(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).</p> <p>When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.</p> <p>3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.</p> <p>4. Food business operators shall:</p>	

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	<ul style="list-style-type: none"> <li>(a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;</li> <li>(b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;</li> <li>(c) retain any other documents and records for an appropriate period.</li> </ul>	
<p><b>7.2 Preliminary Steps</b>  <b>7.2.1 Composition of HACCP team</b>  The capacity of personnel in plant HACCP team shall meet the specialized technical requirements of food production in this plant; the team shall consist of personnel from different departments, including the departments of sanitary quality control, product R&amp;D, production process technology, equipment and facility management, raw material purchasing, marketing, storing and transporting. Where necessary, outside expert may be invited. Team members shall be provided with professional knowledge and experience on product, process and hazard involved in this plant, and shall be properly trained. Top management shall designate a HACCP team leader, and empower him with responsibility and authority on the following aspects:</p>		<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex II, Heading 3: Preliminary activities</b>  <b>3.1 Assembly of a multidisciplinary HACCP team</b>  This team, which involves all parts of the food business concerned with the product, should include the whole range of specific knowledge and expertise appropriate to the product under consideration, its production (manufacture, storage, and distribution), its consumption and the associated potential hazards and should also involve as much as possible the higher management levels. The team should get the full support of the management who should consider itself owner of the HACCP plan and overall FSMS. Where necessary, the team should be assisted by specialists who will help it to solve its difficulties as regards assessment</p>

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<p>a) Ensure that the process required for HACCP system is established, implemented and maintained;</p> <p>b) Report the effectiveness, suitability and updating or improving demand (if any) of HACCP system to top management;</p> <p>c) Lead and organize the work of HACCP team, and ensure that the HACCP team members are continuously improved in professional knowledge, skill and experience through education, training and practice. Record of education background, experience, training, approval and activity of HACCP team member shall be maintained.</p> <p><b>7.2.2 Product description</b> HACCP team shall identify and determine the applicable information (as listed below) required for hazard analysis in allusion to the product:</p> <p>a) Name, category, composition as well as biological, chemical and physical properties of raw material and food packaging material;</p>		<p>and control of critical points. The team may include specialists and technicians:</p> <ul style="list-style-type: none"> <li>— who understand the biological, chemical or physical hazards connected with a particular product group,</li> <li>— who have responsibility for, or are closely involved with, the technical process of manufacturing the product under study,</li> <li>— who have a working knowledge of the hygiene and operation of the process plant and equipment,</li> <li>— any other person with specialist knowledge of. microbiology, hygiene or food technology.</li> </ul> <p>One person may fulfil several or all of these roles, provided all relevant information is available to the team and is used to ensure that the system developed is reliable. Where expertise is not available in the establishment, advice should be obtained from other sources (consultancy, guides of good hygiene practices, etc. not excluding other companies of the same group (at sectorial or association level) where expertise is available).</p> <p><b>3.2 Description of the product(s) at the end of process (called hereafter ‘end product’)</b> A full description of the end product should be drawn up, including relevant safety information such as:</p> <ul style="list-style-type: none"> <li>— Origin of ingredients/raw materials, which may help identify certain hazards,</li> <li>— composition (e.g. raw materials, ingredients, additives, possible allergens etc.),</li> </ul>

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<p>b) Source, production, packaging, storage, transportation and delivery mode of raw material and food packaging material;</p> <p>c) Reception requirement, reception mode and use mode of raw material and food packaging material;</p> <p>d) Name, category, composition as well as biological, chemical and physical properties of the product;</p> <p>e) Processing mode of the product;</p> <p>f) Packaging, storage, transportation and delivery modes of the product;</p> <p>g) Marketing mode and mark of the product;</p> <p>h) Other necessary information.</p> <p>Record of product description shall be maintained.</p> <p><b>7.2.3 Determination of intended use</b> HACCP team shall identify and determine the applicable information (as listed below) required for hazard analysis on the basis of product description:</p> <p>a) Consumption or use expectation of the customer on the product;</p> <p>b) Intended use, storage condition and warranty period of the product;</p> <p>c) Intended edible or use modes of the product; d) Intended customer of the product;</p> <p>e) Applicability of directly consumed product to vulnerable group;</p> <p>f) Unintended (but much more likely to occur) edible or use modes of product;</p> <p>g) Other necessary information.</p>		<ul style="list-style-type: none"> <li>— structure and physico-chemical characteristics (e.g. solid, liquid, gel, emulsion, moisture content, pH, water activity, etc.),</li> <li>— processing (e.g. heating, freezing, drying, salting, smoking, etc. and to what extent),</li> <li>— packaging (e.g. hermetic, vacuum, modified atmosphere) and labelling,</li> <li>— storage and distribution conditions, including transport and handling</li> <li>— required shelf life (e.g. ‘use by date’ or ‘best before date’),</li> <li>— instructions for use,</li> <li>— any microbiological or chemical criteria applicable.</li> </ul> <p><b>3.3 Identification of intended use</b> The HACCP team should also define the normal or expected use of the product by the customer and by the consumer target groups for which the product is intended. In specific cases, the suitability of the product for particular groups of consumers, such as institutional caterers, travellers, etc. and for vulnerable groups of the population may have to be considered.</p>

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<p>Record for intended use of the product shall be maintained.</p> <p><b>7.2.4 Establishment of flow diagram</b> HACCP team shall draw process flow diagram of the product according to the operation requirements within the production scope of the plant. This diagram shall include:</p> <ul style="list-style-type: none"> <li>a) Each step and corresponding operation;</li> <li>b) Sequence and interrelationship of such steps;</li> <li>c) Rework point and cycle point (where suitable);</li> <li>d) External process and outsourced content;</li> <li>e) Input point of raw material, auxiliary material and intermediate product;</li> <li>f) Discharge point of waste.</li> </ul> <p>The establishment of flow diagram shall be complete, exact and clear.</p> <p>The operation requirements and process parameters of each processing step shall be listed in process description. If applicable, plant location diagram, plant area plan, workshop plan, people and material flow diagram, supply and drainage network diagram, moth-proof layout diagram shall be provided.</p> <p><b>7.2.5 Confirmation of flow diagram</b> HACCP team personnel who are familiar with operation process shall carry out on-site verification for all operation steps under</p>		<p><b>3.4 Construction of a flow diagram (description of manufacturing process)</b> Whatever format is chosen, all steps involved in the process should be studied in sequence and presented in a detailed flow diagram. 30.7.2016 EN Official Journal of the European Union C 278/11 All processes (from receiving the raw materials to placing the end product on the market) including delays during or between steps, should be mentioned together with sufficient technical data that is relevant for food safety, such as temperature and the duration of heat treatment. Types of data may include but are not limited to:</p> <ul style="list-style-type: none"> <li>— plan of working premises and ancillary premises,</li> <li>— equipment layout and characteristics,</li> <li>— sequence of all process steps (including the incorporation of raw materials, ingredients or additives and delays during or between steps),</li> <li>— technical parameters of operations (in particular time and temperature, including delays),</li> <li>— flow of products (including potential cross-contamination),</li> <li>— segregation of clean and dirty areas (or high/low risk areas).</li> </ul> <p><b>3.5 On-site confirmation of flow diagram</b> After the flow diagram has been drawn up, the HACCP team should confirm it on site during operating hours. Any observed deviation must</p>

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operating state, so as to confirm and verify that they are consistent with the established flow diagrams, and to carry out modification where necessary. The confirmed flow diagram shall be maintained.		result in an amendment of the original flow diagram to make it accurate.
<b>7.3 Hazard Analysis and Control Measures Preparation</b> <b>7.3.1 Hazard identification</b> HACCP team shall consider the following factors when analyzing the biological, chemical and physical hazards in processing step according to the food risk degree: <ul style="list-style-type: none"> <li>a) Product, operation and environment;</li> <li>b) Safety and sanitation requirements for product, raw material and food packaging materials by the consumers, customers, laws and regulations;</li> <li>c) Monitoring and assessment results on edible and use safety of the product;</li> <li>d) Disposal, correction, recall and emergency plan of unsafe product;</li> <li>e) Historical and current data and food safety accidents on epidemiology, animal and plant epidemic situation or morbidity statistics;</li> <li>f) Scientific and technical literature, including hazard control guideline for relevant product;</li> <li>g) Effect of other step on the product within the scope of hazard identification;</li> <li>h) Artificial destruction and deliberate contamination.</li> <li>i) Experience.</li> </ul>	<b>Regulation (EC) No 178/2002, Article 3 (14):</b> A hazard is a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect.	Guidance document <b>Commission Notice 2016/C 278/01, Annex II, Heading 4. Hazard analysis (Principle 1)</b> <b>4.1 Listing of relevant hazards</b> All major potential biological, chemical or physical hazards that may be reasonably expected to occur at each process step (including production, acquisition, storage, transport and handling of raw materials and ingredients and delays during manufacture) should be identified and listed. It may be useful to consult external source of information (e.g. the Rapid Alert System for Food and Feed).

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<p>For each considered hazard from raw material production to final consumption, all potential hazards and their causes in each operation step on intended introduction, generation and increase shall be identified.</p> <p>Where any factor affecting the identification result is changed, HACCP team shall repeat the hazard identification.</p> <p>Records of hazard identification criterion and result shall be maintained.</p> <p><b>7.3.2 Hazard assessment</b></p> <p>HACCP team shall assess its severity and probability in allusion to the identified potential hazard. If this potential hazard is much more likely to occur and will result in serious consequence in this step, it shall be determined as significant hazard.</p> <p>Records of hazard assessment criterion and result shall be maintained.</p>		<p>The HACCP team should next conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food (end product). In conducting the hazard analysis, the following should be considered:</p> <ul style="list-style-type: none"> <li>— the likelihood of occurrence of hazards and severity of their adverse health effects;</li> <li>— the qualitative and/or quantitative evaluation of the presence of hazards;</li> <li>— the survival or multiplication of pathogenic micro-organisms and unacceptable generation of chemicals in intermediate products, end products, production line or line environment;</li> <li>— the production or persistence in foods of toxins or other undesirable products of microbial metabolism, chemicals or physical agents or allergens;</li> <li>— the contamination (or recontamination), of a biological (micro-organisms, parasites),</li> </ul>

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<p><b>7.3.3 Establishment of control measures</b>  HACCP team shall establish corresponding control measures in allusion to each significant hazard, and provide evidence to verify its effectiveness; it shall define corresponding relationship between significant hazard and control measures, and consider the conditions where one control measure controls multiple significant hazards or multiple control measures control one significant hazard. Food defense plan shall be established as a control measure in allusion to the significant hazard caused by artificial destruction or deliberate contamination. Where operating change is involved in such measures, corresponding change shall be carried out and flow diagram shall be modified. Since effective control measures for some significant hazard can't be established under existing technical conditions, plant shall plan and implement necessary technical renovation, and change the process, product (including raw material) or intended use where necessary, until establishing effective control measures. All established control measures shall be confirmed. Where the effectiveness of control measures is affected, such measures shall be assessed, updated, improved and then reconfirmed. Establishment criterion and</p>		<p>chemical or physical nature, of raw materials, intermediate products or end products.</p> <p><b>4.2 Control measures</b>  The FBO should consider and describe what control measures, if any, can be applied for each hazard.  Control measures are those actions and activities that can be used to prevent hazards, eliminate them or reduce their impact or likelihood of occurrence to acceptable levels. Many preventive control measures are part of PRPs and are intended to avoid contamination from the production environment (e.g. personnel, pest, water, maintenance which are listed as examples in Annex I). Other control measures aiming at reduction or elimination of hazards are more specifically linked to particular production process e.g. pasteurization, fermentation and may result in the establishment of CCPs or operational PRPs (oPRPs).  More than one control measure may be required to control an identified hazard e.g. pasteurization controlled by time, temperature and flow rate of the fluid and more than one hazard may be controlled by one control measure e.g. pasteurization or controlled heat treatment may provide sufficient assurance of reduction of the level of several pathogenic micro-organisms such as <i>Salmonella</i> and <i>Listeria</i>.</p>

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<p>document of control measures shall be maintained.</p> <p><b>7.3.4 Hazard analysis sheet</b> HACCP team shall provide hazard analysis sheet for documentation according to the results of process flow, hazard identification, hazard assessment and control measures, including processing step, considered potential hazard, judgment criterion of significant hazard and control measures; it shall also define the interrelationship among factors. Relationship between control measures and corresponding significant hazard shall be described in the hazard analysis sheet, so as to provide criterion for the determination of critical control point. HACCP team shall make necessary update or revision for hazard analysis sheet where the hazard analysis result is affected. Hazard analysis sheet for documentation shall be maintained.</p>		<p>Control measures should be validated. Control measures should be supported by detailed procedures and specifications to ensure their effective implementation.</p> <p><i>Documentation requirements are listed separately in the Guidance document Commission Notice 2016/C 278/01, Annex II, heading 10.</i></p>
<p><b>7.4 Determination of Critical Control Point (CCP)</b> HACCP team shall identify proper step for control of each significant hazard according to the relationship between significant hazard and control measures provided in hazard analysis, so as to determine CCP, and ensure that all significant hazards are effectively controlled. Plant shall adopt suitable method (like judgment tree in Appendix A) to</p>		<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex II, Heading 5. Identification of critical control points (CCP) (Principle 2)</b> The identification of a CCP requires a logical approach. Such an approach can be facilitated by the use of a decision tree or other methods, according to the knowledge and experience of the HACCP team.</p>

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<p>determine CCP However, the following factors shall be considered when adopting judgment tree:</p> <p>a) Judgment tree is only a tool contributing to the determine CCP, and cannot supersede professional knowledge;</p> <p>b) Judgment tree is used after hazard analysis and during determination of significant hazard;</p> <p>c) Subsequent processing step may be more effective to control hazard, and may be the preferred CCP which shall be selected;</p> <p>d) In processing, above 1 step may control 1 hazard.</p> <p>Where significant hazard or control measures are changed, HACCP team shall repeat the hazard analysis to judge CCP.</p> <p>Criterion and document determined by CCP shall be maintained. Where standard operating procedure (SOP) control is identical with CCP control according to analysis, the criterion, parameter document determined by SOP shall be maintained.</p>		<p>The identification of CCPs has two consequences for the HACCP team which should then:</p> <ul style="list-style-type: none"> <li>— ensure that appropriate control measures are effectively designed and implemented. In particular, if a hazard has been identified at a step where control is necessary for product safety and no control measure exists at that step, or at any other further on in the production process, then the product or process should be modified at that step or at an earlier or later stage, to include a control measure;</li> <li>— establish and implement a monitoring system at each CCP.</li> </ul> <p>Each process step identified in the flow diagram should be considered in sequence. At each step, the decision tree and/or risk evaluation should be applied to each hazard that may be reasonably expected to occur or be introduced and each control measure identified. Application should be flexible, considering the whole manufacturing process in order to avoid, whenever possible, unnecessary CCPs. Training in the application of a method to identify CCPs is recommended.</p> <p>As illustrated in the Appendices, the hazard analysis may identify different levels of risks for each process step:</p> <ul style="list-style-type: none"> <li>— For lower risk levels it can be concluded that, if robust PRPs are in place, these PRPs are sufficient to control the hazards</li> </ul>

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		<p>— For intermediate levels of risks identified, ‘intermediate’ measures can be proposed, such as ‘operational PRPs (oPRPs (sometimes other wording is used such as ‘Control Point (CP)’, as not all intermediate measures are linked to an operation, or ‘Points of Attention’ (PoA)).</p> <p>— oPRPs are PRPs that are typically linked to the production process and are identified by the hazard analysis as essential, in order to control the likelihood of the introduction, survival and/or proliferation of food safety hazards in the product(s) or in the processing environment. Similarly to CCPs, operational PRPs include measurable or observable action criteria or action limits (but targets rather than critical limits), monitoring of the implementation of control measures, monitoring records and corrective actions if needed. Examples are:</p> <p>— Control of washing process of vegetables (e.g. by frequency of wash water refreshment to avoid microbial cross-contamination, mechanical action in the water to remove physical hazards as stones, pieces of wood)</p> <p>— Control of blanching process for the deep freezing industry (time/temperature)</p> <p>Washing and blanching processes can usually not be considered as CCPs because neither full elimination of the microbial hazards nor reduction to an acceptable level can be achieved or is aimed at. However, they will impact the microbial load of the processed products.</p>

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		<ul style="list-style-type: none"> <li>— More intensive cleaning and disinfection in high care areas, more strict personal hygiene in high care areas, for example in packaging areas of ready to eat food.</li> <li>— More severe incoming check upon reception of raw materials if supplier is not guaranteeing the desired quality/safety level (e.g. mycotoxins in spices).</li> <li>— Control of allergens by a sanitation program</li> <li>— For high level of risks, which are not controlled by PRPs or oPRPs, CCPs should be established.</li> </ul>
<p><b>7.5 Determination of Critical Limit</b>  HACCP team shall establish a critical limit for each CCP, and one CCP may have one or more critical limit (s).  The establishment of critical limit shall be scientific, visual and easy for monitoring, so as to ensure that the product safety hazard is effectively controlled and within the acceptable level.  The assessed competent personnel shall carry out monitoring and judgment based on perceptive critical limit.  HACCP team should establish CCP operation limit to prevent or reduce deviation from critical limit. Records of critical limit determination criterion and result shall be maintained.  Note: critical limits may be time, rate, temperature, humidity, moisture content, water activity, pH value and salt content.</p>		<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex II, Heading 6. Critical limits at CCPs (Principle 3)</b>  Each control measure associated with a critical control point should give rise to the specification of critical limits.  Critical limits correspond to the extreme values acceptable with regard to product safety. They separate acceptability from unacceptability. They are set for observable or measurable parameters which can demonstrate that the critical point is under control. They should be based on substantiated evidence that the chosen values will result in process control.  Examples of such parameters include temperature, time, pH, moisture content, amount of additive, preservative or salt, sensory parameters such as visual appearance or texture, etc.</p>

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		<p>In some cases, to reduce the likelihood of exceeding a critical limit due to process variations, it may be necessary to specify more stringent levels (i.e. target levels) to assure that critical limits are observed.</p> <p>Critical limits should be validated and should have clear, specific values.</p> <p>Critical limits may be derived from a variety of sources. When not taken from regulatory standards or from guides of good hygiene practices, the HACCP team should ascertain their validity relative to the control of identified hazards at CCPs.</p>
<p><b>7.6 CCP Monitoring</b></p> <p>Plant shall establish and implement effective monitoring measures in allusion to each CCP, and guarantee that CCP is controlled; monitoring measures include monitoring object, method, frequency and personnel.</p> <p>Monitoring objects shall include all critical limits involved with each CCP; the monitoring method shall be exact and timely; generally, continuous monitoring shall be implemented; where discontinuous monitoring is adopted, its frequency shall be able to guarantee the control requirements of CCP; monitoring personnel shall accept suitable training, understand monitoring purpose and importance, get familiar with monitoring operation, and timely and accurately record and report the monitoring result.</p>		<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex II, Heading 7. Monitoring procedures at CCPs (Principle 4)</b></p> <p>An essential part of HACCP-based procedures is a program of observations or measurements performed at each CCP to ensure compliance with specified critical limits.</p> <p>Observations or measurements must be able to detect loss of control at CCPs and provide information in time for corrective action to be taken.</p> <p>Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be made before a deviation occurs (the critical limit is not met). Data derived from monitoring must be evaluated by a designated and experienced person with</p>

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<b>Chinese National standard GB-27341</b>	<b>EU Regulation (EC) No 852/2004</b>	<b>Implementing rules and remarks</b>
<p>Where deviation from operation limit is indicated in monitoring, monitoring personnel shall timely take correction to prevent deviation from critical limit.</p> <p>Where deviation critical limit is indicated in monitoring, the monitoring personnel shall immediately stop the operation procedure, and timely take correction measures.</p> <p>Monitoring record shall be maintained.</p>		<p>knowledge and authority to carry out corrective actions when indicated.</p> <p>Observations or measurements can be made continuously or intermittently. When observations or measurements are not continuous, it is necessary to establish a frequency of observations or measurements which provides information in time for corrective actions to be taken.</p> <p>The HACCP plan should describe the methods, the frequency of observations or measurements and the recording procedure for monitoring at CCPs:</p> <ul style="list-style-type: none"> <li>— who is to perform monitoring and checking,</li> <li>— when monitoring and checking is performed,</li> <li>— how monitoring and checking is performed.</li> </ul> <p>The frequency of monitoring should be risk based e.g. depending on the likelihood of hazard occurrence in the product, the volume of production, the distribution of the product, the potential consumers, the number of workers directly handling the product, ...</p> <p>Records associated with monitoring CCPs must be signed by the person(s) doing the monitoring and when records are verified by staff of the company responsible for reviewing.</p>
<p><b>7.7 Correction Measures for Establishment of Critical Limit Deviation</b></p> <p>Plant shall pre-establish correction measures for deviation of each critical limit of CCP for implementation upon deviation.</p>		<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex II, Heading 8. Corrective actions (Principle 5)</b></p> <p>For each CCP, corrective actions should be planned in advance by the HACCP team, so that they can be taken without hesitation when</p>

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Chinese National standard GB-27341	EU Regulation (EC) No 852/2004	Implementing rules and remarks
<p>Correction measures shall include personnel implementing correction measures and releasing affected products, identification and elimination of deviation causes, as well as isolation, assessment and disposal of affected products. Measurement or inspection for biological, chemical or physical properties may be carried out when assessing affected products; where the inspection result shows that the hazard is within the acceptable index, the product may be released to subsequent operation; otherwise, it shall be reworked, degraded, altered or discarded.</p> <p>Correction personnel shall be familiar with product and HACCP plan, and shall be properly trained and authorized.</p> <p>Where the monitoring result of a critical limit repeatedly deviates or the deviation cause involves the control ability of corresponding control measures, HACCP team shall reassess the effectiveness and suitability of relevant control measures, and improve and update them where necessary.</p> <p>Correction record shall be maintained.</p>		<p>monitoring indicates a deviation from the critical limit.</p> <p>Such corrective actions should include:</p> <ul style="list-style-type: none"> <li>— proper identification of the person(s) responsible for the implementation of the corrective action,</li> <li>— means and action required to correct the observed deviation,</li> <li>— action(s) (sometimes called 'corrections' to differentiate from other corrective actions) to be taken with regard to products that have been manufactured during the period when the process was out of control,</li> <li>— written record of measures taken indicating all relevant information (for example: date, time, type of action, actor and subsequent verification check).</li> </ul> <p>Monitoring may indicate that preventive measures (PRPs or their robustness) or the process and its CCPs shall have to be reviewed if corrective actions for the same procedure have to be taken repeatedly.</p>
<p><b>7.8 Confirmation and Verification for HACCP Plan</b></p> <p>Plant shall establish and implement confirmation and verification procedures for HACCP plan, so as to verify the integrity, suitability and effectiveness of HACCP plan.</p> <p>Confirmation procedure shall include effectiveness verification for all elements of</p>		<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex II, Heading 9. Verification (and validation) procedures (Principle 6)</b></p> <p>The HACCP team should specify the methods and procedures to be used for determining if the HACCP-based procedures are working correctly. Methods for verification may include in</p>

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<b>Chinese National standard GB-27341</b>	<b>EU Regulation (EC) No 852/2004</b>	<b>Implementing rules and remarks</b>
<p>HACCP plan. Confirmation shall be carried out before the implementation or after change of HACCP plan.</p> <p>Verification procedure shall include: criterion, method, frequency, personnel, content, result, measure and record of verification.</p> <p>Monitor the review of equipment alignment record; where necessary, carry out technical verification for the required control equipment and method through qualified inspection organization, and provide technical verification report for documentation.</p> <p>Verification result shall be input into the management review to ensure that such data resources are duly considered and can contribute to the continuous improvement of the whole HACCP system; where the verification result fails to meet the requirements, corrective measures shall be taken and then verification shall be repeated.</p>		<p>particular random sampling and analysis, reinforced analysis or tests at selected critical points, intensified analysis of intermediate or end products, surveys on actual condition during storage, distribution and sale and on actual use of the product.</p> <p>The frequency of verification should be sufficient to confirm that HACCP-based procedures are working effectively. The frequency of verification shall depend on the characteristics of the business (output, number of employees, nature of the food handled), the monitoring frequency, the accuracies of the employees, the number of deviations detected over time and the hazards involved.</p> <p>Verification procedures may include:</p> <ul style="list-style-type: none"> <li>— Audits of HACCP-based procedures and their records,</li> <li>— Inspection of operations (people compliance),</li> <li>— Confirmation that CCPs monitoring is implemented and maintained,</li> <li>— Review of deviations and product dispositions; corrective actions taken with regard to the product.</li> </ul> <p>The frequency of verification will greatly influence the amount of recheck or recall required in case a deviation exceeding the critical limits has been detected. Verification should comprise all of the following elements, but not necessarily all at the same time:</p> <ul style="list-style-type: none"> <li>— check on the correctness of the records and analysis of deviations,</li> </ul>

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		<p>— check on the person monitoring processing, storage and/or transport activities,  — physical check on the process being monitored,  — calibration of instruments used for monitoring. Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.</p> <p>At the start of a process or in case of a change, validation activities should be carried out and should gather evidence to confirm the efficacy of all elements of the HACCP plan. Such evidence includes scientific publications, in-house testing, predictive microbiology, ... demonstrating that the critical limits set, will, if adhered to, result in the intended effect on the hazard (no growth, reduction, ...).</p> <p>Examples of changes that may require re-validation include:</p> <ul style="list-style-type: none"> <li>— change in raw material or in product, processing conditions (factory layout and environment, process equipment, cleaning and disinfection program),</li> <li>— change in packaging, storage or distribution conditions,</li> <li>— change in consumer use,</li> </ul>

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		<p>— receipt of any information on a new hazard associated with the product.</p> <p>Where necessary, such a review must result in the amendment of the procedures laid down. The changes should be fully incorporated into the documentation and record-keeping system in order to ensure that accurate up-to-date information is available.</p>
<p><b>7.9 Maintenance of HACCP Plan Record</b></p> <p>Establishment, operation and verification records of HACCP plan shall be maintained. Control of HACCP plan record shall be consistent with that of the system record. HACCP plan record shall include relevant information. Verification record shall at least include the following information:</p> <p>a) Product description record: name and address of plant; processing category; type, name, dosing and characteristic of the product; intended use and customer; edible (use) method; packaging type; storage condition and warranty period; label instruction; marketing and transportation requirements.</p> <p>b) Monitoring record: name of address of plant; product name; processing date; operation procedure; CCP; significant hazard; critical limit (operation limit); control measure; monitoring method and frequency; actually measured or observed result; monitoring personnel signature; monitoring date; review signature and date of monitoring record.</p>		<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex II, Heading 10. Documentation and record keeping (Principle 7)</b></p> <p>Efficient and accurate record keeping is essential to the application of HACCP-based procedures. HACCP-based procedures should be documented in the HACCP-plan and continuously supplemented by records on findings. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP-based procedures are in place and being maintained. Documents and records should be kept for a sufficient period of time beyond the shelf life of the product for traceability purposes, for the regular revision of the procedures by the FBO and to allow the competent authority to audit the HACCP-based procedures. Expert developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilized as part of the documentation, provided that those materials reflect the specific food operations of the</p>

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<p>c) Correction record: name and address of plant; product name; processing date; description and cause of deviation; correction measure and result; batch, isolated location, assessment method and result and final disposal of affected product; correction personnel signature; correction date; review signature and date of correction record.</p> <p>d) Proper records for HACCP plan shall be maintained. For example, main records required for verification activity are HACCP plan amendment record, semi-finished product and finished product periodical inspection record, CCP monitoring review record, CCP correction review record and CCP site verification record.</p>		<p>business. Documents should be signed by a responsible reviewing official of the company. Recommended documentation includes:</p> <ul style="list-style-type: none"> <li>— PRPs applied, working instructions, standard operational procedures, control instructions;</li> <li>— Description of the preparatory stages (before 7 principles);</li> <li>— Hazard analysis;</li> <li>— CCP (+/- oPRPs) identification;</li> <li>— Critical limit determination;</li> <li>— Validation activities;</li> <li>— Corrective actions anticipated;</li> <li>— Description of planned monitoring and verification activities (what, who, when);</li> <li>— Record forms;</li> <li>— Modifications to the HACCP-based procedures;</li> <li>— Supporting documents (generic guides, scientific evidence, ...).</li> </ul> <p>A systematic, integrated approach can be taken by using worksheets for the development of the HACCP plan as provided in the Annex to CAC/RCP 1-1969, Diagram 3. Starting from the flow diagram, at each step of processing the potential hazards are described, relevant control measures (PRPs) listed, CCPs identified (if appropriate based on the hazards analysis) along with their critical limits, monitoring procedures, corrective actions and available records.</p> <p>Record examples are:</p> <ul style="list-style-type: none"> <li>— Outcome of CCP monitoring activities;</li> </ul>

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		<p>— Observed deviations and executed corrective actions;</p> <p>— Outcome of verification activities.</p> <p>Records should be kept for an appropriate period of time. That period should be long enough to ensure information to be available in case of an alert that can be traced back to the food in question. For certain foods the date of consumption is certain. For instance, in food catering, consumption takes place shortly after the time of production. For food for which the date of consumption is uncertain, records should be kept for a reasonably short period after the expiry date of the food. Records are an important tool for the competent authorities to allow verification of the proper functioning of the food businesses' FSMS.</p> <p>A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures (see also Annex III).</p>

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### 1.1.5 National standard GB 2762-2017 – Maximum levels of contaminants in foods

Chinese National standard GB 2762	EU Regulation (EC) No 1881/2006	Implementing rules and remarks
<p><b>1. Scope</b> This standard sets limits for lead, cadmium, mercury, arsenic, tin, nickel, chromium, nitrite, nitrate, Benzo[a]pyrene, N-nitrosodimethylamine, polychlorinated biphenyl, 3-chloro-1, 2-propanediol in foods.</p>	<p><b>Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs</b> <b>Article 1 General rules</b> 1. The foodstuffs listed in the Annex shall not be placed on the market where they contain a contaminant listed in the Annex at a level exceeding the maximum level set out in the Annex. 2. The maximum levels specified in the Annex shall apply to the edible part of the foodstuffs concerned, unless otherwise specified in the Annex</p>	
<p><b>2 Terminologies and definitions</b> <b>2.1 Contaminants</b> Hazardous chemical substance, not intentionally added to food, but brought into such foods in food production (crop growing, animal husbandry and veterinary medicine), processing, packaging, storage, transportation, distribution, and consumption, or introduced a result of environmental contamination. Contaminants in this standard refer to contaminants other than pesticide residue, veterinary drug residue, biotoxin, and radionuclides.</p> <p><b>2.2 Edible part</b></p>	<p><b>Council Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food, Article 1</b> 1. This Regulation concerns contaminants contained in food. 'Contaminant' means any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, reparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Extraneous matter, such as, for example, insect fragments, animal hair, etc, is not covered by this definition.</p>	

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<b>Chinese National standard GB 2762</b>	<b>EU Regulation (EC) No 1881/2006</b>	<b>Implementing rules and remarks</b>
<p>The part of food material for edible use, which is the remaining part after mechanical processing that removes the non-edible part (such as grain husk, fruit peeling, nut shell, bones in meat/fish, shell of shellfish).</p> <p>Note 1: the non-edible parts cannot be removed by non-mechanical means (such as refining of crude vegetable oil);</p> <p>Note 2: quantity of the edible parts may vary when different production techniques are used to produce the same food materials. For example, the edible part could be 100% when processing cereal and wholewheat flour from wheat, while the edible part is calculated by the actual flour extraction rate when producing wheat flour from wheat.</p> <p><b>2.3 Limit</b></p> <p>The maximum content of contaminants in food materials and/or the edible part of the finished food products.</p>		
<p><b>3 Principles of (Standard) Application</b></p> <p>3.1 Regardless of existence of the contaminant limits, the food producers and processors should take control measures to keep the contaminant content in foods at the minimum level.</p> <p>3.2 This standard lists the contaminants that may pose high risks to the public health; the foods with contaminant limits are foods that pose higher impact on consumers’ dietary exposure.</p>		

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<b>Chinese National standard GB 2762</b>	<b>EU Regulation (EC) No 1881/2006</b>	<b>Implementing rules and remarks</b>
<p>3.3 Explanation of the Food Categories (Appendix A) is for defining scope of application of the contaminant limits, and is only applicable to this standard. When a contaminant limit is applied to a certain food category, all types of foods in the food category are subject to the limit unless otherwise specified.</p> <p>3.4 Levels of contaminants in foods are calculated based on the edible parts of the food unless otherwise specified.</p> <p>3.5 When there are limits sets on processed products, the contaminant limits for dried foods are calculated by the dehydration ratio or the concentration ratio of the corresponding fresh foods. The dehydration ratio or the concentration ratio could be determined by analysis of the food, by the information provided by the producer, or by other available data, unless otherwise specified.</p>		
<p><b>4 Specifications</b></p> <p><b>4.1 Lead</b></p> <p>4.1.1 Please refer to Table 1 for lead limits in foods.</p> <p>Table 1 <b>Lead limits in foods:</b> limit (Pb) mg/kg</p> <p>Aquatic animal and its products</p> <p>Fresh, frozen aquatic animal (excluding fish, crustacean, bivalves) 1.0 (viscera removed)</p> <p>Fish, crustacean 0.5</p>	<p><b>Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs,</b></p> <p>Annex: maximum levels for certain contaminants in foodstuffs, Section 3: Metals</p> <p><b>3.1 Lead</b></p> <p>3.1.8 Muscle meat of fish 0,30</p> <p>3.1.9 Cephalopods (without viscera) 0,30</p>	

Chinese National standard GB 2762	EU Regulation (EC) No 1881/2006	Implementing rules and remarks
<p>Bivalves 1.5 Aquatic products (excluding jellyfish products) 1.0 Jellyfish products 2.0</p> <p><b>4.2 Cadmium</b> Limit (in Cd basis) mg/kg Aquatic animal and its products Fresh, frozen aquatic animal</p> <p>Fish 0.1</p> <p>Crustacean 0.5</p>	<p>Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster 0,50 Bivalve molluscs 1,50</p> <p><b>3.2 Cadmium</b></p> <p>3.2.15 Products of animal origin- fish, fish products and any other marine and freshwater food product Muscle meat of fish, excluding species listed under points 3.2.15.2, 3.2.15.3 and 3.2.15.4 0,050 3.2.15.2 Muscle meat of the following fish: mackerel (<i>Scomber species</i>), tuna (<i>Thunnus species</i>, <i>Katsuwonus pelamis</i>, <i>Euthynnus species</i>), bichique (<i>Sicyopterus lagocephalus</i>) 0,10 3.2.15.3 Muscle meat of the following fish: bullet tuna (<i>Auxis species</i>) 0,15 3.2.15.4 Muscle meat of the following fish: anchovy (<i>Engraulis species</i>), swordfish (<i>Xiphias gladius</i>) and sardine (<i>Sardina pilchardus</i>) 0,25 3.2.8 Crustaceans: muscle meat from appendages and abdomen. In case of crabs and crab-like crustaceans (<i>Brachyura</i> and</p>	

Chinese National standard GB 2762	EU Regulation (EC) No 1881/2006	Implementing rules and remarks
<p>Bivalves, gastropods, cephalopods, echinoderms 2.0 (viscera removed)</p> <p>Aquatic products</p> <p>Canned fish (excluding canned anchovy and canned sailfish) 0.2</p> <p>Canned anchovy and canned sailfish 0.3</p> <p>Other fish products (excluding anchovy and sailfish products) 0.1</p> <p>Anchovy and sailfish products 0.3</p> <p><b>4.3 Mercury</b></p> <p>Mercury limits in foods: limit (in Hg basis) mg/kg</p> <p>Aquatic animal and its products (excluding carnivorous fishes and its products) 0.5*</p> <p>Carnivorous fishes and its products 1.0*</p> <p>* for aquatic animal and its products, total mercury could be tested first; if the total mercury level is lower than the limit of methyl mercury, it is not necessary to test the methyl mercury; otherwise, the methyl mercury shall be tested.</p>	<p><i>Anomura</i>) muscle meat from appendages 0,50</p> <p>3.2.9 Bivalve molluscs 1,0</p> <p>3.2.10 Cephalopods (without viscera) 1,0</p> <p><b>3.3 Mercury</b></p> <p>Fishery products and muscle meat of fish, excluding species listed in 3.3.2. The maximum level for crustaceans applies to muscle meat from appendages and abdomen. In case of crabs and crab-like crustaceans (<i>Brachyura</i> and <i>Anomura</i>) it applies to muscle meat from appendages. 0,5</p> <p>Muscle meat of the following fish: anglerfish (<i>Lophius species</i>), atlantic catfish (<i>Anarhichas lupus</i>), bonito (<i>Sarda sarda</i>), eel (<i>Anguilla species</i>), emperor, orange roughy, rosy soldierfish (<i>Hoplostethus species</i>), grenadier (<i>Coryphaenoides rupestris</i>), halibut (<i>Hippoglossus hippoglossus</i>), kingklip (<i>Genypterus capensis</i>), marlin (<i>Makaira species</i>), megrim</p>	

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Chinese National standard GB 2762	EU Regulation (EC) No 1881/2006	Implementing rules and remarks
<p><b>4.4 Arsenic</b> Table 4 Arsenic limits in foods: limit (in As basis) mg/kg Aquatic animal and its products (excluding fish and fish products) 0.5* Fish and fish products 0.1* * for products that should have inorganic arsenic limit, total arsenic should be tested first; when the total arsenic level is lower or equals to the inorganic arsenic limit, it is not necessary to test the inorganic arsenic;</p>	<p>(<i>Lepidorhombus</i> species), mullet (<i>Mullus</i> species), pink cusk eel (<i>Genypterus blacodes</i>), pike (<i>Esox lucius</i>), plain bonito (<i>Orcynopsis unicolor</i>), poor cod (<i>Tricopterus minutes</i>), Portuguese dogfish (<i>Centroscymnus coelolepis</i>), rays (<i>Raja</i> species), redfish (<i>Sebastes marinus</i>, <i>S. mentella</i>, <i>S. viviparus</i>), sail fish (<i>Istiophorus platypterus</i>), scabbard fish (<i>Lepidopus caudatus</i>, <i>Aphanopus carbo</i>), seabream pandora (<i>Pagellus</i> species), shark (all species), butterflyfish (<i>Lepidocybium flavobrunneum</i>, <i>Ruvettus pretiosus</i>, <i>Gempylus serpens</i>), sturgeon (<i>Acipenser</i> species), swordfish (<i>Xiphias gladius</i>), tuna (<i>Thunnus</i> species, <i>Euthynnus</i> species, <i>Katsuwonus pelamis</i>) 1,0</p> <p><b>3.5 Arsenic (inorganic)</b></p> <p>No EU limits defined</p>	

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<p>otherwise, the inorganic arsenic should be tested again.</p> <p>4.4.2 Testing methods: using methods provided in GB 5009.11.</p> <p><b>4.5 Tin</b> Tin limits in foods: limit (in Sn basis) mg/kg Foods (excluding beverages, formula for infants and young children, complementary foods for infants and young children)* 250 * only apply to foods packaged in containers of tinned plate sheet</p> <p><b>4.7 Chromium</b> chromium limits in foods, limit (in Cr basis) mg/kg Aquatic animal and its products 2.0</p>	<p><b>3.4 Tin (inorganic)</b> Canned foods other than beverages 200</p> <p>No EU limits defined</p>	<p><i>No limit values have been laid down for arsenic or chromium in fish or fishery products in EU legislation.</i></p> <p><i>The ALARA Principle applies (as low as reasonably achievable).</i></p>
<p><b>4.9 Benzo[a]pyrene</b> 4.9.1 Please refer to Table 9 for Benzo[a]pyrene limits in foods. Table 9 Benzo[a]pyrene limits in foods. Aquatic animal and its products Smoked, roasted aquatic products 5.0</p>	<p><b>Section 6: Polycyclic aromatic hydrocarbons</b> maximum levels (µg/kg) <b>6.1.5</b> Muscle meat of smoked fish and smoked fishery products, excluding fishery products listed in points 6.1.6 and 6.1.7. The maximum level for smoked crustaceans applies to muscle meat from appendages and abdomen. In case of smoked crabs and crab-like crustaceans (<i>Brachyura</i> and <i>Anomura</i>) it applies to muscle meat from appendages. 2,0 and 12,0 <b>6.1.6</b> Smoked sprats and canned smoked sprats</p>	<p><i>Benzo[a]pyrene (BaP) belongs to the group of compounds known as polycyclic aromatic hydrocarbons (PAHs).</i></p>

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	( <i>Sprattus sprattus</i> ); Smoked Baltic herring ≤ 14 cm length and canned smoked Baltic herring ≤ 14 cm length ( <i>Clupea harengus membras</i> ); Katsuobushi (dried bonito, <i>Katsuwonus pelamis</i> ); bivalve molluscs (fresh, chilled or frozen); heat treated meat and heat treated meat products sold to the final consumer 5,0 and 30,0 <b>6.1.7</b> Bivalve molluscs (smoked) 6,0 and 35,0	
<b>4.10 N-Nitrosodimethylamine</b> 4.10.1 Please refer to Table 10 for N-Nitrosodimethylamine limits in foods. Table 10 - N-Nitrosodimethylamine limits in foods: limit µg/kg Aquatic animal and its products Aquatic products (excluding canned aquatic products) 4.0 Dried aquatic products 4.0		<i>No limits have been laid down for testing of nitrosamines in fish or fishery products in EU legislation.</i> <i>The ALARA Principle applies (as low as reasonably achievable).</i>
<b>4.11 Polychlorinated biphenyl</b> 4.11.1 Please refer to Table 11 for polychlorinated biphenyl limits in foods. Table 11 Polychlorinated biphenyl limits in foods: Limit mg/kg* Aquatic animal and its products 0.5 mg/kg	<b>Section 5: Dioxins and PCBs</b> <b>5.3</b> Muscle meat of fish and fishery products and products thereof, 3,5 pg/g wet weight <sup>1</sup> 6,5 pg/g wet weight <sup>2</sup> 75 ng/g wet weight <sup>3</sup> with the exemption of: — wild caught eel — wild caught spiny dogfish ( <i>Squalus acanthias</i> ) — wild caught fresh water fish, with the exception of diadromous fish species caught	

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<p>* Polychlorinated biphenyl is calculated by total of PCB28, PCB52, PCB101, PCB118, PCB138, PCB153 and PCB180.</p>	<p>in fresh water — fish liver and derived products — marine oils The maximum level for crustaceans applies to muscle meat from appendages and abdomen. In case of crabs and crab-like crustaceans (<i>Brachyura</i> and <i>Anomura</i>) it applies to muscle meat from appendages.</p> <p><b>5.4</b> Muscle meat of wild caught fresh water fish, with the exception of diadromous fish species caught in fresh water, and products thereof 3,5 pg/g wet weight<sup>1</sup> 6,5 pg/g wet weight<sup>2</sup> 125 ng/g wet weight<sup>3</sup></p> <p><b>5.4a</b> Muscle meat of wild caught spiny dogfish (<i>Squalus acanthias</i>) and products thereof 3,5 pg/g wet weight<sup>1</sup> 6,5 pg/g wet weight<sup>2</sup> 200 ng/g wet weight<sup>3</sup></p> <p><b>5.5</b> Muscle meat of wild caught eel (<i>Anguilla anguilla</i>) and products thereof 3,5 pg/g wet weight<sup>1</sup> 10 pg/g wet weight<sup>2</sup> 300 ng/g wet weight<sup>3</sup></p> <p><b>5.6</b> Fish liver and derived products thereof with the exception of marine oils referred to in point 5.7 -- pg/g wet weight<sup>1</sup> 20 pg/g wet weight<sup>2</sup> 200 ng/g wet weight<sup>3</sup></p>	

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	<p><b>5.7</b> Marine oils (fish body oil, fish liver oil and oils of other marine organisms intended for human consumption) 1,75 pg/g wet weight<sup>1</sup></p> <p>6 pg/g wet weight<sup>2</sup></p> <p>200 ng/g wet weight<sup>3</sup></p> <p><sup>1</sup> Sum of dioxins (WHO-PCDD/F-TEQ)</p> <p><sup>2</sup> Sum of dioxins and dioxin-like PCBS (WHO-PCDD/F-PCB-TEQ)</p> <p><sup>3</sup> Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180 (ICES – 6)</p>	

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### 1.1.6 National standard GB 2763-2021 – Maximum residue limits for pesticides in food

<b>Chinese National standard GB 2763</b>	<b>EU Regulation (EC) No 396/2005</b>	<b>Implementing rules and remarks</b>
<p><b>1. Scope</b> This standard regulates 10,092 maximum residue limits of 564 pesticides (including 2,4-DB) in food. The standard applies to foods related to residue limits. The food categories and testing parts (Appendix A) are used to define the application scope of the pesticides' maximum residue limits, which applies only to this standard. For instance, the maximum residue limit of a pesticide is applicable for a certain food category, thus all foods in this category will be applicable to this MRL, except otherwise specified. The list of pesticides that are exempted from developing MRL standards in food (Appendix B) is used to define scope of pesticides that do not need to have MRL developed.</p>	<p><b>Regulation (EC) No 396/2005, Article 1, Subject matter</b> This Regulation establishes, in accordance with the general principles laid down in Regulation (EC) No 178/2002, in particular the need to ensure a high level of consumer protection and harmonised Community provisions relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin.</p> <p><b>Article 2, Scope</b> 1. This Regulation shall apply to products of plant and animal origin or parts thereof covered by Annex I to be used as fresh, processed and/or composite food or feed in or on which pesticide residues may be present.</p>	
<p><b>2 Normative reference</b> The following documents are essential terms of this document through normative reference by the standard. For dated references, only the dated versions apply to this standard. For not dated references, the latest versions (including all modifications) apply to this standard. The supporting testing methods that meet the testing requirements are selected for testing. After the release of this standard, the newly released and implemented national food safety standard (GB 23200)</p>	<p><b>Regulation (EC) No 396/2005, Chapter II, Procedure for applications for MRL's, Articles 6 to 17.</b></p>	<p><i>Only three of the 194 Chinese testing methods mentioned in the national standard apply to animal</i></p>

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<p>is also applicable to the testing of corresponding parameters.</p>		<p><i>tissues (namely: 49. GB/T 19650 Method for determination of 478 pesticides and related chemicals residues in animal muscles - GC-MS method; 53. GB/T 20772 Determination of 461 pesticides and related chemicals residues in animal muscles - LC-MS-MS method; 99. GB23200.104 National food safety standards - Determination of MCPA and MCPB residues in meat and meat product by liquid chromatography - mass spectrometry). Several more Chinese testing methods mentioned in the national standard are applicable to “food”.</i></p>
<p><b>3 Terms and definitions</b> The terms and definitions below apply to this document.</p> <p><b>3.1 Residue definition</b> Any particular substance in food, agricultural products and animal feed due to the use of pesticides, including the pesticide derivatives which is considered to have toxicological significance, such as pesticide conversion products, metabolites, reaction products and impurities, etc.</p> <p><b>3.2 Maximum residue limit (MRL)</b> The statutory maximum concentration of pesticide residues allowed in the internal or on surface of foods or agricultural products, expressed as the milligrams of pesticide residues per kilogram of foods or agricultural products (mg/kg).</p> <p><b>3.3 Extraneous maximum residue limit (EMRL)</b></p>	<p><b>Article 3, Definitions</b></p> <p>(c) ‘pesticide residues’ means residues, including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant protection products as defined in Article 2, point 1 of Directive 91/414/EEC, which are present in or on the products covered by Annex I to this Regulation, including in particular those which may arise as a result of use in plant protection, in veterinary medicine and as a biocide;</p> <p>(d) ‘maximum residue level’ (MRL) means the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with this Regulation, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers;</p>	

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<p>Although some persistent residual pesticides have been banned, they will present in the environment for a long time, which is in the formation of residues in food once again. The residue limits in food are developed in order to control contamination of such pesticides in foods; EMRL is expressed as the milligrams of pesticide residues per kilogram of food or agricultural products (mg/kg).</p> <p><b>3.4 Acceptable daily intake (ADI)</b> The estimated amount of a substance, consumed daily for a person’s lifetime, without generating detectable health hazards; expressed by the amount of intake per kilogram of body weight (mg/kg).</p>	<p>(j) ‘acceptable daily intake’ means the estimate of the amount of substances in food expressed on a body weight basis, that can be ingested daily over a lifetime, without appreciable risk to any consumer on the basis of all known facts at the time of evaluation, taking into account sensitive groups within the population (e.g. children and the unborn).</p>	
<p><b>4 Technical requirements</b> <b>4.540 (DDT)</b> 4.540.1 Major purpose of use: insecticide. 4.540.2 ADI: 0.01 mg/kg bw. 4.540.3 Residue definition: The sum of p,p'-DDT, o,p'-DDT, p,p'-DDE and p,p'-DDD. 4.540.4 Extraneous Maximum Residue Limit, mg/kg: Shall comply with provisions in the Table 540 Table 540: Extraneous Maximum Residue Limit, mg/kg, mg/kg: Aquatic products 0.5</p>	<p><b>Regulation (EC) No 396/2005, Annex I, Part A, Products of plant and animal origin referred to in Article 2(1) to which MRLs apply:</b> 1100000 -Products of animal origin Fish, fish products and any other marine and freshwater food products* * No MRLs are applicable until individual products have been identified and listed within this category.</p>	<p><i>According to the Chinese National standard, aquatic products must be tested for the presence of DDT, while no requirements for testing or monitoring for DDT of fish or fishery products have been laid down in EU legislation. Environmental contamination with DDT is generally very low.</i></p>
<p><b>4.544 (HCH)</b></p>		<p><i>According to the Chinese National standard, aquatic products must be tested for the presence of</i></p>



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### 1.1.7 National standard GB 2760-2014 – Uses of food additives

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
<p><b>1. Scope</b> This standard specifies the principles for application of food additives, allowed food additive varieties, scope of application, and maximum level or residue levels.</p>	<p><b>Regulation (EC) No 1333/2008 on food additives, Article 2: Scope</b> 1. This Regulation shall apply to food additives.</p>	
<p><b>2 Definitions</b> <b>2.1 Food Additive</b> An artificially chemosynthetic or natural substance to be added to foods in order to improve food quality, color, fragrance and taste, and for the purpose of preservation and processing technology. Flavoring substances, gum-based substances in the paste base candy, processing aids in food industry are also included in food additives. <b>2.2 Maximum Use Level</b> The maximum allowable adding level at the time of application of food additives. <b>2.3 Maximum Residue Level</b> The permissible residual level of a food additive or its decomposition products in final food products. <b>2.4 Processing Aid</b> The various kinds of substances to enable food processing to go smoothly, irrelative to food itself, for example, filtration aids, clarifiers, absorbents, lubricants, mold release agents, decoloring agents, peeling agents, extraction solvents, and nutritional substances for fermentation, etc.</p>	<p><b>Regulation (EC) No 1333/2008, Article 3: Definitions</b> (a) ‘food additive’ shall mean any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods;  (b) ‘processing aid’ shall mean any substance which: (i) is not consumed as a food by itself; (ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and</p>	<p><i>For the definition of MRL see:</i> <b>Regulation (EC) No 396/2005, Article 3, Definitions</b> (d) ‘maximum residue level’ (MRL) means the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with this Regulation, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers;</p>

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Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
<p><b>2.5 International Numbering System (ins)</b> The international numbering of food additives, which is used in lieu of the description of complicated chemical structure names.</p> <p><b>2.6 Chinese Number System (cns)</b> The Chinese numbering of food additives, which consists of category code of food additive functions (see appendix d) and its serial number under such function.</p>	<p>(iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;</p>	
<p><b>3 Principles for use of food additives</b></p> <p><b>3.1 The use of food additives should observe the following basic requirements:</b></p> <p>a) Not to harm human health in any form; b) Not to cover up putrefied and deteriorated foods; c) Not to conceal quality defects or for the purpose of adulteration and counterfeiting; d) Not to reduce the nutrition value of food; e) To reduce the level of use in foods as much as possible on the precondition of reaching anticipated results; f) Food processing aids should generally be removed before the finished products are produced, unless a residue level is specified in the food product.</p> <p><b>3.2 Food additives could be applied in the following cases:</b></p> <p>a) To keep or improve the nutrition value of food itself;</p>	<p><b>Article 6</b></p> <p>1. A food additive may be included in the Community lists in Annexes II and III only if it meets the following conditions and, where relevant, other legitimate factors, including environmental factors:</p> <p>(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed; (b) there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means; and (c) its use does not mislead the consumer.</p> <p>2. To be included in the Community lists in Annexes II and III a food additive must have advantages and benefits for the consumer and therefore serve one or more of the following purposes:</p> <p>(a) preserving the nutritional quality of the food;</p>	

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<b>Chinese National standard GB 2760</b>	<b>EU Regulation (EC) No 1333/2008</b>	<b>Implementing rules and remarks</b>
<p>b) To serve as essential ingredients or components in some special dietary foods; c) To improve the quality and stability of food, as well as its sensory properties; d) To facilitate production, processing, packaging, transport or storage of foods</p> <p><b>3.3 Quality standards of food additives</b> Food additives used in accordance with this standard shall comply with corresponding quality standards.</p> <p><b>3.4 Carry-over of principles</b> 3.4.1 In the following cases, food additives can be introduced into foods through ingredients (including food additives) :</p> <p>a) The additive is acceptable for use in the food ingredients according to this standard; b) The amount of the additive in the ingredients does not exceed the maximum use level specified in this standard</p>	<p>(b) providing necessary ingredients or constituents for foods manufactured for groups of consumers with special dietary needs; (c) enhancing the keeping quality or stability of a food or improving its organoleptic properties, provided that the nature, substance or quality of the food is not changed in such a way as to mislead the consumer; (d) aiding in the manufacture, processing, preparation, treatment, packing, transport or storage of food, including food additives, food enzymes and food flavourings, provided that the food additive is not used to disguise the effects of the use of faulty raw materials or of any undesirable practices or techniques, including unhygienic practices or techniques, during the course of any such activities.</p> <p><b>Article 18</b> 1. The presence of a food additive shall be permitted: (a) in a compound food other than as referred to in Annex II, where the food additive is permitted in one of the ingredients of the compound food; (b) in a food to which a food additive, food enzyme or food flavouring has been added, where the food additive:</p>	

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<p>c) The food additive shall be used under proper technological conditions, and the quantity of the ingredient in the food shall not be greater than would be introduced by the use of ingredients;</p> <p>d) The quantity of the additive carried over by the ingredients shall be much lower than the required level by directly adding the food additive into the food.</p> <p>3.4.2 An additive may be used in or added to an ingredient if the ingredient is used exclusively in the preparation of a food that is in conformity with the provisions of this standard, including that quantity of the food additive in the finished food product shall conform with this standard. Label of the ingredient of the specific food shall clearly mark that the food ingredient is used for production of the specific food.</p>	<p>(i) is permitted in the food additive, food enzyme or food flavouring in accordance with this Regulation; and</p> <p>(ii) has been carried over to the food via the food additive, food enzyme or food flavouring; and</p> <p>(iii) has no technological function in the final food;</p> <p>(c) in a food which is to be used solely in the preparation of a compound food and provided that the compound food complies with this Regulation.</p>	
<p><b>4 Food category system</b></p> <p>The food category system is a tool for defining scope of food additive use in this standard, and only applies in this standard, as in appendix e. When an additive is recognized for use in a general category, it is recognized for use in all its sub-categories, unless otherwise stated.</p>		
<p><b>5 Provisions for use of food additives</b></p> <p>The use of food additives shall comply with the provisions in the appendix a.</p>	<p><b>Article 15</b></p> <p>Food additives shall not be used in unprocessed foods, except where such use is specifically provided for in Annex II.</p>	

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<b>Chinese National standard GB 2760</b>	<b>EU Regulation (EC) No 1333/2008</b>	<b>Implementing rules and remarks</b>
<b>6 Flavoring substances</b> The use of flavoring substances shall comply with the provisions of the appendix b.	<b>Regulation (EC) No 1334/2008, Annex I: Union list of flavourings and source materials</b>	
<b>7 Food processing aids</b> The use of food processing aids shall comply with the provisions of Annex C		<i>See the definition (mentioned above) in Regulation (EC) No 1333/2008, Article 3, 2, b). However, these processing aids, including filtration aids and release agents, are excluded from the scope of Commission Regulation 1333/2008. There is no specific European legislation regarding processing aids.</i>
<b>Appendix A Provisions for the use of food additives</b> A.1 The Table A.1 provides the additives permitted for use in certain food categories of applicable foods and maximum level or residue level. <b>Tea polyphenol (TP)</b> CNS 04.005 INS – Function: antioxidant 09.03 Pre-processed fish and fish products (half-finished product) 0.3 Max Level (g/kg) Note: as catechin in fat 09.04 Fully preserved fish and fish products (can be directly consumed) 0.3 Max Level (g/kg) Note: as catechin in fat 09.05 Canned fish products 0.3 Max Level (g/kg) Note: as catechin in fat	<b>Regulation (EU) No 1129/2011 amending Annex II to Regulation (EC) No 1333/2008, Annex II, Part E, Authorised food additives and conditions of use in food categories</b>  <i>Contains lists for</i> <b>09.1.1 Unprocessed fish</b> 10 E numbers are mentioned, each with a name of the additive, maximum level (mg/l or mg/kg as appropriate), footnote and restrictions/exceptions.  <b>09.1.2 Unprocessed molluscs and crustaceans</b> 13 E numbers are mentioned, each with a name of the additive, maximum level (mg/l or mg/kg as appropriate), footnote and restrictions/exceptions.	

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<p><b>Phydroxy benzoates and its salts</b> (sodium methyl p-hydroxy benzoate, ethyl p-hydroxy benzoate, sodium ethyl p-hydroxy benzoate) CNS 17.032, 17.007, 17.036 INS 219, 214, 215 Function: preservative 12.10.03.04 Oyster sauce, shrimp oil, fish gravy 0.25 Max Level (g/kg) Note: as para-hydroxybenzoic</p> <p><b>Butylated hydroxyanisole (BHA)</b> CNS 04.001 INS 320 Function: antioxidant 09.03.04 Dried fish and fishery product 0.2 Max Level (g/kg) Note: As BHA in fats</p> <p><b>Butylated hydroxytoluene (BHT)</b> CNS 04.002 INS 321 Function: antioxidant 09.03.04 Dried fish and fishery product 0.2 Max Level (g/kg) Note: as BHT in fats</p> <p><b>Neotame</b> CNS 19.019 INS 961 Function: sweeteners 09.03 Pre-processed fish and fish products (semi-finished product) 0.01 Max Level (g/kg) 09.05 Canned fish products 0.01 Max Level (g/kg)</p>	<p><b>09.2 Processed fish and fishery products including molluscs and crustacean</b> 87 E numbers are mentioned, each with a name of the additive, maximum level (mg/l or mg/kg as appropriate), footnote and restrictions/exceptions.</p> <p><b>09.3 Fish roe</b> 7 E numbers are mentioned, each with a name of the additive, maximum level (mg/l or mg/kg as appropriate), footnote and restrictions/exceptions.</p> <p><b>E 321 Butylated hydroxytoluene (BHT)</b> 100 Maximum level (mg/l or mg/kg as appropriate) Restrictions/exceptions: only fats and oils for the professional manufacture of heat-treated foods; frying oil and frying fat (excluding olive an pomace oil) and lard, fish oil, beef, poultry and sheep fat.</p>	<p><i>Butylated hydroxyanisole (BHA) has in the EU legislation as E number: E320</i></p> <p><i>Neotame has in the EU legislation as E number: E961</i></p>

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<p><b>Monosodium fumarate</b> CNS 01.311 INS 365 Function: acidity regulator 09.0 Fish and fish products (including fish, crustaceans, shellfish, mollusks, and echinode, and their processed products (other than fresh fish in 09.01)) Max level: GMP</p> <p><b>Antioxidant of glycyrrhiza</b> CNS 04.008 INS – Function: antioxidant 09.03.02 Pickled fish and fish products 0.2 Max Level (g/kg) Note: as glycyrrhetic acid</p> <p><b>Beta-carotene</b> CNS 08.010 INS 160 (a) Function: colour 09.02.03 Frozen minced and creamed fish products (including fish balls) 1.0 09.03 Pre-processed fish and fish products (semi-finished product) 1.0 09.04 Fully preserved fish and fish products (can be directly consumed) 1.0 09.05 Canned fish products 0.5</p> <p><b>Curdlan</b> CNS 20.042 INS 424 Function: stabilizer and coagulant, thickener 09.02.03 Frozen minced and creamed fish products (including fish balls) Max level: GMP</p>		<p><i><b>Carotenes</b> have in the EU legislation as E number: E 160a</i></p>



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<b>Chinese National standard GB 2760</b>	<b>EU Regulation (EC) No 1333/2008</b>	<b>Implementing rules and remarks</b>
<p>(dicalcium orthophosphate), tricalcium orthophosphate (calcium phosphate), tripotassium orthophosphate, trisodium orthophosphate, sodium polyphosphate, sodium tripolyphosphate, sodium dihydrogen phosphate, sodium phosphatedibasic, trisodium monohydrogen diphosphate potassium polymetaphosphate, calcium acid pyrophosphate</p> <p>Function: humectant, bulking agent, Acidity regulator, stabilizer, coagulant, anticaking agent</p> <p>09.02.01 Frozen aquatic products 5.0 Max Level (g/kg) Note: Singly or in combination, Max level calculated by PO43-</p> <p>09.02.03 Frozen minced and creamed fish products (including fish balls) 5.0 Max Level (g/kg) Note: Singly or in combination, Max level calculated by PO43-</p> <p>09.03 Pre-processed fish and fish products (half-finished product) 1.0 Max Level (g/kg) Note: Singly or in combination, Max level calculated by PO43-</p> <p>09.05 Canned fish products 1.0 Max Level (g/kg) Note: Singly or in combination, Max level calculated by PO43-</p> <p><b>Aluminium potassium sulfate, aluminium ammonium sulfate</b></p>	<p>Listed under 09.1.2 Unprocessed molluscs and crustaceans (<i>see lists mentioned above</i>).</p> <p><b>E 338-452 Phosphoric acid — phosphates — di-, tri- and polyphosphates</b> 5 000 Maximum level (mg/l or mg/kg as appropriate) The maximum level is expressed as P<sub>2</sub>O<sub>5</sub> Restrictions/exceptions: only frozen and deep-frozen fish fillets.</p> <p><b>E 338-452 Phosphoric acid — phosphates — di-, tri- and polyphosphates</b> 1 000 Maximum level (mg/l or mg/kg as appropriate) The maximum level is expressed as P<sub>2</sub>O<sub>5</sub> Restrictions/exceptions: only canned crustaceans products; surimi and similar products.</p> <p><b>E 338-452 Phosphoric acid — phosphates — di-, tri- and polyphosphates</b> 5 000 Maximum level (mg/l or mg/kg as appropriate) The maximum level is expressed as P<sub>2</sub>O<sub>5</sub> Restrictions/exceptions: only fish and crustacean paste and in processed frozen and deep-frozen molluscs and crustaceans. Listed under 09.1.1 Unprocessed fish, under 09.1.2 Unprocessed molluscs and crustaceans, 09.2 Processed fish and</p>	

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Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
<p>CNS 06.004, 06.005 INS 522, 523 Function: bulking agent, stabilizer 09.03.02 Pickled fish and fish products (only used for jelly fish) Max level: GMP Note: Aluminum residual <math>\leq</math> 500mg/kg (as Al in instant jelly fish)</p> <p><b>Maltitol and maltitol syrup</b> CNS 19.005, 19.022 INS 965 (i), 965 (ii) Function: sweeteners, stabilizer, humectant, emulsifier, bulking agent, thickener 09.02.03 Frozen minced and creamed fish products (including fish balls) 0.5 Max Level (g/kg)</p> <p><b>Propyl gallate (PG)</b> CNS 04.003 INS 310 Function: antioxidant 09.03.04 Dried fish and fishery product 0.1 Max Level (g/kg) Note: as PG in fats</p> <p><b>Rosemary extract</b> CNS 04.017 INS – Function: antioxidant 02.01.02 Animal fats (including lard, tallow, fish oil, and other animal fats) 0.3 g/kg</p>	<p>fishery products including molluscs and crustaceans (<i>see lists mentioned above</i>).</p>	<p><i>Maltitols have in the EU legislation as E number: E 965.</i></p> <p><i>Propyl gallate has in the EU legislation as E number: E 310.</i></p>

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Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
<p><b>Pullulan</b> CNS 14.011 INS 1204 Function: glazing agent, thickener 09.03 Pre-processed fish and fish products 30.0 Max Level (g/kg)</p> <p><b>Nisin</b> CNS 17.019 INS 234 Function: preservative Fully preserved fish and fish products (can be directly consumed) 0.5 Max Level (g/kg)</p> <p><b>Rtemisia gum (sa-hao seed gum)</b> CNS 20.037 INS – Function: thickener 09.02.03 Frozen minced and creamed fish products (including fish balls) 0.5 Max Level (g/kg)</p> <p><b>Sorbic acid, potassium sorbate</b> CNS 17.003, 17.004 INS 200, 202 Function: preservative, antioxidant, stabilizer Pre-processed fish and fish products (half-finished product) 0.075 g/kg Note: as sorbic acid Dried fish and fishery product 1.0 g/kg Note: as sorbic acid Fully preserved fish and fish products (can be directly consumed) 1.0 g/kg Note: as sorbic acid Other fish and fish products 1.0 g/kg Note: as sorbic acid</p>	<p><b>E 392 Extracts of rosemary</b> 50 Maximum level (mg/l or mg/kg as appropriate) Restrictions/exceptions: only fish oil and algal oil; lard, beef, poultry sheep and porcine fat; fat and oils for the professional manufacture of heat-treated foods; frying oils and frying fat, excluding olive oil and pomace oil.</p> <p><b>E 200-203 Sorbic acid — sorbates</b> 1 000</p>	<p><i>Pullulan has in the EU legislation as E number: E 1204.</i></p> <p><i>Nisin has in the EU legislation as E number: E 234.</i></p>

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Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
<p><b>Sorbitol and sorbitol syrup</b> CNS 19.006, 19.023 INS 420 (i), 420 (ii) Function: sweeteners, bulking agent, emulsifier, humectant, stabilizer, thickener 09.02.03 Frozen minced and creamed fish products (including fish balls) 0.5 g/kg</p> <p><b>Sodium diacetate</b> CNS 17.013 INS 262ii Function: preservative Fully preserved fish and fish products (can be directly consumed) 1.0 g/kg</p> <p><b>Diacetyl tartaric acid ester of mono (di) glycerides (DATEM)</b> CNS 10.010 INS 472e Function: emulsifier, thickener 09.0 Aquatic products (excluding fresh aquatic products) 10.0 g/kg</p>	<p>Maximum level (mg/l or mg/kg as appropriate) Restrictions/exceptions: aspic <b>Sorbic acid — sorbates; Benzoic acid — benzoates</b> 200</p> <p>Maximum level (mg/l or mg/kg as appropriate) Restrictions/exceptions: only salted, dried fish <b>Sorbic acid — sorbates; Benzoic acid — benzoates</b> 2000 mg/l or mg/kg Restrictions/exceptions: only semi-preserved fish and fisheries products including crustaceans, molluscs, surimi and fish/crustacean paste; cooked crustaceans and molluscs.</p> <p><b>Sorbic acid — sorbates; Benzoic acid — benzoates</b> 6000 mg/l or mg/kg Restrictions/exceptions: only cooked <i>Crangon crangon</i> and <i>Crangon vulgaris</i>.</p> <p><b>Sorbic acid — sorbates; Benzoic acid — benzoates</b> 2000 mg/l or mg/kg Restrictions/exceptions: only semi-preserved fish products including fish roe products.</p>	<p><i>Sorbitols</i> have in the EU legislation as E number: E 420.</p>

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Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
<p><b>Tertiary butylhydroquinone (TBHQ)</b> CNS 04.007 INS 319 Function: antioxidant 09.03.04 Dried fish and fishery product 0.2 Max Level (g/kg) Note: as TBHQ in fats</p> <p><b>Aspartame</b> CNS 19.004 INS 951 Function: sweeteners Frozen battered fish and fish products 0.3 g/kg Frozen minced and creamed fish products (including fish balls) 0.3 g/kg Pre-processed fish and fish products (semi-finished product) 0.3g/kg Fully preserved fish and fish products (can be directly consumed) 0.3 g/kg Canned fish products 0.3 g/kg</p> <p><b>Stabilized chlorine dioxide</b> CNS 17.028 INS 926 Function: preservative Aquatic products (including fish, crustaceans, shellfish, mollusks, and echinode, and their processed products) (fish processing only) 0.05 g/kg</p> <p><b>Phytic acid (inositol hexaphosphoric acid), sodium phytate</b> CNS 04.006 INS – Function: antioxidant Fresh aquatic products (shrimp only) Max Level (g/kg): GMP ≤20mg/kg</p>	<p><b>E 951 Aspartame</b> 300 mg/l or mg/kg Restrictions/exceptions: only sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs.</p> <p><b>E 962 Salt of aspartame-acesulfame</b> 200 mg/l or mg/kg Restrictions/exceptions: only sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs.</p>	<p><i><b>Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids</b> have in the EU legislation as E number: E 472e.</i></p> <p><i><b>Tertiary butylhydroquinone (TBHQ)</b> have in the EU legislation as E number: E 319.</i></p>

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Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
<p><b>Antioxidant of bamboo leaves</b>  CNS 04.019 INS –  Function: antioxidant  Aquatic products (including fish, crustaceans, shellfish, mollusks, and echinode, and their processed products)  0.5 g/kg</p> <p>A.2 In the Tables A.1, food additives with the same functional class (colorings of same color, preservatives, and antioxidant), when used together, the sum of their respective ratios to the maximum level should not exceed 1.</p> <p>A.3 The Table A.2 lists all food additives that can be used in all types of foods (excluding the food categories in the Table A.3) in the appropriate dose as required in production, i.e. GMP (the term used by the CODEX standard).</p> <p>A.4 The Table A.3 provides the food categories that are excluded in the Table A.2, and such food categories, in using food additives, shall comply with provisions of the Table A. Meanwhile, such food categories are prohibited to use the food additives permitted in the higher level food category. A.5 The Table A.1 and the Table A.2 do not regulate Flavoring substances or food additives used as the food processing aid.</p>		

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A.6 The “function” item in the aforementioned Tables are the main functions of the additive for reference in use.		

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### 1.1.8 National standard GB 5749 – Drinking water quality

<b>Chinese legislation: National standard GB 5749</b>	<b>EU legislation: Council Directive 98/83/EC</b>	<b>Implementing rules and comparative evaluation</b>
<p><b>1. Scope</b> <b>GB 5749-2006</b> <b>Standards for Drinking Water Quality</b> The sanitary requirements of the drinking water and its source, centralized water supply unit, secondary water supply and health security products related to drinking water as well as water quality monitoring and testing methods. This standard applies to drinking water from all kinds of centralized water supply in urban and rural areas, and also applies to decentralized drinking water supply.</p>	<p><b>Scope</b> This Directive applies to the quality of water intended for human consumption in all food chain.</p>	<p>Chinese Standards and European Legislation pursue the same objectives and limit values defined are largely identical.</p> <p>Under harmonized EU law there are fewer potential contaminants listed for obligatory monitoring by all Member States. However, all authorities must monitor potential hazards that might be relevant under local conditions (Article 5 of Directive 98/83/EC). Guiding principle is the high level of protection and precaution set forth by the General Food Law in Regulation (EC) No 178/2002, in particular Articles 5 and 7.</p>
<p><b>3 Terms and Definitions</b> <b>3.1 Drinking water</b> Water and domestic water for people to live. <b>3.2 Type of water supply</b> <b>3.2.1 Central water supply</b> The method of getting water from the source and then deliver it to the user or public water supply spot through the water transport and distribution network, including self-built water supply facilities. The water supply stations providing daily drinking water for users and water supply for public places and residents community also belong to central water supply.</p>	<p><b>Definitions</b> <b>Council Directive 98/83/EC, Article 2</b> 1. ‘water intended for human consumption’ shall mean: (a) all water either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, from a tanker, or in bottles or containers; (b) all water used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent national authorities are</p>	<p>Definitions are compatible. For the purpose of this document the most relevant provision is that water used in processing of food products must be monitored and fulfill the quality criteria established.</p>

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Chinese legislation: National standard GB 5749	EU legislation: Council Directive 98/83/EC	Implementing rules and comparative evaluation
<p>3.2.2 Secondary water supply Centralized water goes through storage, high pressure and disinfection or deep processing once again before delivering to the users through pipes or containers.</p> <p>3.2.3 Small central water supply Daily water supply is less than 1000 ma in rural area (or water supply population is under 10000).</p> <p>3.2.4 Non-central water supply Getting water directly from the water source by dispersive residents with no or just simple facilities.</p> <p><b>3.3 Regular indices</b> The index that can reflect the basic drinking water quality.</p> <p><b>3.4 Non-regular indices</b> Drinking water quality indices that need to be adopted according to the region, time or special circumstances.</p>	<p>satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form;</p> <p>2. 'domestic distribution system' shall mean the pipework, fittings and appliances which are installed between the taps that are normally used for human consumption and the distribution network but only if they are not the responsibility of the water supplier, in its capacity as a water supplier, according to the relevant national law.</p>	
<p><b>4. Hygiene requirements for drinking water</b></p> <p>4.1 The quality of drinking water should meet the following basic requirements to ensure the safety of users.</p> <p>4.1.1 Pathogenic microorganisms should not be contained in the drinking water.</p> <p>4.1.2 Chemicals in drinking water should not be harmful to human health.</p> <p>4.1.3 Radioactive substances in drinking water should not be harmful to human health.</p>	<p><b>Council Directive 98/83/EC, Article 4 General obligations:</b></p> <p>Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean. For the purposes of the minimum requirements of this Directive, water intended for human consumption shall be wholesome and clean if it:</p> <p>(a) is free from any micro-organisms and parasites and from any substances which, in</p>	

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Chinese legislation: National standard GB 5749	EU legislation: Council Directive 98/83/EC	Implementing rules and comparative evaluation
<p>4.1.4 Sensory properties of drinking water should be good.</p> <p>4.1.5 Drinking water should be through sterilization processing.</p> <p>4.1.6 The drinking water quality shall meet the hygienic requirements in table 1 and table 3. The disinfectant limit of drinking water from centralized water supply factory and the disinfectant residue in the finished water and want in the end of pipe network shall meet the requirements in Table 2.</p> <p>4.1.7 Due to some restrictions, some quality indices of water from small centralized and decentralized water supply should be temporarily implemented in accordance with Table 4. While the rest of the index should still refer to Table 1, 2 and 3.</p> <p>4.1.8 In the event of unexpected public events impacting water quality, sensory properties and general chemical indicators can be eased appropriately with the approval of the municipal people's government at or above.</p> <p>4.1.9 When drinking water contains the indicators listed in Table A.1 in Appendix A, the limit in this table can be referred to for evaluation.</p>	<p>numbers or concentrations, constitute a potential danger to human health, and (b) meets the minimum requirements set out in Annex I, Parts A and B of this Directive.</p> <p><b>Article 5: Quality standards</b></p> <p>3. A Member State shall set values for additional parameters not included in Annex I where the protection of human health within its national territory or part of it so requires.</p> <p><b>Article 6: Point of compliance</b></p> <p>1. The parametric values set shall be complied with:</p> <p>...</p> <p>(d) in the case of water used in a food-production undertaking, at the point where the water is used in the undertaking.</p> <p><b>Annex II Monitoring:</b></p> <p>1. Monitoring programmes for water intended for human consumption must:</p> <p>(a) verify that the measures in place to control risks to human health throughout the water supply chain from the catchment area through abstraction, treatment and storage to distribution are working effectively and that water at the point of compliance is wholesome and clean;</p> <p>(b) provide information on the quality of the water supplied for human consumption to demonstrate that the obligations set out in</p>	

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	<p>Articles 4 and 5, and the parametric values laid down in Annex I, are being met;</p> <p>(c) identify the most appropriate means of mitigating the risk to human health.</p> <p>2. Pursuant to Article 7(2), competent authorities shall establish monitoring programmes complying with the parameters and frequencies set out in Part B of this Annex which consist of:</p> <p>(a) collection and analysis of discrete water samples; or</p> <p>(b) measurements recorded by a continuous monitoring process.</p> <p>In addition, monitoring programmes may consist of:</p> <p>(a) inspections of records of the functionality and maintenance status of equipment; and/or</p> <p>(b) inspections of the catchment area, water abstraction, treatment, storage and distribution infrastructure.</p> <p>3. Monitoring programmes may be based on a risk assessment as set out in Part C.</p> <p>4. Member States shall ensure that monitoring programmes are reviewed on a continuous basis and updated or reconfirmed at least every 5 years</p>	
<p><b>6. Hygiene requirements for centralized water supply unit</b></p> <p>The Sanitation requirements of centralized water supply unit should refer to Hygienic Standard for the Drinking Water Centralized Supply Unit promulgated Ministry of Health.</p>	<p>See above. Monitoring programmes must ensure that water complies with the standards set forth at all points throughout the distribution network.</p>	

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<p><b>7. Hygiene requirements for secondary water supply</b> Secondary water supply facilities and treatment requirements shall follow conditions regarding the type of disinfectant to be used, and the operating procedure, as well as limits, residues in the final water and still residues in the water at the end of the net.</p>	See above. Monitoring programmes must ensure that water complies with the standards set forth at all points throughout the distribution network.	
<p><b>8. Hygiene requirements for health security products related to drinking water</b> 8.1 Chemical treatment agents with the functions of flocculation, coagulation, disinfection, oxidation, and adsorption, pH adjustment, rust prevention, anti-scaling, etc. which are used for treating the drink water should not pollute the water. 8.2 Water transport and distribution equipment, protective materials and treatment materials of drinking water should not pollute drinking water.</p>	<p><b>Council Directive 98/83/EC, Article 4 General obligations:</b> Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean.</p>	
<p><b>9. Water quality monitoring</b> <b>9.1</b> Water quality detection of the water supply unit <b>9.1.1</b> Non-regular water quality indicators of water supply unit should be decided after the negotiation between local water supply administrative department at or above the county level and the administrative department of health.</p>	See above. Monitoring programmes must ensure that water complies with the standards set forth at all points throughout the distribution network.	

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Chinese legislation: National standard GB 5749	EU legislation: Council Directive 98/83/EC	Implementing rules and comparative evaluation
<p><b>9.1.4</b> Test results of the water of the water supply unit should be submitted to the local administrative department of health regularly; the contents and method that submitted should be agreed upon by the local administrative department of water supply and the health administrative department.</p> <p><b>9.1.5</b> When the quality of drinking water is abnormal, it should be reported to the local water supply administrative department and the administrative department of health in time.</p> <p><b>9.2</b> Water quality monitoring of health supervision</p> <p><b>9.2.1</b> The health administrative departments at all levels should periodically implement water quality supervision and monitoring towards all kinds of water supply units according to the actual need.</p> <p><b>9.2.2</b> In the event of unexpected public events impacting water quality, the health administrative department at or above the county level shall make plans on drinking water supervision and monitoring according to needs.</p> <p><b>9.2.3</b> Water quality monitoring scope, project, frequency of health supervision should be determined by the health administrative department at or above the local municipal.</p>		

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**Table: Limit values for drinking water parameters** (showing the differences in parameters and values between European and Chinese legislation).

<b>Main indicators for water quality: EU Indicators and limits as per Council Directive 98/83/EC in comparison with GB Standard GB 5749-2006 for regular and non-regular water</b>		
<b>Main indicators</b>	<b>EU limits</b>	<b>GB 5749-2006 limits</b>
COD (chemical oxygen demand) mg/l	Not mentioned	3, (5 when restricted to water source when original COD is over 6 mg/l)
Petroleum mg/l	Not mentioned	0.3 mg/l
pH	Not mentioned	6.5<x<8.5
TOC Total organic carbon	No abnormal changes	5 mg/l
TDS (Total dissolved Solids)	Not mentioned	1000 mg/l
Total hardness (as CaCO <sub>3</sub> ) mg/l	Not mentioned	450 mg/l
Barium (Ba)	Not mentioned	0.7 mg/l
Beryllium (Be)	Not mentioned	0.002 mg/l
Boron (B)	1.00 mg/l	0.5 mg/l
Copper (Cu)	2.0 mg/l	1 mg/l
Molybdenum (Mo)	Not mentioned	0.07 mg/l
Silver (Ag)	Not mentioned	0.05 mg/l
Thallium	Not mentioned	0.0001 mg/l
Zinc (Zn)	Not mentioned	1 mg/l
Chlorite	Not mentioned	0.7 mg/l
Cyanogen chloride	Not mentioned	0.07 mg/l
Chlorate	Not mentioned	0.7 mg/l
Bromodichloromethane	Not mentioned	0.06 mg/l
Chlorodibromomethane	Not mentioned	0.1 mg/l
Methylene chloride	Not mentioned	0.02 mg/l
<a href="#">Fluoride (F)</a>	1.5 mg/l	1.0 mg/l
Nitrate (NO <sub>3</sub> ) (conversion factor nitrogen to nitrate; 4.43)	50 mg/l	As (N) 10 mg/l, or 20 mg/l when restricted by ground water
Escherichia coli	0 in 250 ml	0 in 100 ml
Enterococci	0 in 250 ml	0 in 100 ml
Pseudomonas aeruginosa	0 in 250 ml	0 in 100 ml
Giardia	Not mentioned	< 1 per 10l
Cryptosporidium	Not mentioned	< 1 per 10l

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<b>Main indicators for water quality: EU Indicators and limits as per Council Directive 98/83/EC in comparison with GB Standard GB 5749-2006 for regular and non-regular water</b>				
<b>Main indicators</b>	<b>EU limits</b>		<b>GB 5749-2006 limits</b>	
Dichloroacetic acid	Not mentioned		0.05 mg/l	
Trichloroacetic acid	Not mentioned		0.1 mg/l	
Trihalomethane(the total of chloroform, chlorodibromomethane, bromodichloromethane,and methyl bromide)	Not mentioned		The sum of the ratio of the concentration of various compounds to their own limits should not exceed 1mg/l	
Trichloroethane	Not mentioned		2 mg/l	
Trihalomethanes	0.1 mg/l		0.06 mg/l	
Volatile phenols mg/l	Not mentioned		0.002 mg/l	
Radioactivity index	Tritium	100 Bq/l	Total radioactivity $\alpha$	0.5 Bq/l
	Total indicative dose	0.10 mSv/year	Total radioactivity $\beta$	1 Bq/l

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## 1.2 Specific requirements for fishery products

### 1.2.1 National standard GB 20941-2016 – Hygienic practice of aquatic products

Chinese National standard GB 20941	EU Regulation (EC) No 853/2004	Implementing rules and remarks
<p><b>Scope</b> This standard specifies the basic requirements and management guidelines for sites, facilities and personnel for material purchasing, accepting, processing, packaging, storage and transportation in the production process of aquatic products. This standard is applicable to the production of aquatic products.</p>	<p><b>Article 1 Scope</b> This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.</p>	
<p><b>2. Terms and Definitions</b> For the purpose of this standard, the terms and definitions specified in GB 14881-2013 apply.</p> <p><b>2.1 aquatic products</b> Foods processed from fish, shrimps, crabs, cephalopods, shellfish, echinoderms, coelentera, algae and other edible aquatic organisms.</p> <p><b>2.2 temporary breeding</b> Process of breeding live aquatic products in clean water for a period of time.</p> <p><b>2.3 shellfish purification</b> Process of breeding live shellfish caught in areas meeting fishery water quality standards in natural or artificially cleaned seawater for a period of time to reduce the number of microorganisms in the body.</p>	<p><b>Regulation (EC) No 853/2004, Annex I Definitions</b></p> <p><b>3.1. 'Fishery products'</b> means all seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such animals.</p> <p><b>2.1. 'Bivalve molluscs'</b> means filter-feeding lamellibranch molluscs.</p> <p><b>2.5. 'Production area'</b> means any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for the cultivation of bivalve molluscs, and from which live bivalve molluscs are taken.</p>	<p>In EU food hygiene legislation aquatic products are subdivided in fishery products and bivalve molluscs. In EU legislation production areas and relaying areas are defined (for bivalve molluscs). No definition is provided for temporary breeding or for shellfish purification.</p>

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Chinese National standard GB 20941	EU Regulation (EC) No 853/2004	Implementing rules and remarks
	<p><b>2.6. 'Relaying area'</b> means any sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs.</p> <p><b>Regulation (EU) 2016/429, Article 4 Definitions</b> <b>(3) 'aquatic animals'</b> means animals of the following species, at all life stages, including eggs, sperm and gametes: (a) fish belonging to the superclass Agnatha and to the classes Chondrichthyes, Sarcopterygii and Actinopterygii; (b) aquatic molluscs belonging to the phylum Mollusca; (c) aquatic crustaceans belonging to the subphylum Crustacea;</p>	
<p><b>3. Site selection and plant surroundings</b> <b>3.1 Site selection</b> Site selection shall meet the requirements of 3.1 in GB 14881-2013. <b>3.2 Plant environment</b> 3.2.1 Plant environment shall meet the requirements of 3.2 in GB 14881-2013. 3.2.2 Animals not concerned with production and processing shall not be bred in the area.</p>	<p><b>Regulation (EC) No 852/2004, Annex I, Part A, II, 4. (f):</b> as far as possible to prevent animals and pests from causing contamination; <b>Regulation (EC) No 852/2004, Annex II, Chapter I, 2. (c):</b> permit good food hygiene</p>	<p>EU food hygiene legislation lays down in several places that contamination by other animals should be prevented.</p>

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Chinese National standard GB 20941	EU Regulation (EC) No 853/2004	Implementing rules and remarks
	<p>practices, including protection against contamination and, in particular, pest control;  <b>Regulation (EC) No 852/2004, Annex II, Chapter IX, 4.:</b> Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).  <b>Delegated Regulation (EU) 2020/691, Annex I, Part I, 2.:</b>  (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose and the environmental constraints of the aquaculture establishment;</p>	<p>In EU animal health legislation predator control measures are laid down</p>
<p><b>5 Facilities and equipment</b>  <b>5.1 Facilities</b>  5.1.1 Water supply facilities  5.1.1.1 Water supply facilities shall meet the requirements of 5.1.1 in GB 14881-2013.  5.1.1.2 The processing water shall be equipped with water purification or disinfection facilities according to the local water quality characteristics and product requirements. If necessary, water storage facilities shall be arranged in non-contaminated areas and these facilities shall be made of non-toxic, odorless, anti-corrosive and non-shedding materials, which are convenient for regular cleaning and disinfection, and they shall be</p>	<p><b>Regulation (EC) No 852/2004, Annex II, Chapter VII, 1.:</b>  (a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated; (b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When clean water is used,</p>	<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's</b>  2.8 water and air control  b) As a general rule, only potable water may be used on food of animal origin. At least clean water or where applicable clean sea water should be used in other cases.</p>

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Chinese National standard GB 20941	EU Regulation (EC) No 853/2004	Implementing rules and remarks
<p>sealed and properly protected to ensure the safety and hygiene of processing water.</p> <p>5.1.2 Drainage facilities Drainage facilities shall meet the requirements of 5.1.2 in GB 14881-2013.</p> <p>5.1.3 Cleaning and disinfection facilities Cleaning and disinfection facilities shall meet the requirements of 5.1.3 in GB 14881-2013.</p> <p>5.1.4 Waste storage facilities 5.1.4.1 Waste storage facilities shall meet the requirements of 5.1.4 in GB 14881-2013. 5.1.4.2 Waste containers shall be waterproof, corrosion resistant and leak proof. If pipes are used to transport wastes, the installation, maintenance and use of pipes shall not contaminate the product.</p>	<p>adequate facilities and procedures are to be available for its supply to ensure that such use is not a source of contamination for the foodstuff.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VII, Chapter III, 2.:</b> Tanks and water storage containers must meet the following requirements: (a) Internal surfaces must be smooth, durable, impermeable and easy to clean. (b) They must be constructed so as to allow complete draining of water. (c) Any water intake must be situated in a position that avoids contamination of the water supply.</p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter VI,</b> 2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate</p>	

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Chinese National standard GB 20941	EU Regulation (EC) No 853/2004	Implementing rules and remarks
<p>5.1.5 Personal sanitary facilities Personal sanitary facilities shall meet the requirements of 5.1.5 in GB 14881-2013.</p> <p>5.1.6 Ventilation facilities Ventilation facilities shall meet the requirements of 5.1.6 in GB 14881-2013.</p> <p>5.1.7 Lighting facilities Lighting facilities shall meet the requirements of 5.1.7 in GB 14881-2013.</p> <p>5.1.8 Storage facilities Storage facilities shall meet the requirements of 5.1.8 in GB 14881-2013.</p> <p>5.1.9 Temperature control facilities Temperature control facilities shall meet the requirements of 5.1.9 in GB 14881-2013.</p>	<p>construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.</p> <p>3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.</p> <p>4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.</p>	
<p><b>5.2 Equipment</b></p> <p>5.2.1 Production equipment</p> <p>5.2.1.1 General requirements General requirements shall meet the requirements of 5.2.1.1 in GB 14881-2013.</p> <p>5.2.1.2 Materials</p>	<p><b>Regulation (EC) No 852/2004, Annex II, Chapter V:</b></p> <p>1. All articles, fittings and equipment with which food comes into contact are to:</p>	

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<p>Materials shall meet the requirements of 5.2.1.2 in GB 14881-2013.</p> <p>5.2.1.3 Design</p> <p>5.2.1.3.1 The design shall meet the requirements of 5.2.1.3 in GB 14881-2013.</p> <p>5.2.1.3.2 The design and manufacture of equipment, containers and utensils being in contact with aquatic products shall be easy to drain, clean, disinfect and maintain.</p> <p>5.2.1.3.3 Equipment and tools shall be smooth to avoid obvious internal corners, humps, gaps or cracks so as to prevent material or dust from sticking.</p> <p>5.2.2 Monitoring equipment</p> <p>Monitoring equipment shall meet the requirements of 5.2.2 in GB 14881-2013.</p> <p>5.2.3 Equipment maintenance and repair</p> <p>5.2.3.1 Equipment maintenance and repair shall meet the requirements of 5.2.3 in GB 14881-2013.</p> <p>5.2.3.2 The equipment maintenance shall not contaminate the product; after maintenance, the maintenance area shall be cleaned and disinfected; the raw material pretreatment equipment shall be kept free from rust.</p>	<p>(a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;</p> <p>(b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;</p> <p>(c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected; and (d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.</p>	
<p><b>6 Hygiene management</b></p> <p><b>6.1 Hygiene management system</b></p> <p>6.1.1 Hygiene management system shall meet the requirements of 6.1 in GB 14881-2013.</p> <p>6.1.2 Special containers shall be clearly marked, and material containers at different</p>		<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's, 2.1:</b></p> <p>k) Attention should be paid to the different possibilities whereby the use of equipment can result in (cross-) contamination of food:</p>

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Chinese National standard GB 20941	EU Regulation (EC) No 853/2004	Implementing rules and remarks
<p>processing stages shall not be mixed with each other.</p> <p><b>6.2 Hygiene management for plant and facilities</b> They shall meet the requirements of 6.2 in GB 14881-1913.</p> <p><b>6.3 Health management and hygienic requirements for aquatic products processing personnel</b> They shall be in accordance with the requirements of relevant national laws and regulations.</p>	<p><b>Regulation (EC) No 852/2004, Annex II, Chapter VIII, Personal hygiene</b></p> <p>1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.</p> <p>2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.</p>	<p>i. Prevention of contamination of the equipment by the environment e.g. condensation dripping from ceilings;</p> <p>ii. Prevention of contamination within the food handling equipment e.g. accumulation of food residues in slicing devices;</p> <p>iii. Prevention of contamination by raw materials: separate equipment (or cleaning and disinfection between use) for raw products and cooked products (chopping boards, knives, dishes, ...).</p> <p><b>Delegated Regulation (EU) 2020/691, Annex I, Part I,:</b></p> <p>2. The requirements in relation to facilities and equipment of aquaculture establishments as referred to in point (c) of Article 7, shall be the following:</p> <p>(a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept on the aquaculture establishment;</p> <p>(b) the aquaculture establishment must provide for good standards of hygiene and allow adequate health monitoring to be carried out;</p> <p>(c) as far as possible, equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;</p>

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Chinese National standard GB 20941	EU Regulation (EC) No 853/2004	Implementing rules and remarks
<p><b>6.4 Pest control</b> Pest control shall meet the requirements of 6.4 in GB 14881-2013.</p> <p><b>6.5 Disposal of waste</b> 6.5.1 The storage and disposal system of discarded raw materials and packaging materials and wastes such as parasites, shells, sea urchin shells, shrimp guts, sea cucumber calcareous mouths, etc., which are sorted out during processing, shall be formulated and these wastes shall be disposed in a timely and effective manner so as not to contaminate the aquatic products, aquatic products contact surfaces, water supply and the ground. 6.5.2 Waste location outside the workshop shall be isolated from food processing site to prevent contamination; objectionable odor like stinking smell shall be prevented from escaping and insect pest shall be prevented from breeding.</p> <p><b>6.6 Management of work clothes</b></p>	<p><b>Regulation (EC) No 852/2004, Annex II, Chapter VI, Food waste</b> 1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation. 2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect. 3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests. 4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.</p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter VIII, Personal hygiene</b> 1. Every person working in a food-handling area is to maintain a high degree of personal</p>	

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<b>Chinese National standard GB 20941</b>	<b>EU Regulation (EC) No 853/2004</b>	<b>Implementing rules and remarks</b>
<p>6.6.1 Management of work clothes shall meet the requirements of 6.6 in GB 14881-2013.</p> <p>6.6.2 Special waterproof work clothes such as gloves, sleeves, aprons, shoes and boots shall be provided.</p>	<p>cleanliness and is to wear suitable, clean and, where necessary, protective clothing.</p>	
<p><b>7 Raw materials, food additives and food related products</b></p> <p><b>7.1 General requirements</b> General requirements shall meet the requirements of 7.1 in GB 14881-2013.</p> <p><b>7.2 Raw materials</b></p> <p>7.2.1 Raw materials shall meet the requirements of 7.2 in GB 14881-2013.</p> <p>7.2.2 All raw materials shall be from waters meeting the requirements of relevant national standards.</p> <p>7.2.3 The water quality for temporary breeding and transportation of seawater aquatic products and freshwater aquatic products shall meet the requirements of the relevant national standards.</p> <p>7.2.4 The raw materials of animal aquatic products shall meet the requirements of GB 2733, and the raw materials of algae products shall meet the requirements of GB 19643.</p> <p>7.2.5 If non-muscle tissues such as viscera, eggs, skin, fins, scales, bones, shells, etc. of</p>	<p><b>Regulation (EC) No 852/2004, Annex II, Chapter VII, Water supply</b></p> <p>1. (a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;</p> <p>(b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When clean water is used, adequate facilities and procedures are to be available for its supply to ensure that such use is not a source of contamination for the foodstuff.</p>	<p>See discussion of GB 2733</p> <p>See discussion of GB 19643.</p>

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Chinese National standard GB 20941	EU Regulation (EC) No 853/2004	Implementing rules and remarks
<p>aquatic animals are used as raw materials of aquatic products, they shall meet the requirements of GB 2733.</p> <p>7.2.6 Dead jaundice, mantis shrimp, river crab and shellfish shall not be used as raw materials for production and processing.</p> <p>7.2.7 If necessary, bivalve molluscs shall be subjected to shellfish purification.</p> <p>7.2.8 Toxin detection shall be carried out for raw materials of aquatic products with biotoxins such as bivalve molluscs and puffer fish, and these raw materials shall be accepted and treated according to relevant regulations to ensure safety.</p>	<p><b>Regulation (EC) No 853/2004, Annex III, Section VII, Chapter II, A Requirements for production areas</b></p> <p>3. Food business operators may place live bivalve molluscs collected from class B production areas on the market for human consumption only after treatment in a purification centre or after relaying.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VII, Chapter V Health standards for live bivalve molluscs</b></p> <p>In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.</p> <p>1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.</p> <p>2. They must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits: <i>(details are listed below)</i></p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter III, D Requirements concerning parasites</b></p>	<p>See discussion of GB 2733</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter V, E Toxins harmful to human health:</b></p> <p>2. Fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII and comply with the standards laid down in Chapter V, point 2, of that section (<i>see middle column of this row</i>)</p>

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<b>Chinese National standard GB 20941</b>	<b>EU Regulation (EC) No 853/2004</b>	<b>Implementing rules and remarks</b>
<p>7.2.9 Raw materials for raw aquatic products shall be subjected to pathogenic bacteria, viruses, parasites and eggs inspection.</p> <p><b>7.3 Food additives</b></p> <p>7.3.1 Food additives shall meet the requirements of 7.3 in GB 14881-2013.</p> <p>7.3.2 Food additives shall be used according to those specified in GB 2760.</p> <p><b>7.4 Food related products</b></p> <p>7.4.1 Food related products shall meet the relevant requirements of 7.4 in GB 14881-2013</p> <p>7.4.2 Processing water, ice-making water, thawing water and steam water shall meet the requirements of GB 5749.</p> <p>7.4.3 The manufacture, crushing, transportation and storage of ice used in the processing shall be carried out under hygienic conditions; the containers used for containing, transportation and storage shall be easy to clean and avoid contamination.</p>	<p>1. Food business operators placing on the market the following fishery products derived from finfish or cephalopod molluscs:</p> <p>(a) fishery products intended to be consumed raw; or</p> <p>(b) marinated, salted and any other treated fishery products, if the treatment is insufficient to kill the viable parasite; must ensure that the raw material or finished product undergo a freezing treatment in order to kill viable parasites that may be a risk to the health of the consumer.</p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter VII, Water supply</b></p> <p>4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.</p>	<p>See discussion of GB 2760</p> <p>See discussion of GB 5749</p>

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<p><b>8 Food safety control in production process</b></p> <p><b>8.1 Product contamination risk control</b></p> <p>8.1.1 It shall meet the requirements of 8.1 in GB 14881-2013.</p> <p>8.1.2 The quality and safety management system based on hazard analysis shall be established and implemented, and the necessary food safety control measures shall be taken. In the risk assessment of hazards, different process characteristics of aquatic products shall be fully considered to determine the hazard prevention measures and critical control point.</p> <p>8.1.3 Raw material pretreatment, freezing, cooking, drying, smoking, salting and other processing processes shall be relatively isolated according to their respective processing techniques and product characteristics to prevent cross-contamination of human flow, logistics and airflow.</p>	<p><b>Regulation (EC) No 852/2004, Article 5</b></p> <p>1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</p> <p><b>Regulation (EC) No 852/2004, Chapter II</b></p> <p>1. In rooms where food is prepared, treated or processed the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations.</p>	<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's, 2.1:</b></p> <p>b) Lay-out should strictly separate between contaminated (low care) and clean areas (high care) (or separation in time and suitable cleaning in between); suitable arrangements of rooms should be made for one-direction production flow and cooled rooms or heating facilities should be insulated.</p> <p>k) Attention should be paid to the different possibilities whereby the use of equipment can result in (cross-) contamination of food: i. Prevention of contamination of the equipment by the environment e.g. condensation dripping from ceilings; ii. Prevention of contamination within the food handling equipment e.g. accumulation of food residues in slicing devices; iii. Prevention of contamination by raw materials: separate equipment (or</p>

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<p>8.1.4 Waste water and waste shall be avoided to cause contamination to raw materials and products.</p> <p><b>8.2 Control of biological contamination</b></p> <p>8.2.1 Cleaning and disinfection Cleaning and disinfection shall meet the requirements of 8.2.1 in GB 14881-2013.</p> <p>8.2.2 Microbe control in the processing of aquatic products</p> <p>8.2.2.1 General requirements</p> <p>8.2.2.1.1 General requirements shall meet the requirements of 8.2.2 in GB 14881-2013.</p> <p>8.2.2.1.2 The plan for microbe monitoring of the environment and production process is determined according to the characteristics of aquatic products and may be implemented by reference of the requirements of Annex A. If necessary, the monitoring procedures for pathogenic bacteria in the processing of aquatic products shall be established.</p>	<p><b>Regulation (EC) No 852/2004, Chapter VI</b></p> <p>1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.</p> <p>4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.</p> <p><b>Regulation (EC) No 2073/2005, Article 3</b></p> <p>1. Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I. To this end the food business operators at each stage of food production, processing and distribution, including retail, shall take measures, as part of their procedures based on HACCP principles together with the implementation of good hygiene practice, to ensure the following: (a) that the supply, handling and processing of raw materials and foodstuffs under their control are carried out in</p>	<p>cleaning and disinfection between use) for raw products and cooked products (chopping boards, knives, dishes, ...).</p> <p><b>Regulation (EC) No 852/2004, Chapter VII</b></p> <p>(b) Clean water may be used with whole fishery products.</p> <p>Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When clean water is used, adequate facilities and procedures are to be available for its supply to ensure that such use is not a source of contamination for the foodstuff.</p> <p><b>Regulation (EC) No 2073/2005, Article 4</b></p> <p>1. Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.</p> <p>2. Food business operators shall decide the appropriate sampling frequencies, except where Annex I provides for specific sampling frequencies, in which case the sampling</p>

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<p>8.2.2.1.3 Where there is an abnormality in the monitoring indicators of aquatic products at the end of the production line, the sampling frequency of microbe monitoring in the environment shall be increased, the quantity of sampling points shall be appropriately increased according to the situation, and appropriate corrective measures shall be taken.</p> <p>8.2.2.1.4 A temperature indicator shall be installed in the process or place where temperature control is required.</p>	<p>such a way that the process hygiene criteria are met, (b) that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.</p> <p><b>Regulation (EC) No 2073/2005, Article 5</b> 2. Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method</p> <p><b>Regulation (EC) No 2073/2005, Article 7</b> 1. When the results of testing against the criteria set out in Annex I are unsatisfactory, the food business operators shall take the measures laid down in paragraphs 2 to 4 of this Article together with other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers. In addition, they shall take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place.</p> <p><b>Regulation (EC) No 852/2004, Chapter V</b> 2. Where necessary, equipment is to be fitted with any appropriate control device to</p>	<p>frequency shall be at least that provided for in Annex I. Food business operators shall make this decision in the context of their procedures based on HACCP principles and good hygiene practice, taking into account the instructions for use of the foodstuff.</p> <p>Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's:</b></p>

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<p>8.2.2.1.5 The operation in need of steam shall be provided with adequate pressure and steam. 8.2.2.1.6 The thawing time and temperature of raw materials for aquatic products shall be strictly controlled.</p> <p>8.2.2.2 Microbe control of aquatic products in different processes</p> <p>8.2.2.2.1 Refrigerated aquatic products</p> <p>8.2.2.2.1.1 Cooling measures shall be provided in processing workshop.</p> <p>8.2.2.2.1.2 The processed aquatic products shall be moved to a refrigerated environment as soon as possible, and a temperature indicator shall be provided in the refrigerator.</p> <p>8.2.2.2.2 Frozen aquatic products</p> <p>8.2.2.2.2.1 The freezing time and temperature shall be determined according to the natural</p>	<p>guarantee fulfilment of this Regulation's objectives.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter IV:</b></p> <p>A. REQUIREMENTS FOR COOKING OF CRUSTACEANS AND MOLLUSCS</p> <p>1. Rapid cooling must follow cooking. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.</p> <p>3. After shelling or shucking, cooked products must be frozen immediately, or be chilled as soon as possible to the temperature set out in Chapter VII.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter VII</b></p> <p>2. Frozen fishery products must be kept at a temperature of not more than – 18 °C in all parts of the product; however, whole fish initially frozen in brine intended for the</p>	<p>2.11 Temperature control of storage environment</p> <p>a) Temperature and humidity should be (automatically) recorded where relevant. Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's, 2.11:</b></p> <p>b) Alarm devices should preferably be automatic. c) Temperature fluctuations should be minimized e.g. by using a separate room/freezer to freeze products from that used for storage of frozen products.</p> <p>d) Chilling/heating capacity should be adapted to the amounts involved.</p> <p>e) Temperatures in the product and during transport should also be monitored.</p> <p>f) Verification should occur regularly</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter V</b></p> <p>In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter.</p>

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<p>state of the aquatic product such as thickness, shape, production quantity, etc., to ensure that the maximum ice crystal formation zone is passed as soon as possible.</p> <p>8.2.2.2.2 Adequate cold treatment shall be ensured for raw seafood to kill parasites harmful to human body.</p> <p>8.2.2.2.3 Where the product is packaged after freezing, the packaging operation shall be carried out in a temperature-controlled environment to ensure that the temperature of the frozen product center is lower than -18°C.</p>	<p>manufacture of canned food may be kept at a temperature of not more than – 9 °C.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter III, D Requirements concerning parasites</b></p> <p>1. Food business operators placing on the market the following fishery products derived from finfish or cephalopod molluscs:</p> <p>(a) fishery products intended to be consumed raw; or</p> <p>(b) marinated, salted and any other treated fishery products, if the treatment is insufficient to kill the viable parasite; must ensure that the raw material or finished product undergo a freezing treatment in order to kill viable parasites that may be a risk to the health of the consumer.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter I, C. Requirements for freezer vessels</b></p> <p>Freezer vessels must:</p> <p>1. have freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, so as to achieve a core temperature of not more than – 18 °C;</p> <p>2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than – 18 °C. Storage holds must not be used for freezing unless they fulfil the conditions laid down in point 1, and must be equipped with a temperature-recording device in a place</p>	<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's</b></p> <p>2.11 Temperature control of storage environment</p> <p>d) Chilling/heating capacity should be adapted to the amounts involved.</p> <p>Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's</b></p> <p>2.11 Temperature control of storage environment</p> <p>a) Temperature and humidity should be (automatically) recorded where relevant.</p> <p>c) Temperature fluctuations should be minimized e.g. by using a separate room/freezer to freeze products from that used for storage of frozen products.</p>

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<p>8.2.2.2.3 Dried aquatic products</p> <p>8.2.2.2.3.1 The drying process shall be done in a pest-proof and dust-proof manner.</p> <p>8.2.2.2.3.2 The drying time, drying temperature and ambient humidity of dry products shall be strictly controlled to ensure that the water activity of dry products is within safe limits.</p> <p>8.2.2.2.4 Pickled aquatic products</p>	<p>where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest;</p> <p><b>Chapter III, B. Requirements for frozen products</b></p> <p>Establishments on land that freeze or store frozen fishery products must have equipment, adapted to the activity carried out, that satisfies the requirements for freezer vessels...</p> <p><b>Chapter VII: Storage of fishery products</b></p> <p>2. Frozen fishery products must be kept at a temperature of not more than – 18 °C in all parts of the product;</p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter IX:</b></p> <p>4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).</p>	<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's, 2.3</b></p> <p>f) A pest control program should be available:</p> <p>i. Baits and traps (inside/outside) should be considered in appropriate numbers and strategic placement;</p> <p>ii. The program should cover rodents, crawling, walking and flying pests;</p> <p>iii. Dead pests and insects should be frequently removed ensuring no possible contact with food;</p> <p>iv. The cause should be determined in case of a recurrent problem;</p> <p>v. Pesticides should be stored and used so that there is no possible contact with food, packaging material, equipment, ...</p> <p><b>Remark:</b> <i>General requirements are laid down in EU legislation, detailed procedures such as drying and pickling procedures are laid down in</i></p>

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<p>8.2.2.2.4.1 Appropriate salinity shall be provided for the production of pickled products to prevent the proliferation of non-halophilic bacteria.</p> <p>8.2.2.2.4.2 Installations preventing the infestation of mosquitoes and flies shall be provided.</p> <p>8.2.2.2.5 Canned aquatic products Adequate sterilization temperature and time shall be ensured.</p> <p><b>8.3 Control of chemical contamination</b></p> <p>8.3.1 It shall meet the requirements of 8.3 in GB 14881-2013.</p>	<p><b>Regulation (EC) No 852/2004, Annex II, Chapter XI, Heat treatment:</b></p> <p>The following requirements apply only to food placed on the market in hermetically sealed containers:</p> <p>1. any heat treatment process used to process an unprocessed product or to process further a processed product is:</p> <p>(a) to raise every party of the product treated to a given temperature for a given period of time; and (b) to prevent the product from becoming contaminated during the process;</p> <p>2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices;</p> <p>3. the process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation)</p>	<p><i>guides to good practice developed by the sector (either national guides or community guides; see examples given below on page ).</i></p> <p>Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's, 2.3</b></p> <p>b) Insect screen should be placed at windows. c) Doors should be kept closed except when loading and or unloading.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VII, Chapter II, A:</b></p> <p>5. After purification or relaying, live bivalve molluscs from class B or C production areas must meet all of the requirements of Chapter V. However, live bivalve molluscs from such areas that have not been submitted for purification or relaying may be sent to a processing establishment, where they must undergo treatment to eliminate pathogenic micro-organisms (where appropriate, after removal of sand, mud or slime in the same or another establishment). The permitted treatment methods are:</p> <p>(a) sterilisation in hermetically sealed containers; and (b) heat treatments (involving ...)</p>

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<p>8.3.2 The cleaning and disinfection plan shall be formulated according to the characteristics of different types of aquatic products, and shall be implemented by designated personnel. The detergents and disinfectants used shall respectively comply with the requirements of GB 14930.1 and GB 14930.2.</p> <p>8.3.3 There shall be no disinfectant residue on the contact surface of aquatic products.</p> <p>8.3.4 Packaging materials in contact with aquatic products shall comply with the corresponding standards to prevent the migration of harmful substances to food so as to ensure human health.</p> <p><b>8.4 Control of physical contamination</b> It shall meet the requirements of 8.4 in GB 14881-2013.</p> <p><b>8.5 Packaging</b> 8.5.1 Packaging shall meet the requirements of 8.5 in GB 14881-2013. 8.5.2 Packaging materials for frozen aquatic products shall be selected from materials with low temperature resistance and good water resistance.</p>	<p><b>Regulation (EC) No 852/2004, Annex II, Chapter X:</b> 1. Material used for wrapping and packaging are not to be a source of contamination.</p> <p><b>Regulation (EC) No 852/2004, Annex II, Chapter X:</b></p>	<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's:</b> 2.2 Cleaning and disinfection a) What, when and how should be considered. b) Typical steps should be removal of visible dirt → cleaning → rinsing → disinfection → rinsing. c) Materials and approach for cleaning equipment should be different between low and highly contaminated areas. d) Hot water should be used as much as possible for cleaning. e) Technical information should be available regarding detergents, disinfection agents (e.g. active component, contact time, concentration). f) Visual checks on cleaning and sampling for analysis (e.g. hygienogram) should be used to control disinfection activities. See above: b) Typical steps should be removal of visible dirt → cleaning → rinsing → disinfection → rinsing.</p>

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<p>8.5.3 The tanks of canned aquatic products shall be made of corrosion-resistant materials.</p> <p><b>10 Storage and transportation of aquatic products</b>  <b>10.1 General requirements</b>            General requirements shall meet the relevant requirements of Clause 10 in GB 14881- 2013.  <b>10.2 Storage</b>            10.2.1 The goods in warehouse shall be kept at a certain distance from the wall, the ground</p>	<p>3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VII, Chapter III, Structural requirements for dispatch and purification centres:</b>            2. Tanks and water storage containers must meet the following requirements:            (a) Internal surfaces must be smooth, durable, impermeable and easy to clean.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter I, I Structural and equipment requirements, A. Requirements for all vessels:</b>            2. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter VII: Storage of fishery products</b>            Food business operators storing fishery products must ensure compliance with the following requirements.</p>	<p>Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's:</b>            2.10 Raw materials (supplier selection, specifications)            a) Consideration should be given not only to the supply of raw materials themselves but also to the supply of additives, processing aids, packaging material and food contact material.</p> <p>Guidance document <b>Commission Notice 2016/C 278/01, Annex I, 2 Examples of PRP's:</b>            2.11 Temperature control and storage environment            c) Temperature fluctuations should be minimized e.g. by using a separate room/freezer to freeze products from that used for storage of frozen products.</p>

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<p>and the ceiling, stored separately and clearly marked.</p> <p>10.2.2 The storage warehouse shall be kept clean and tidy and meet the food hygiene requirements.</p> <p>10.2.3 The temperature and humidity of the storage warehouse shall meet the requirements of product characteristics. The temperature of refrigerating room shall be maintained at 0°C~4°C. The temperature of frozen room shall be controlled below -18°C.</p> <p><b>10.3 Transportation</b> During transportation, insulation or cooling measures shall be provided for refrigerated aquatic products and frozen aquatic products, and the transportation time and temperature fluctuations shall be minimized.</p>	<p>1. Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice.</p> <p>2. Frozen fishery products must be kept at a temperature of not more than – 18 °C in all parts of the product; however, whole fish initially frozen in brine intended for the manufacture of canned food may be kept at a temperature of not more than – 9 °C.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter VIII: Transport of fishery products</b> Food business operators transporting fishery products must ensure compliance with the following requirements.</p> <p>1. During transport, fishery products must be maintained at the required temperature. In particular:</p> <p>(a) fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice;</p> <p>(b) frozen fishery products, with the exception of whole fish initially frozen in brine intended for the manufacture of canned food, must be maintained during transport at an even</p>	

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<p><b>Annex A</b> <b>Guidelines for microbe monitoring program for processing of aquatic products</b></p> <p>Monitoring item: Microbe monitoring in environment - Contact surface of aquatic products - Contact surface adjacent to aquatic products or aquatic product contact surface - ambient air in processing area</p> <p>Microbe monitoring during processing</p>	<p>temperature of not more than – 18 °C in all parts of the product, possibly with short upward fluctuations of not more than 3 °C.</p> <p><b>Regulation (EC) No 2073/2004 on microbiological criteria for foodstuffs.</b> <b>Article 4</b> 1. Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice. 2. Food business operators shall decide the appropriate sampling frequencies, except where Annex I provides for specific sampling frequencies, in which case the sampling frequency shall be at least that provided for in Annex I. Food business operators shall make this decision in the context of their procedures based on HACCP principles and good hygiene practice, taking into account the instructions for use of the foodstuff.</p> <p><b>Article 5</b> 1. The analytical methods and the sampling plans and methods in Annex I shall be applied as reference methods 2. Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method.</p>	<p><i>In the Chinese national standard the suggested frequency for environmental microbial monitoring is every two weeks or every month to test for aerobic bacteria count and coliform bacteria.</i></p> <p><i>In the EU legislation the frequency will be determined by the food business operator as part of the prerequisite programs and the procedures based on the HACCP principles put in place in the food production establishment.</i></p>

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<p>A.2 The treatment requirements for inconformity condition of microbe monitoring: the monitoring result of each monitoring point shall meet the monitoring index limit and remain stable; where the slight inconformity appears, measures such as increasing sampling frequency may be adopted to strengthen monitoring; where the severe inconformity appears, correction shall be carried out immediately and the reason leading to problem shall be found out at the same time to determine whether the corresponding corrective measures are taken for microbe monitoring program.</p>	<p><b>Article 4</b> 1. Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.</p> <p><b>Article 5</b> 4. If the aim of the testing is to specifically assess the acceptability of a certain batch of foodstuffs or a process, the sampling plans set out in Annex I shall be respected as a minimum.</p> <p><b>Regulation (EC) No 2073/2004 on microbiological criteria for foodstuffs.</b> <b>Article 7</b> 1. When the results of testing against the criteria set out in Annex I are unsatisfactory, the food business operators shall take the measures laid down in paragraphs 2 to 4 of this Article together with other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers. In addition, they shall take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the</p>	<p><i>In the Chinese national standard the suggested frequency is the product produced in the first time of shift beginning and every week (every two weeks or every month) of subsequent continuous production process to test for aerobic bacteria count, coliform bacteria, yeast and mold or other indicator bacteria.</i></p> <p><i>In the EU legislation details (micro-organism, sampling plan, limits, analytical reference method, stage where the criterion applies and action in case of unsatisfactory results) have been laid down regarding food safety criteria for live bivalve molluscs and live echinoderms, tunicates and gastropods, for fishery products from fish species associated with a high amount of histidine, for fishery products, which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine and for fish sauce produced by fermentation of fishery products in Annex I, Chapter 1 of Regulation (EC) No 2073/2004. Furthermore, in the EU legislation details (micro-organism, sampling plan, limits, analytical reference method, stage where the criterion applies and action in case of unsatisfactory results) have been laid down regarding process hygiene criteria for shelled and shucked products of cooked crustaceans and molluscan shellfish in Annex I, Chapter 2.4 of Regulation (EC) No 2073/2004.</i></p>

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	<p>HACCP-based procedures or other food hygiene control measures in place.</p> <p>2. When testing against food safety criteria set out in Chapter 1 of Annex I provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002. However, products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.</p> <p>4. In the event of unsatisfactory results as regards process hygiene criteria the actions laid down in Annex I, Chapter 2 shall be taken.</p>	

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## 1.2.2 National standard GB 10136-2015 - Aquatic products of animal origin

Chinese National standard GB 10136	EU Regulation (EC) No 853/2004	Implementing rules and remarks
<p><b>1. Scope</b> This Standard applies to aquatic products of animal origin.</p>	<p><b>Regulation (EC) No 853/2004 Article 1. Scope</b> 1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.</p>	
<p><b>2 Terms and definitions</b> <b>2.1 aquatic products of animal origin</b> aquatic products made from fresh and frozen aquatic products of animal origin with or without excipients and processed by corresponding processes, including instant aquatic products of animal origin, pre-braking aquatic products of animal origin and other aquatic products of animal origin, excluding canned aquatic products of animal origin <b>2.2 instant aquatic products of animal origin</b> aquatic products of animal origin that can be eaten directly without further heat treatment, including instant brake aquatic products and cooked brake aquatic products 2.2.1 instant brake aquatic products: aquatic products that can be directly consumed, which are made of fresh and frozen aquatic products of animal origin and have been cleaned and processed</p>	<p><b>Regulation (EC) No 853/2004 Annex I Definitions</b> 3.1. 'Fishery products' means all seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such animals.  3.5. 'Fresh fishery products' means unprocessed fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling.</p>	

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<b>Chinese National standard GB 10136</b>	<b>EU Regulation (EC) No 853/2004</b>	<b>Implementing rules and remarks</b>
<p>before eating, without being heated and cooked when eating, including marinated raw aquatic products of animal origin and instant raw aquatic products of animal origin.</p> <p>2.2.1.1 marinated raw aquatic products of animal origin: pickled products that can be eaten directly, which use live mud snails, shellfish, freshwater crabs and fresh or frozen sea crabs, fish seeds and other animal water products as raw materials, are made by salting or pickling, drunk processing</p> <p>2.2.1.2 instant raw aquatic products of animal origin: aquatic products that can be eaten directly, which use fresh, live, refrigerated and frozen fish, crustaceans, shellfish, cephalopods, etc. as raw materials, are made by clean processing, without being salted or cooked.</p> <p>2.2.2 cooked brake aquatic products: aquatic products that can be eaten directly, which use fresh and frozen aquatic products of animal origin as raw materials, are made by cooking, being deepfried, smoked, dried, etc.</p>		

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Chinese National standard GB 10136	EU Regulation (EC) No 853/2004	Implementing rules and remarks
<p><b>2.3 pre-braking aquatic products of animal origin<sup>1</sup></b> products that are not directly edible, which use fresh and frozen aquatic products of animal origin as raw materials, with or without excipients, are made by being pickled, dried, prepared, starching, etc., including semi-finished products such as salted aquatic products, pre-made dried aquatic products, surimi products, frozen hanging pulp products, bread crumbs or batter-wrapped fish pieces and fish fillets, excluding raw aquatic products after being cleaned (cut or shelled)</p> <p>2.3.1 salted fish salted aquatic products made from fresh and frozen fish, being salted and processed, which are not directly edible.</p> <p>2.3.2 prefabricated aquatic dried products dried aquatic products that are not directly edible, which use fresh and frozen aquatic products of animal origin as raw materials, with or without excipients, are made by drying process.</p>	<p>3.6. 'Prepared fishery products' means unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting, and chopping</p>	

<sup>1</sup> Pre-baking refers to Use the fresh or frozen product Originally from Aquatic Animal Products, to process ( add another product or not - such as sauces, salt ) food that not for direct eat – such as fish balls. This **pre-braking aquatic products of animal origin ( no matter fresh or frozen)** is exclusive the **aquatic products that just being cleaned or cut , or pilled out the shell from aquatic .**

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<p><b>3 Technical requirements</b></p> <p><b>3.1 Requirements for raw material</b></p> <p>3.1.1 Raw material shall comply with the provisions of GB 2733.</p> <p>3.1.2 Excipients shall comply with the corresponding food standards and relevant regulations.</p> <p><b>3.2 Sensory requirements</b></p> <p>Sensory requirements shall comply with the provisions of Table 1.</p> <p>Table 1 Sensory requirements:</p> <p>Color: With the color that the product shall have</p> <p>Taste, odor: With the normal taste, odor, no smell, no rancidity</p> <p>State: With the normal shape and tissue state of the product, no foreign matter visible in normal vision, no mold, no insects</p> <p>Inspection method: Take an appropriate amount of the sample on a white porcelain plate and observe the color and state under natural light. Smell the odor, rinse the mouth with warm water, taste its taste.</p>	<p><b>Regulation (EC) No 853/2004, Annex III, Section VII, Chapter V: Health standards for live bivalve molluscs</b></p> <p>In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.</p> <p>1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter V: Health standards for fishery products</b></p> <p>In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human</p>	<p>See discussion of GB 2733</p> <p><b>Regulation (EC) No 2406/96</b> laying down common marketing standards for certain fishery products, Annex I Freshness ratings</p> <p>The ratings established in this Annex apply to the following products or groups of products, by reference to appraisal criteria specific to each of them.</p> <p>A. Whitefish</p> <p>Haddock, cod, saithe, pollack, redfish, whiting, ling, hake, Ray's bream, anglerfish, pouting and poor cod, bogue, picarel, conger, gurnard, mullet, plaice, megrim, sole, dab, lemon sole, flounder, scabbard fish.</p> <p>B. Bluefish</p> <p>Albacore or longfinned tuna, bluefin tuna, bigeye tuna, blue whiting, herring, sardines, mackerel, horse mackerel, anchovy, sprat.</p> <p>C. Selachii</p> <p>Dogfish, skate.</p> <p>D. Cephalopods</p> <p>Cuttlefish.</p>

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	<p>consumption meet the standards laid down in this Chapter.</p> <p>A. Organoleptic properties of fishery products</p> <p>Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.</p> <p><b>Regulation (EC) No 2074/2005, Annex II, Section I, Chapter II Visual inspection</b></p> <p>1. Visual inspection shall be performed on a representative number of samples. The persons in charge of establishments on land and qualified persons on board factory vessels shall determine the scale and frequency of the inspections by reference to the type of fishery products, their geographical origin and their use. During production, visual inspection of eviscerated fish must be carried out by qualified persons on the abdominal cavity and livers and roes intended for human consumption. Depending on the system of gutting used, the visual inspection must be carried out:</p> <p>(a) in the case of manual evisceration, in a continuous manner by the handler at the time of evisceration and washing;</p> <p>(b) in the case of mechanical evisceration, by sampling carried out on a representative number of samples being not less than 10 fish per batch.</p>	<p>E. Crustaceans</p> <ol style="list-style-type: none"> <li>1. Shrimps,</li> <li>2. Norway lobster</li> </ol> <p><i>Detailed criteria are laid down for these products.</i></p>

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	2. The visual inspection of fish fillets or fish slices must be carried out by qualified persons during trimming and after filleting or slicing. Where an individual examination is not possible because of the size of the fillets or the filleting operations, a sampling plan must be drawn up and kept available for the competent authority in accordance with Chapter II (4) of Section VIII of Annex III to Regulation (EC) No 853/2004. Where candling of fillets is necessary from a technical viewpoint, it must be included in the sampling plan.	
<b>3.3 Physical and chemical indicators</b> Physical and chemical indicators shall comply with the provisions of Table 2. Physical and chemical indicators: Peroxide value (by fat) (g/100g): - Salted fish (Chinese herring, Spanish mackerel, salmon) ≤ 4.0 - Salted fish (excluding Chinese herring, Spanish mackerel, salmon) ≤ 2.5 - Prefabricated aquatic products ≤ 0.6	The EU Regulations does not stipulate criteria for peroxide values in fishery products	Compliance with freshness and other criteria will ensure also compliant peroxide formation.
Histamine (mg/100g): - Salted fish (high histamine fish ≤ 40 - Salted fish (excluding high histamine fish) ≤ 20	<b>Regulation (EC) No 2073/2005, Annex I, Chapter 1. Food safety criteria</b> 1.26 Fishery products from fish species associated with a high amount of histidine: 9 units comprise the sample 2 sample units may give values between 100 and 200 mg/kg for products placed on the market during their shelf-life 1.27 Fishery products, except those in food category 1.27a, which have undergone	high amount of histidine: particularly fish species of the families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombrosidae

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	<p>enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine</p> <p>9 units comprise the sample</p> <p>2 sample units may give values between 200 and 400 mg/kg for products placed on the market during their shelf-life</p> <p>1.27a Fish sauce produced by fermentation of fishery products</p> <p>1 unit comprise the sample</p> <p>0 sample units may give values above 400 mg/kg for products placed on the market during their shelf-life.</p>	
<p>Volatile base nitrogen / (mg/100g):</p> <p>Marinated raw aquatic products of animal origin ≤ 25</p> <p>Pre-brake aquatic products of animal origin (excluding dry and salted products) ≤ 30</p>	<p><b>Regulation (EC) No 627/2019, Annex VI, Chapter II</b></p> <p>1. Unprocessed fishery products belonging to the species categories listed in Chapter II shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:</p> <p>(a) 25 mg of nitrogen/100 g of flesh for the species referred to in point 1 of Chapter II;</p> <p>(b) 30 mg of nitrogen/100 g of flesh for the species referred to in point 2 of Chapter II</p> <p>(c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Chapter II.</p> <p>The reference method to be used for</p>	<p><i>TVB-N = total volatile basic nitrogen.</i></p>

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	<p>checking the TVB-N limit involves distilling an extract deproteinised by perchloric acid as set out in Chapter III.</p> <p><b>Regulation (EC) 627/2019, Annex VI, Chapter II</b></p> <ol style="list-style-type: none"> <li>1. Sebastes spp., Helicolenus dactylopterus, Sebastichthys capensis.</li> <li>2. Species belonging to the Pleuronectidae family (with the exception of halibut: Hippoglossus spp.).</li> <li>3. Salmo salar, species belonging to the Merlucciidae family, species belonging to the Gadidae family.</li> </ol>	
<p><b>3.4 Contaminant limits</b> Contaminant limits shall comply with the provisions of GB 2762.</p> <p><b>3.5 Pesticide residue limits and veterinary drug residue limits</b></p> <p>3.5.1 Pesticide residue limits shall comply with the provisions of GB 2763.</p> <p>3.5.2 Veterinary drug residue limits shall comply with relevant national regulations and announcements.</p>		<p>See discussion of GB 2762</p> <p>See discussion of GB 2763</p>
<p><b>3.6 Microbial limits</b></p> <p>3.6.1 Pathogenic bacteria limits of cooked brake aquatic products and instant brake aquatic products of animal origin shall comply with the provisions of GB 29921 on cooked aquatic products and instant raw aquatic products, respectively.</p>		<p>See discussion of GB 29921</p>

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<p>3.6.2 The microbial limits of instant aquatic products of animal origin shall also comply with the requirements of Table 3.</p> <p>Table 3 Microbial limits:</p> <ul style="list-style-type: none"> <li>- Total number of colonies / (CFU/g)</li> <li>5 units comprise the sample</li> <li>2 sample units may give values between <math>5 \times 10^4</math> and <math>10^5</math> CFU/g</li> <li>Coliform group / (CFU/g)</li> <li>5 units comprise the sample</li> <li>2 sample units may give values between <math>10</math> and <math>10^2</math> CFU/g</li> </ul>	<p><b>Regulation (EC) No 2073/2005, Annex I, Chapter 1. Food safety criteria</b></p> <p>1.16 Cooked crustaceans and molluscan shellfish <i>Salmonella</i> - 5 units comprise the sample and 0 sample units may contain bacteria in 25 g for products placed on the market during their shelf-life</p> <p>1.17 Live bivalve molluscs and live echinoderms, tunicates and gastropods <i>Salmonella</i> - 5 units comprise the sample and 0 sample units may contain bacteria in 25 g for products placed on the market during their shelf-life</p> <p>1.25 Live bivalve molluscs and live echinoderms, tunicates and marine gastropods <i>E. coli</i> – 5 units comprise the sample and 1 sample unit may contain between 230 and 700 MPN/ 100 g of flesh and intravalvular liquid for products placed on the market during their shelf-life.</p> <p><b>Regulation (EC) No 2073/2005, Annex I, Chapter 2. Process hygiene criteria</b></p> <p>2.4 Fishery products</p> <p>2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish <i>E. coli</i> - 5 units comprise the sample and 2 sample units may contain between 1 and 10 MPN/g</p>	<p>Microbial testing requirements differ between Chinese National standards and EU rules. Both standards seek to exclude contamination with potentially pathogenic, faecal bacteria. Indicator organisms used are different but very likely cross compliance will apply. The differences are, therefore, not considered to be of relevance for consumer safety.</p>

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	Coagulase-positive staphylococci - 5 units comprise the sample and 2 sample units may contain between 100 and 1000 cfu/g at the end of the manufacturing process.	
<b>3.7 Parasite indicators</b> Parasite indicators of aquatic products of animal origin shall comply with the provisions of Table 4. Table 4 Parasite indicators - sphincter must not be detected (see annex A) - nematode larva must not be detected (see annex A) - locust mites must not be detected (see annex A)	See below the comparative assessment of Annex A	
<b>3.8 Food additives</b> The use of food additives shall comply with the provisions of GB 2760.		See discussion of GB 2760
<b>4 Other</b> <b>4.1 Marks</b> Product marks shall comply with the provisions of GB 7718. Indicate the edible methods. <b>4.2 Storage</b> The products shall be stored at the temperature specified. Frozen aquatic products shall be kept below -18°C.	<b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter VII: Storage of fishery products</b> 2. Frozen fishery products must be kept at a temperature of not more than – 18 °C in all parts of the product;	<i>GB 7718 relates to the labelling of food products, which is outside the scope of the current study.</i>
<b>Annex A</b> - Method for testing sphincter, nematode larva, locust mites in instant brake aquatic products	<b>Regulation (EU) No 1276/2011 amends Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter III</b> D. Requirements concerning parasites	

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<b>Chinese National standard GB 10136</b>	<b>EU Regulation (EC) No 853/2004</b>	<b>Implementing rules and remarks</b>
<p>A.1 Visual inspection Large-sized insects such as anisakis larvae, broad-striped locust, can be directly inspected by the naked eyes after the muscles and internal organs are torn open. Perform identification by microscopy if necessary.</p> <p>A.2 Microscopic examination</p> <p>A.2.1 Reagents Artificial digestive juice: take 5g of pepsin, dissolve in 900mL of distilled water, add 7mL of concentrated hydrochloric acid, then add water till 1000mL; completely mix, place for 15min for use.</p> <p>A.2.2 Apparatus and equipment</p> <p>A.2.2.1 Microscope (multiple: 10×10).</p> <p>A.2.2.2 Water bath or incubator (37°C).</p> <p>A.2.2.3 Tissue masher.</p> <p>A.2.3 Specimen preparation</p> <p>Take appropriate amount of muscle to beat with tissue masher (low speed, sample smashing). Set in an Erlenmeyer, add artificial digestive juice in a ratio of 1:10. Stir well. Place in a 37°C water bath or incubator for 4h~5h so as to make the muscles fully digested. Absorb supernatant. Add an appropriate amount of distilled water. Conduct precipitation after stirring for 20min~30min. Then absorb supernatant. Rinse several times until the supernatant is clear. Perform precipitation for use.</p> <p>A.2.4 Inspection</p>	<p>1. Food business operators placing on the market the following fishery products derived from finfish or cephalopod molluscs:</p> <p>(a) fishery products intended to be consumed raw; or</p> <p>(b) marinated, salted and any other treated fishery products, if the treatment is insufficient to kill the viable parasite; must ensure that the raw material or finished product undergo a freezing treatment in order to kill viable parasites that may be a risk to the health of the consumer.</p> <p>2. For parasites other than trematodes the freezing treatment must consist of lowering the temperature in all parts of the product to at least: (a) – 20 °C for not less than 24 hours; or (b) – 35 °C for not less than 15 hours.</p> <p>3. Food business operators need not carry out the freezing treatment set out in point 1 for fishery products:</p> <p>(a) that have undergone, or are intended to undergo before consumption a heat treatment that kills the viable parasite. In the case of parasites other than trematodes the product is heated to a core temperature of 60 °C or more for at least one minute;</p> <p>(b) that have been preserved as frozen fishery products for a sufficiently long period to kill the viable parasites;</p> <p>(c) from wild catches, provided that:</p>	

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<p>Take precipitate processed in A.2.3. Dilute with distilled water under the microscope to observe the parasite.</p> <p>A.3 Result report</p> <p>When parasites are found by naked eye and microscopic examination, it shall be reported as parasite is detected. And indicate the type of parasite. When parasites are not found by naked eye and microscopic examination, it shall be reported as parasite is not detected.</p>	<p>(i) there are epidemiological data available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites; and</p> <p>(ii) the competent authority so authorises;</p> <p>(d) derived from fish farming, cultured from embryos and have been fed exclusively on a diet that cannot contain viable parasites that present a health hazard, and one of the following requirements is complied with:</p> <p>(i) have been exclusively reared in an environment that is free from viable parasites; or (ii) the food business operator verifies through procedures, approved by the competent authority, that the fishery products do not represent a health hazard with regard to the presence of viable parasites.</p> <p>4. (a) When placing on the market, except when supplied to the final consumer, fishery products referred to in point 1 must be accompanied by a document issued by the food business operator performing the freezing treatment, stating the type of freezing treatment that the products have undergone. (b) Before placing on the market fishery products referred to in points 3(c) and (d) which have not undergone the freezing treatment or which are not intended to undergo before consumption a treatment that kills viable parasites that present a health hazard, a food business operator must ensure that the fishery</p>	

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	products originate from a fishing ground or fish farming which complies with the specific conditions referred to in one of those points. This provision may be met by information in the commercial document or by any other information accompanying the fishery products.	

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### 1.2.3 National standard GB 2733-2015 – Fresh, frozen aquatic products of animal origin

<b>Chinese National standard GB2733</b>	<b>EU Regulation (EC) No 853/2004</b>	<b>Implementing rules and remarks</b>
<p><b>1. Scope</b> The standard applies to fresh, frozen aquatic products of animal origin, including marine products and freshwater products.</p>	<p><b>Scope</b> <b>Regulation (EC) No 853/2004 Article 1. Scope</b> 1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.</p>	
<p><b>2 Technical requirements</b> <b>2.1 Sensory requirements</b> The sensory requirements should conform to the stipulation in Table 1. Table 1 Sensory requirements: - Color - shall conform to normal color of aquatic products - Smell - Should conform to the normal smell of aquatic products, no strange smell - Status - The organization of aquatic products shall be normal, tight muscle, elastic Testing method: Take some sample and place on the white porcelain, observe the color and status under the natural light, and smell</p>	<p><b>Regulation (EC) No 853/2004, Annex III, Section VII, Chapter V: Health standards for live bivalve molluscs</b> In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter. 1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid. <b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter V: Health standards for fishery products</b> In addition to ensuring compliance with microbiological criteria adopted in</p>	

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Chinese National standard GB2733	EU Regulation (EC) No 853/2004	Implementing rules and remarks
	<p>accordance with Regulation (EC) No 852/2004, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter.</p> <p>A. Organoleptic properties of fishery products</p> <p>Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.</p> <p><b>Regulation (EC) No 2074/2005, Annex II, Section I, Chapter II Visual inspection</b></p> <p>1. Visual inspection shall be performed on a representative number of samples. The persons in charge of establishments on land and qualified persons on board factory vessels shall determine the scale and frequency of the inspections by reference to the type of fishery products, their geographical origin and their use. During production, visual inspection of eviscerated fish must be carried out by qualified persons on the abdominal cavity and livers and roes intended for human consumption. Depending on the system of gutting used, the visual inspection must be carried out:</p> <p>(a) in the case of manual evisceration, in a continuous manner by the handler at the time of evisceration and washing;</p>	

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	<p>(b) in the case of mechanical evisceration, by sampling carried out on a representative number of samples being not less than 10 fish per batch.</p> <p>2. The visual inspection of fish fillets or fish slices must be carried out by qualified persons during trimming and after filleting or slicing. Where an individual examination is not possible because of the size of the fillets or the filleting operations, a sampling plan must be drawn up and kept available for the competent authority in accordance with Chapter II (4) of Section VIII of Annex III to Regulation (EC) No 853/2004. Where candling of fillets is necessary from a technical viewpoint, it must be included in the sampling plan.</p>									
<p><b>2.2 Physical and chemical index</b> The physical and chemical index shall conform to the stipulations in Table 2. Table 2 Physical and chemical indicators: - Total volatile basic nitrogen a / (mg/100g)</p> <table border="0"> <tr> <td>Seawater fish and shrimp</td> <td>≤ 30</td> </tr> <tr> <td>Sea crab</td> <td>≤ 25</td> </tr> <tr> <td>Freshwater fish and shrimp</td> <td>≤ 20</td> </tr> <tr> <td>Frozen shellfish</td> <td>≤ 15</td> </tr> </table>	Seawater fish and shrimp	≤ 30	Sea crab	≤ 25	Freshwater fish and shrimp	≤ 20	Frozen shellfish	≤ 15	<p><b>Regulation (EC) 627/2019, Annex VI, Chapter II</b></p> <p>1. Unprocessed fishery products belonging to the species categories listed in Chapter II shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded: (a) 25 mg of nitrogen/100 g of flesh for the species referred to in point 1 of Chapter II; (b) 30 mg of nitrogen/100 g of flesh for the species referred to in point 2 of Chapter II (c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Chapter II.</p>	
Seawater fish and shrimp	≤ 30									
Sea crab	≤ 25									
Freshwater fish and shrimp	≤ 20									
Frozen shellfish	≤ 15									

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Chinese National standard GB2733	EU Regulation (EC) No 853/2004	Implementing rules and remarks
<p>- Histamine (not apply to live aquatic products) mg/100g  Fishes with High Histamine<sup>a</sup> ≤ 40  Other sea fish ≤ 20  <sup>a</sup> Fishes with High Histamine: refer to <i>Scomber japonicus</i>, Horse mackerel, scad, mackerel, skipjack, tuna, saury, Spanish mackerel, <i>Pneumatophorus japonicas</i> and sardine, etc.</p>	<p>The reference method to be used for checking the TVB-N limit involves distilling an extract deproteinised by perchloric acid as set out in Chapter III.</p> <p><b>Regulation (EC) 627/2019, Annex VI, Chapter II, Species categories for which TVB-N limit values are fixed</b></p> <ol style="list-style-type: none"> <li><i>Sebastes</i> spp., <i>Helicolenus dactylopterus</i>, <i>Sebastichthys capensis</i>.</li> <li>Species belonging to the Pleuronectidae family (with the exception of halibut: <i>Hippoglossus</i> spp.).</li> <li><i>Salmo salar</i>, species belonging to the <i>Merlucciidae</i> family, species belonging to the <i>Gadidae</i> family.</li> </ol> <p><b>Regulation (EC) No 2073/2005, Annex I, Chapter 1. Food safety criteria</b></p> <p>1.26 Fishery products from fish species associated with a high amount of histidine:  9 units comprise the sample  2 sample units may give values between 100 and 200 mg/kg for products placed on the market during their shelf-life</p> <p>1.27 Fishery products, except those in food category 1.27a, which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine  9 units comprise the sample  2 sample units may give values between 200 and 400 mg/kg for products placed on the market during their shelf-life</p>	

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	1.27a Fish sauce produced by fermentation of fishery products 1 unit comprise the sample 0 sample units may give values above 400 mg/kg for products placed on the market during their shelf-life.	
<b>2.3 Pollutant limits</b> The pollutant limits should conform to the stipulations in GB 2762.		See discussion of GB 2762
<b>2.4 shellfish toxin limits</b> The shellfish toxin limits shall conform to the stipulations in Table 3. Table 3 Shellfish toxin limits: - Paralytic shellfish toxin (PSP) (MU/g) Shellfish $\leq 4$ - Diarrhetic shellfish poison (DSP) (MU/g) Shellfish $\leq 0.05$	<b>Regulation (EC) No 853/2004, Annex III, Section VII, Chapter V:</b> 2. They must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits: (a) for paralytic shellfish poison (PSP), 800 micrograms of saxitoxin equivalents diHCl per kilogram; (b) for amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram; (c) for okadaic acid and dinophysistoxins together 160 micrograms of okadaic acid equivalents per kilogram; (d) for yessotoxins, 3,75 milligrams of yessotoxin equivalent per kilogram; and (e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.	<i>Prescribed limit values are based on different analytical methods. It is expected that compliance with EU limits will also result in compliance with Chinese national standards.</i>
<b>2.5 Pesticide residues and veterinary drug residues</b> 2.5.1 Pesticide residues limits shall conform to the stipulations in GB 2763.		See discussion of GB 2763

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<b>Chinese National standard GB2733</b>	<b>EU Regulation (EC) No 853/2004</b>	<b>Implementing rules and remarks</b>
2.5.2 Veterinary drug residues limits shall conform related national stipulations and notice.	<b>Regulation (EC) No 470/2009</b> lays down procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin.	
<b>2.6 Food additive</b> The usage of food additive shall conform to the stipulations in GB 2760.		See discussion of GB 2760
<b>3 Others</b> 3.1 Shellfish, freshwater crabs, turtles, trionyx sinensis, ricefield eel shall be processed in vivo, its freezers shall be cleaned (killed or shelled) in vivo and then frozen.	<b>Regulation (EC) No 853/2004, Annex III, Section VIII:</b> 4. In relation to fishery products: (b) associated operations cover any of the following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping; they also include: 1. the transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within fish farms on land; and 2. the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination. <b>Chapter I: requirements for vessels</b> <b>Part I, C. Requirements for freezer vessels</b> Freezer vessels must: 1. have freezing equipment with sufficient capacity to freeze as quickly as possible in a continuous process and with a thermal arrest period as short as possible, so as to	

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Chinese National standard GB2733	EU Regulation (EC) No 853/2004	Implementing rules and remarks
<p>3.2 Frozen aquatic products of animal origin shall be stored in -18°C or even lower. It is forbidden to store toxic, harmful and odor products in the same warehouse.</p>	<p>achieve a core temperature of not more than – 18 °C;  B. Requirements for frozen products  Establishments on land that freeze or store frozen fishery products must have equipment, adapted to the activity carried out, that satisfies the requirements for freezer vessels laid down in Section VIII, Chapter I part I.C, points 1 and 2 and.  <b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter VII:</b>  Food business operators storing fishery products must ensure compliance with the following requirements.  1. Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice.  2. Frozen fishery products must be kept at a temperature of not more than – 18 °C in all parts of the product;  3. Fishery products kept alive must be kept at a temperature and in a manner that does not adversely affect food safety or their viability.</p>	

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## 1.2.4 National standard GB 10133-2014 – Aquatic product condiments

Chinese: National standard GB 10133	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
<p><b>1. Coverage</b> This standard applies to aquatic product condiments.</p>	<p><b>Commission Regulation (EU) No 1129/2011 amending Annex II of Regulation (EC) No 1333/2008 lays down in Part E, 12.2.2 a list of additives permitted in seasonings and condiments.</b></p>	
<p><b>2. Definition</b> <b>2.1 Aquatic product condiments</b> With fish, shrimp, shellfish and crab as main raw materials. And with the corresponding processing technology made of condiments.</p>		
<p><b>Technical requirements</b> <b>3.1 Material requirements</b> 3.1.1 The fish, shrimp, shellfish and crab should comply with the specifications of GB 2733. 3.1.2 Other raw materials shall comply with the relevant food standards and regulations. <b>3.2 Sensory requirements</b> The sensory requirements shall comply with below table 1 requirements. <b>Table 1 sensory requirements</b> Taste and odour: no peculiar smell State: No foreign materials Test method: take proper amount of sample in the white disk. Under a natural light, observe its state, smell the odour. With warm boiled water gargle, taste the flavor.</p>	<p><b>Regulation (EC) No 853/2004, Annex III, Section VII, Chapter V: Health standards for live bivalve molluscs</b> In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.</p>	<p>See discussion of <i>GB 2733</i></p>

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Chinese: National standard GB 10133	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
<p><b>3.3 Contaminants limit</b> The contaminants limited shall comply with the specifications of GB 2762.</p> <p><b>3.4 Microorganisms limit</b> 3.4.1 The pathogen limit shall comply with the specifications of GB 29921. 3.4.2 The micro-organisms limit shall comply with below table 2 requirements. <b>Table 2 micro-organisms limit</b></p>	<p>1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.</p> <p><b>Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter V: Health standards for fishery products</b></p> <p>In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter.</p> <p>A. Organoleptic properties of fishery products</p> <p>Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.</p> <p><b>Regulation (EC) No 2073/2005 Annex I, Chapter 1. Food safety criteria</b></p>	<p>See discussion of <i>GB 2762</i></p> <p>See discussion of <i>GB 29921</i></p>

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<b>Chinese: National standard GB 10133</b>	<b>EU Regulation (EC) No 2073/2005</b>	<b>Implementing rules and remarks</b>
<p>Total number of bacterial colony/(CFU/g or CFU/ml) n=5, c=2, m= 10<sup>1</sup>, M=10<sup>5</sup></p> <p><i>Escherichia coli</i>/(CFU/g or CFU/ml) n=5, c=2, m= 10, M=10<sup>2</sup></p> <p>Sample analysis and treatment shall comply with GB 4789.1 and GB/T 4789.22 to carry out.</p> <p><b>3.5 Food additives</b> The use of food additives shall comply with the specifications of GB 2760.</p>	<p>1.25 Live bivalve molluscs and live echinoderms, tunicates and marine gastropods: <i>E. coli</i> (used as an indicator of faecal contamination): n = 1, c = 0, m = 230 MPN/100g of flesh and intra-valvular liquid (Products placed on the market during their shelf-life)</p> <p><b>Annex I, Chapter 2. Process hygiene criteria</b></p> <p><b>2.4. Fishery products</b></p> <p>2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish: <i>E. coli</i>: n = 5, c = 2, m = 1 cfu/g and M = 10 cfu/g (End of the manufacturing process)</p> <p>2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish: Coagulase-positive staphylococci: n = 5, c = 2, m = 100 cfu/g and M = 1000 cfu/g (End of the manufacturing process).</p> <p>n = number of units comprising the sample; c = number of sample units giving values between m and M.</p>	<p>See discussion of GB 2760</p>

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## 1.2.5 National standard GB 31602-2015 – Dried sea cucumbers

<b>Chinese National standard GB 31602</b>	<b>EU Regulation (EC) No 853/2004</b>	<b>Implementing rules and remarks</b>
<p><b>1. Scope</b></p> <p>This standard applies to dried sea cucumbers.</p>	<p><b>Article 1, Scope</b></p> <p>1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.</p>	<p><i>No specific legislation has been issued in the EU concerning sea cucumbers.</i></p>
<p><b>2 Terms and Definitions</b></p> <p><b>2.1 Dried sea cucumbers</b></p> <p>use sea cucumbers such as sea cucumbers as raw materials, which are gutted, boiled, and salted (or not salted). Products made from processes such as desalination (or no de-benefiting) and dry drying; or products made from salted sea cucumbers as raw materials through desalination (or no desalination), drying and other processes.</p> <p>Note: During the harvest season of sea cucumbers, the usual practice is to cook fresh sea cucumbers and salt them to make semi-finished products (i.e. salt sea cucumbers) and store them in the cold storage as raw materials for the production of dried sea cucumbers.</p> <p><b>2.2 Dry weight rate after rehydration</b></p>	<p><b>Regulation (EC) No 853/2004, Annex III, Section VIII Fishery products</b> applies.</p>	

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<b>Chinese National standard GB 31602</b>	<b>EU Regulation (EC) No 853/2004</b>	<b>Implementing rules and remarks</b>
The percentage of dry matter mass obtained from dried sea cucumbers after rehydration.		
<p><b>3 Technical requirements</b></p> <p><b>3.1 Sensory requirements</b></p> <p>Sensory requirements should meet the requirements of Table 1.</p> <p>Table 1 Sensory Requirements</p> <p>Natural colors: such as dark brown, black gray, gray or tan, with white frost on the surface, and a more uniform color.</p> <p>Smell: its smell has the unique fresh house odor of sea cucumbers, without peculiar smell,</p> <p>State: the appearance of sea cucumbers is white, a small amount of lime is allowed to be exposed, and the remaining ginseng is buried long and straight, and the state is basically complete.</p> <p>Inspection Methods: Take an appropriate amount of sample and push it into a white porcelain plate, and observe the color and lustre and the organization state, under natural light. Smelling the samples.</p>		General sensory requirements for fishery products apply concerning freshness indicators, colour and odor.
<p><b>3.2 Physical and chemical indicators</b></p> <p>Physical and chemical indicators should meet the requirements of Table 2.</p> <p>Table 2 Physical and chemical index</p>		

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<b>Chinese National standard GB 31602</b>	<b>EU Regulation (EC) No 853/2004</b>	<b>Implementing rules and remarks</b>
<p>protein (g/100 g) index: <math>\geq 40</math></p> <p>inspection method: take the sample processed according to A.2 of this standard, and check according to the provisions of GB 5009.5.</p> <p>moisture (g/100 g) index: <math>\leq 15</math></p> <p>inspection method: take the sample processed according to A.2 of this standard. According to the requirements of GB 5009.3.</p> <p>salinity (g/100 g) index: <math>\leq 40</math></p> <p>inspection method: take the samples processed according to A.2 of this standard, and check according to the regulations of GB 5009.44.</p> <p>total water solubility (g/100 g) index: <math>\leq 3</math></p> <p>inspection method: take according to A. 3.4.4 The 100 ml of the obtained test solution shall be tested according to GB/T 15672's requirements. If necessary, dilute the test solution.</p> <p>dry weight rate after rehydration/% index: <math>\geq 40</math></p> <p>inspection method: in appendix A 4</p> <p>sand content (g/100 g) index: <math>\leq 3</math></p> <p>inspection method: in appendix A 5</p>		

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Chinese National standard GB 31602	EU Regulation (EC) No 853/2004	Implementing rules and remarks
<p><b>3.3 Pollutant limits</b></p> <p>The pollutant limits should comply with GB 2762 Provisions on echinoderms.</p> <p><b>3.4 General drug residue limits</b></p> <p>The veterinary drug residues shall comply with relevant national regulations and announcements.</p>		<p><i>Contaminant limits for fishery products and echinoderms apply..</i></p>
<p><b>4 Other</b></p> <p><b>4.1 The label should indicate the salt content range of the product.</b></p> <p><b>4.2 Inspection of pollutants:</b></p> <p>Take A.3.4.2 samples after rehydration to detect pollutants. The detection method shall be carried out in accordance with the provisions of GB 2762, and the inspection results shall be based on the mass of the sample after rehydration.</p> <p><b>4.3 Inspection of veterinary drug residues:</b> take A.3.4.2 samples after rehydration to detect veterinary drug residues. The detection method adopts the relevant method standards published by country for the detection of veterinary drug residues in sea cucumbers. The test results are based on the quality of the sample after rehydration.</p>		
<b>Appendix A</b>		

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<b>Chinese National standard GB 31602</b>	<b>EU Regulation (EC) No 853/2004</b>	<b>Implementing rules and remarks</b>
<b>Inspection Method</b> A.1 General Provisions A.2 Sample pre-treatment A.3 Rehydration of dried sea cucumbers A.4 Inspection method for dry weight rate of dried sea cucumber after rehydration A.5 Inspection method of sand content in dried sea cucumbers		

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## 1.2.6 National standard GB 19643-2016 – Algae and algae products

Chinese National standard GB 19643	EU Regulation (EU) 2018/848	Implementing rules and comparative evaluation
<p><b>1. Scope</b> This Standard is applicable to the edible algae and algae products.</p>	<p><b>Regulation (EU) 2018/848, Chapter I, Article 2 Scope</b> 1. This Regulation applies to the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union: (a) live or unprocessed agricultural products, including seeds and other plant reproductive material; (b) processed agricultural products for use as food; (c) feed. This Regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.</p>	
<p><b>2 Terms and Definitions</b> <b>2.1 Algae</b> A class of most primitive low aquatic plants that don't have the real root, stem and leaf differentiation. Most of them are marine algae, such as kelp, seaweed, wakame, Sargassum fusiforme, etc.; few of them are freshwater algae, such as spirulina, etc.</p>	<p><b>Regulation (EU) 2018/848, Chapter I, Article 3</b> (9) 'production unit' means all assets of a holding, such as primary production premises, land parcels, pasturages, open air areas, livestock buildings or parts thereof, hives, fish ponds, containment systems and</p>	<p><b>Regulation (EC) No 834/2007, Article 13 provides production rules for seaweed</b> <i>Seaweed is a macroscopic, multicellular marine algae living attached to rocks or any hard substrate in coastal areas (Guiry, 2019c). In terms of taxonomic classification, seaweed is classified into three broad groups based on pigmentation (Díaz-</i></p>

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<b>Chinese National standard GB 19643</b>	<b>EU Regulation (EU) 2018/848</b>	<b>Implementing rules and comparative evaluation</b>
<p><b>2.2 Algae products</b> The products taking algae as the major raw materials, adding or not adding the auxiliary materials, and made by corresponding processing technologies.</p> <p>2.2.1 Instant algae products The algae products taking algae as the major raw materials, made by certain processing technologies, and can be eaten directly.</p> <p>2.2.2 Algae dry products The products taking algae as the major raw materials, gone through the ticking, cleaning and the like pre-treatment; eliminating most of the moisture in the algae by natural drying or mechanical drying processes; adding or not adding auxiliary materials.</p>	<p>sites for algae or aquaculture animals, rearing units, shore or seabed concessions, and premises for the storage of crops, of crop products, of algae products, of animal products, of raw materials and of any other relevant inputs managed as described in point (10), point (11) or point (12);</p> <p>40) ‘production cycle’ means the lifespan of an aquaculture animal or alga, from the earliest life stage (fertilised eggs, in the case of aquaculture animals) to harvesting;</p>	<p><i>Pulido and McCook, 2008): Rhodophyta (red algae), Phaeophyceae (brown algae) and Chlorophyta (green algae). Reference for this paragraph: Safety Considerations of Seaweed and Seaweed-derived Foods Available on the Irish Market (Food Safety Authority of Ireland, 2020, 80 pages).</i></p>
<p><b>3 Technical Requirements</b></p> <p><b>3.1 Requirements for raw materials</b> The raw materials shall conform to the corresponding food standards and relevant provisions.</p> <p><b>3.2 Sensory requirements</b> The sensory requirements shall conform to the provisions of Table 1. Table 1 - Sensory Requirements Color and luster: have the due color and luster of the products. Taste and smell: have the due taste and smell of the products, is odorless.</p>	<p><b>Regulation (EC) No 853/2004, Annex III, Section VIII Fishery products, Chapter V Health standards for fishery products</b> In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure, depending on the nature of the</p>	

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<b>Chinese National standard GB 19643</b>	<b>EU Regulation (EU) 2018/848</b>	<b>Implementing rules and comparative evaluation</b>
<p>State: have the due state of the products, no mildew, no deterioration, no normally visible foreign matters. Test methods: take appropriate amount of specimen onto the clean white dish (porcelain dish or similar container), check under natural light without foreign matters. Smell the odor, use warm water to wash mouth; and taste the algae and algae products that can be eaten directly.</p> <p><b>3.3 Contaminant limits</b> The contaminant limits shall conform to the provisions of GB 2762.</p> <p><b>3.4 Microbial limits</b> 3.4.1 Pathogen limits shall conform to the provisions of GB 29921.</p>	<p>product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter. The requirements of Parts B and D shall not apply to whole fishery products that are used directly for the preparation of fish oil intended for human consumption.</p> <p>A. Organoleptic properties of fishery products Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.</p> <p><b>Commission Recommendation (EU) 2018/464 on the monitoring of metals and iodine in seaweed, halophytes and products based on seaweed</b> has adopted this recommendation: 1. That Member States, in collaboration with food and feed business operators, perform during the years 2018, 2019 and 2020 monitoring on the presence of arsenic, cadmium, iodine, lead and mercury in seaweed, halophytes and products based on seaweed.</p>	<p>See discussion of GB 2762.</p> <p>See discussion of GB 29921.</p>

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<b>Chinese National standard GB 19643</b>	<b>EU Regulation (EU) 2018/848</b>	<b>Implementing rules and comparative evaluation</b>
<p>3.4.2 The microbial limits of instant algae products shall conform to the provisions of Table 2.</p> <p>Table 2 - Microbial limits of instant algae products</p> <p>total number of colonies / (CFU/g):  <math>n = 5, c = 2, m = 3 \times 10^4, M = 10^5</math></p> <p>coli group / (CFU/g):  <math>n = 5, c = 1, m = 3 \times 20, M = 30</math></p> <p>mildew <sup>b</sup> / (CFU/g): <math>3 \times 10^2</math></p> <p><sup>b</sup> Only limited to the instant algae dry products.</p> <p><b>3.5 Food additives</b></p> <p>The use of food additives shall conform to the provisions of GB 2760.</p>		<p><i>Commission Regulation (EC) No 2073/2005, foresees no specific criteria applicable to seaweeds or algae. Criteria for fishery products apply.</i></p> <p>See discussion of GB 2760.</p>

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## 2 LEGAL FRAMEWORK FOR IMPORTATION OF FISHERY PRODUCTS

The Chinese national import control system for fisheries products is largely in line with applicable Codex Alimentarius Guidelines. The Chinese authorities (GACC) approval of the national control system of the competent authority of the exporting country is followed by the Chinese authorities registration of each export business (overseas manufactures) based on the recommendation of the national competent authority who must confirm compliance with applicable Chinese rules and requirements. The Chinese importer is obliged to keep detailed records on the imported foods and to implement a system of supplier audits with focus on examining the suppliers' food safety risk control systems and other laws, regulations and national food safety standards of China.

The Chinese registration of each overseas manufacturer is valid for five years and can be renewed subject to application. In certain cases, such as changes in the ownership, changes of location of production or changes in the national registration system, the overseas manufacturer is obliged to re-apply for registration with updated information.

The Chinese SPS regulation on import and export of food is given in two Decrees that took effect by 1st January 2022. Both decrees are based on the Food Safety Law of the People's Republic of China (hereinafter referred to as the Chinese Food Safety Law).

*Decree 248 on Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food.* The Regulations apply to the registration of overseas manufacturers of production, processing, and storage (hereinafter referred to as "overseas manufacturers of imported foods") that export foods to China.

*Decree 249 on the General Administration of Customs of the People's Republic of China* applies to the general principles of control of food safety of imported food import and food for export, specifically the official control activities by the General Administration of Customs (hereafter called the GACC).

The decrees stipulate that the import and export food producers and operators shall be responsible for the safety of the import and export food they produce and manage, while the GACC shall implement supervision and implement conformity assessment on imported food<sup>2</sup>.

<sup>2</sup> GACC is responsible of border health checks, inspection and quarantine for imported and exported animals, plants, and their products, imported and exported food safety, and commodity inspection. protects imported and exported food safety.

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## 2.1 Decree 248 – Registration of Manufacturers of Imported foods

### 2.1.1 General principles

The decree specifies the requirements to registration of overseas manufacturers of food imported to China (hereafter called the OMs or OM). The GACC is responsible for the registration, including the principles and procedures for registration<sup>3</sup>.

OMs shall be registered with the GACC according to one of two principles, depending of the type of product:

- Registration through the competent authority in own country;
- Self-Registration directly to GACC through a single window system.

### 2.1.2 Registration through the competent authority

The OMs of that shall be registered through the competent authority are producers of the following foods<sup>4</sup>:

- Meat and meat products,
- casings,
- aquatic products,
- dairy products,
- bird's nests and bird's nest products,
- bee products,
- eggs and egg products,
- edible oils and fats,
- oilseeds,
- stuffed pastry products,
- edible grains,
- milled grain industry products and malt,
- fresh and dehydrated vegetables and dried beans,
- condiments,
- nuts and seeds,
- dried fruits,
- unroasted coffee beans and cocoa beans,
- foods for special dietary purposes
- functional foods

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<sup>3</sup> Decree 248 Article 6

<sup>4</sup> Decree 248 article 7

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For producers of aquatic products it should be understood that the listing through the competent authority shall include not only the processing company responsible for a final product, but also other involved actors in the production chain, including aquaculture farms, reefer vessels, freezing and factory vessels, processing establishments and cold stores.

On the GACC Single Window website the competent authority can download an updated list with the specific Chinese SH-codes (Custom codes) that are covered by the requirement to be registered through the competent authority<sup>5</sup>.

The general process for the registration, as it is described in the Decree 248 article 8, is summarized in table below.

*Process of new registration of OM through the competent authority*

<b>Step</b>	<b>Activity</b>	<b>Supporting documentation</b>
1	OM apply for registration by the Competent authority of the country	-
2	Competent authority of the country <sup>6</sup> to assess and confirm that the OM conforms with the Chinese registration requirements. An audit by the Chinese authorities may be needed to confirm the compliance.	-
3	The competent authority of the country recommends the OM to GACC for registration. The recommendation shall be done through the single window system <a href="https://cifer.singlewindow.cn">https://cifer.singlewindow.cn</a>	Required Application Materials: <ul style="list-style-type: none"> <li>- Letter of recommendation by the competent authority of the country/region</li> <li>- Application from the OM (or in case of several OMs, list of the OM and their applications)</li> <li>- Documents certifying the identification of the OM</li> <li>- Statement that the producer recommended by the competent authority of the country/region comply with requirements of Decree 248.</li> <li>- Reports of examinations/inspections/review conducted by the competent authority of the country/region to relevant manufacturers.</li> </ul>

<sup>5</sup> Reference is made to Danish Competent authority website providing a list from February 202 as an example.

<sup>6</sup> The Competent authority of the country on request shall/may establish an account for the OM on the single window portal. The OM shall then make the application directly for evaluation and recommendation by the national competent authority: Reference: Singel Window – User Manual (Overseas Exporters Registration), China Electronic Port data Center

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Step	Activity	Supporting documentation
		Note: it is suggested to check Cifer website for the latest requirements GACC may request documents related to the manufacturer's food safety, sanitation, and protection system, such as floor plans of the factory/workshops/cold storages, and the processing flow chart and others.
4	The GACC or GACC entrusted institutions, set up a review team (of two or more reviewers) to conduct evaluations and reviews of the OM applications for registration.	Internal
5	GACC Review Team conduct review including: <ul style="list-style-type: none"> <li>- document review,</li> <li>- video inspection,</li> <li>- and/or on-site inspection.</li> </ul>	The submitted application documents.
6	Based on <u>satisfactory</u> review result the GACC will register the OM and grant it a Chinese Registration Number which shall be valid for 5 years (start and end date specified).  If review result is <u>not satisfactory</u> , the registration will be rejected	Notification to the competent authority in both cases.

### 2.1.3 Verification and follow up activities

The GACC will establish a team of at least two officers to conduct re-evaluation on whether the OM continuously comply with registration requirements.

If an overseas manufacturer's registration information changes, while the registration is valid, it shall submit an application for change to the GACC through the application path, including:

- A table that exhibits the changed information and the original information;
- Supporting materials related to the changed information.

If a registered OM changes production site, legal representative, or registration number in the country/region where it is located, the OM must re-apply for registration in China, and the original Chinese registration number will become invalid.

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In case an OM of imported foods intends to renew its registration, the competent authority may apply for a new registration through the applicable registration path or apply for a modification to GACC.

In any case, GACC shall renew the registration of manufacturers that comply with the registration requirements and extends the valid period of registration for five years.

The GACC will revoke its registration, notify the competent authorities of the country/region or the registered facility, and issue a public announcement if:

- The OM fails to apply for renewal of registration following relevant provisions;
- The competent authority or the OM applies to revoke the registration;
- The manufacturer is no longer approved/registered by the competent authority of the country where it belongs;
- Severe food safety incidents of imported foods were caused by the manufacturer;
- Food safety problems in foods exported to China were detected in the entry inspection and quarantine, and the circumstance is serious;
- Significant problems exist in the manufacturer’s food safety and sanitation management, which cannot ensure its food export to China conforms with safety and sanitation requirements;
- The manufacturer fails to meet the registration requirements after taking rectification measures;
- The manufacturer provides false materials or conceals relevant facts;
- The manufacturer refuse to cooperate with the GACC in reviews and incident investigations;
- The manufacturer leases, lends, transfers, or resells its registration number, or claims another manufacturer’s registration number;

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## 2.2 Decree 249 –Principles of Import Control

Food imported food to China shall comply with the laws, regulations, and national food safety standards of China and the special requirements of any international treaty or agreement entered into or acceded to by China<sup>7</sup>, and it is stipulated that the food safety of import and export food, is managed by the principles of safety first, prevention of risks in the whole value chain and international co-governance<sup>8</sup>.

The GACC food import conformity assessment activities include the assessment and examination of the national control system of an exporting country, approval and registration of all the exporting business operators as well as different controls at the point of import of a consignment. Article 10 of the translated Decree 249 provides the following list on the principal import control elements:

- the food safety management system of a foreign country (region) exporting food to China (hereinafter referred to as a foreign country (region)),
- the registration of an overseas production enterprise,
- the importer and exporter record and conformity guarantee,
- the quarantine approval of imported animals and plants,
- the inspection of an accompanying certificate of conformity,
- the verification of documentation,
- on-site inspection,
- supervisory sampling inspection,
- the inspection of import and sales records,
- a combination of all these elements.

Article 11 and 12 stipulates that the GACC may assess and examine the food safety management system and food safety status of a foreign country (region)<sup>9</sup>.

Article 13 stipulates that an assessment and examination on the food safety management system of a foreign country (region) shall mainly include the assessment and confirmation of the followings:

- Laws and regulations related to food safety and animal and plant quarantine;
- The organizational structure for supervision and administration on food safety;
- The prevailing animal or plant diseases and prevention and control measures;

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<sup>7</sup> Decree 249 article 9

<sup>8</sup> Decree 249 article 3

<sup>9</sup> and determine corresponding inspection and quarantine requirements based on the results of the assessment and examination ????

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- The management and control of, among others, pathogenic microorganisms, pesticides and veterinary drugs, and contaminants;
- Safety and health control in the procedures of food production, processing, transportation,
- and warehousing;
- Supervision and administration on food safety of foods intended for export;
- Food safety protection, traceability and recall system;
- Early warning and emergency response mechanism;
- Technical support capabilities;
- Others relating to the prevailing animal or plant diseases and food safety.

Articles 14 to 17 provide for the GACC to arrange for experts to undertake the assessment of the national control systems and principal methods for this are provided while article 16 provides for conditions under which the assessment of a national food safety control system may be terminated and approval rejected by GACC.

After completion of an assessment and examination of a national food control system, the GACC shall notify the competent authority of a country (region) of the assessment and examination results.

Article 18 provides for the GACC to establish and maintain registration of the overseas production enterprises that are approved to export food to China and publish a list of enterprises that have been registered.

Further, according to Article 19 an overseas exporter or agent that exports food to China (hereinafter referred to as the "overseas Exporter") as well as the Chinese food importer shall make a filing with the GACC and lists of such shall also be published by GACC. The Chinese food importer is obliged to keep detailed records on the imported food and to implement a system of supplier audits with focus on examining the suppliers' food safety risk control systems and compliance with laws, regulations and national food safety standards of China. The GACC shall conduct "supervisory inspections" to the importers in this regard.

The GACC publishes <sup>10</sup>a list of designated ports and designated supervision zones for conducting of import controls.

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<sup>10</sup> Article 24 of Decree 248

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## 2.3 Health Certificates

Exports of aquatic products from EU to China require one of the following two Chinese health certificates, depending on type of product. GACC Decrees 249, article 10 has provisions for the request of Health Certificates:

- Chinese Health Certificate for Fish and Fishery Products
- Chinese Health Certificate for Live Aquatic Animals

For this purpose Fish and Fishery Products - includes all species of fish, crustaceans and other forms of marine life (not including live fish, crustaceans, molluscs and echinoderms) and any parts or products thereof and live Aquatic Animals include live fish, crustaceans, molluscs and echinoderms.

In cases where a Chinese health certificate is required for a consignment containing a mixture of both farmed <sup>11</sup>and wild caught fishery products, the Chinese authorities request that separate relevant Chinese health certificates be issued for the one consignment as follows:

- Health certificate to certify the aquacultured part of the consignment
- Health certificate to certify the wild caught part of the consignment

Such case would apply to a single consignment including for example smoked salmon derived from aquaculture and cooked crab products from wild catch.

It should be noted that the requirements on health certificates may also depend on the bilateral agreement between a the exporting countries and China. So far specific requirements on in relation to Covid in the health certificates were not found applicable for export from European Member States.

## 2.4 Labelling

Imported aquatic products, shall bear a secure, clear, and legible written information on both its inner and outer packaging. The identification shall be given in both Chinese and English language, or in Chinese and the language of the export country (region). The information shall include:

- name of the goods and scientific name,
- specifications,
- production date, lot number,
- shelf life, and storage conditions,

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<sup>11</sup> Reference is made to <https://www.sfpa.ie/What-We-Do/Trade-Market-Access-Support/Exports/Export-Information-by-Country/Exports-to-China: Information from SFPA website of Ireland>

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- production method (seawater fishing, freshwater fishing, or aquaculture),
- production area
  - o sea area in the case of ocean fishing,
  - o country (region) in the case of freshwater fishing, or
  - o country (region) where the aquaculture product originates),
- the name, registration number, and address (specific to state, province, or city) of each production or processing enterprise involved (including a fishing vessel, processing vessel, transport vessel, or an independent cold store), and
- the place of destination must be indicated as the People's Republic of China.

Food shall be permitted for import only upon passing the conformity assessment by the GACC. During the time of assessment the food shall be kept in places compliant with applicable laws and approved for this by the GACC.

## 2.5 Handling of non-compliant consignments

In cases where the GACC import control find food non-compliant with requirements a “certificate of non-conformity” will be issued according the following principles:

- Cases involving safety, health and environmental protection: By written notice, the importer will be instructed to destroy or return the consignment.
- Other cases: The food may be handled by “technical means” to be compliant within a prescribed time, and thereafter allowed for import. If it is not possible to bring the food in compliance within the prescribed timeline, it shall be destructed or returned.

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## 2.6 Overview on discrepancies identified that may require specific attention

The following table provides a short summary of notable deviations between the EU and Chinese standards, based on the detailed comparison provided above.

<b>Chinese standard</b>	<b>Notable deviations from relevant EU regulations<sup>12</sup></b>
GB 14881-2013, General hygiene practice for food production;	No relevant differences identified.
GB 4789.1-2016 - basic principles of microbiological testing.	The general rules are consistent with the requirements laid down in EU legislation.
GB 29921-2013 – Limit of pathogens in food products	<p>This is a general standard that applies to pre-packed food products, excluding canned food products and specifies criteria for salmonella, vibrio parahaemolyticus and staphylococcus in cooked and raw ready to eat aquatic products and ready to eat algal products as follow:</p> <p><i>Salmonella</i>: n = 5, c = 0, m = 0 (equivalent to absent)  <i>Vibrio parahaemolyticus</i>: n=5, c =1, m = 100 MPN/g, M = 1000 MPN/g  <i>Staphylococcus aureus</i> : n=5, c =1, m = 100 CFU/g, M = 1000 CFU/g</p> <p><b>n</b> is the number of samples collected from the same batch of products;  <b>c</b> is the maximum allowable number of samples exceeding m level;  <b>m</b> is the acceptable limit level for pathogen index;  <b>M</b> is the highest safety limit for pathogen index.</p> <p>The criteria for Salmonella and Staphylococcus in cooked products is similar 207ob e207 EU requirements, except that the EU criteria is specified to coagulase+ staphylococcus, while the EU regulation (EC) 2073/2005 does not specify criteria for Vibrio parahaemolyticus.</p>

<sup>12</sup> The numbering (e.g. *Health Management of staff (6.3.1)*) used in this column is the the section number in the Chinese standard.

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<b>Chinese standard</b>	<b>Notable deviations from relevant EU regulations<sup>12</sup></b>
	<p>The EU regulation (EC) 2073/ 2005 specify criteria for E.coli in cooked crustaceans and molluscan shellfish and in live bivalve molluscs and live echinoderms, tunicates and marine gastropods, which is not the case in the Chinese standard.</p> <p><i>The objective of Chinese and EU standards is the same, i.e. to control contamination in particular with fecal pathogens. Differences in the indicator organisms used are not expected to be relevant in practice as compliance with EU rules will very likely lead to compliance also with Chinese standards.</i></p>
GB/T 27341-2009 – Hazard Analysis and Critical Control Point (HACCP) System – General requirements for food processing plant.	No relevant differences identified.
GB 2762-2017 – Maximum levels of contaminants in foods	<p><u>Arsenic and Chromium:</u> The Chinese standard establishes contamination limits of 0.5-1 ppm for arsenic and 2ppm for chromium. The EU regulation does not include criteria for arsenic or chromium in fisheries products.</p> <p><u>N-nitrosodimethylamine:</u> The Chinese standard establish standard of 4 µg/kg in Aquatic animal and its products (excluding canned aquatic products) and dried aquatic products. In the EU regulation there is no criteria of nitrosamines.</p> <p><u>Benzo[a]pyrene:</u> The Chinese standard establish criteria to 5.0 µg/kg in smoked, roasted aquatic products. This is higher or similar to the criteria established in EU regulation except for smoked bivalve mussels, where the EU criteria is 6µg/kg. The Chinese standard establish criteria only for Benzo[a]pyrene and not for the sum of PAHs as the EU regulation (EC) 1881/2006.</p> <p><i>In EU legislation the general ALARA principle applies for all environmental contaminants (as low as reasonably achievable). The differences identified are not expected to be of practical relevance.</i></p>
GB 2763-2021 – Maximum residue limits for pesticides in food	<p>The standard establish criteria for DDT: 0,5mg/kg and for HCH: 0,1mg/kg.</p> <p>The EU regulation (EC) 396/2005 does not establish criteria for residues of pesticides in aquatic products, hence the default level of 0,01mg/kg applies. The discrepancy is, therefore, not considered relevant.</p>
GB 2760-2014 – Uses of food additives	<p>The standard include general provisions for use of food additives including definitions and specific criteria for allowed amounts of different additives in different products.</p> <p>Not all EU-approved food additives are also authorised in China and Chinese standards include additives not authorised in the EU.</p>

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<b>Chinese standard</b>	<b>Notable deviations from relevant EU regulations<sup>12</sup></b>
	<i>EU establishments must check and document whether additives used comply with GB 2760.</i>
GB 5749, Drinking water quality	No relevant differences identified.
GB 20941-16, Hygienic practice of aquatic products	No relevant differences identified.
GB 10136-2015 – Aquatic Products of animal origin	<p>The standard provides detailed requirements to:</p> <p><i>Physical and chemical indicators (3.3) including:</i>  <u>Peroxide value</u> where limits apply to salted fish of herring and Spanish mackerel and for “prefabricated aquatic products”. This quality criteria is not applied in the EU Regulations.  <u>Histamine</u> where limits apply to salted fish, with a limit of 400mg/kg in histamine sensitive species and 200mg/kg in other species. This is a standard that is a bit less sensitive than the EU standard where it is specified that 2 of 9 samples may have histamine in levels between 100-200 mg/kg in histamine sensitive species and 200-400mg/kg in products that have undergone enzyme maturation treatment.  <u>TVBN</u> where limits apply to marinated raw aquatic products and pre-cooked aquatic animal products. This quality criteria is not applied in the EU Regulations.</p> <p><i>Microbiological limits (3.6) where</i>  <u>Total count</u> should be 10<sup>5</sup> CFU/g and 2 of 5 samples should be maximum between 5x10<sup>4</sup> - 10<sup>5</sup> CFU/g  <u>Coliform group</u> / (CFU/g) should count 10<sup>2</sup> and 2 of 5 samples should be maximum between 10 – 10<sup>2</sup> CFU/g.  This is a standard that is less specific than the EU standard provided in Regulation (EC) 2073/2005. However in some cases it may be considered more restrictive.  <u>Parasites (3.7)</u> where there are detailed requirements for visual inspection by naked eye or by microscopy after performing the digestion method. Both methods may result in “detected” or “not detected”.</p> <p><i>Overall, these differences are not expected to be relevant on practice as compliance with EU rules will very likely lead to compliance also with Chinese standards.</i></p>
GB 2733-2015 - Fresh, frozen aquatic products of animal origin	<p>This is a product standard that applies to fresh and frozen aquatic products of animal origin from seawater and fresh water. The standard provides detailed requirements to:</p> <p><i>Physical and chemical indicators including:</i>  <u>TVBN (2.2)</u> where criteria apply in general as follow:  Seawater fish and shrimp ≤ 30mg/kg</p>

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<b>Chinese standard</b>	<b>Notable deviations from relevant EU regulations<sup>12</sup></b>
	<p>Sea crab ≤ 25mg/kg  Freshwater fish and shrimp ≤ 20mg/kg  Frozen shellfish ≤ 15mg/kg</p> <p>For some species these criteria appear stricter than in the EU Regulation (EC) 627/2019, Annex VI, Chapter II, where criteria between 25 and 35 mg/kg is provided for only certain groups and species of fish.</p> <p><i>Histamine (2.2)</i> where criteria apply in general as follow  Fishes with high Histamine<sup>a</sup> ≤ 400mg/kg  Other sea fish ≤ 200mg/kg</p> <p><sup>a</sup> Fishes with high Histamine refer to <i>Scomber japonicus</i>, Horse mackerel, scad, mackerel, skipjack, tuna, saury, Spanish mackerel, <i>Pneumatophorus japonicas</i> and sardine, etc.</p> <p>This is a standard that is a bit less sensitive than the EU standard where it is specified that 2 of 9 samples of histamine sensitive species may have histamine in levels between 100-200 mg/kg.</p> <p>For <i>Shellfish toxins</i> PSP and for DSP limit values applicable in Chinese and EU regulations are based on different analytical methods.</p> <p><i>These differences are not expected to be relevant in practice as compliance with EU rules will very likely lead to compliance also with Chinese standards.</i></p>
GB 10133-2014 – Aquatic product condiments (flavourings)	<p>This is a product standard that applies to condiments made with fish, shrimp, shellfish or crab as main raw materials. Chinese standards provide for microbial limit values that are not specifically mentioned in EU rules.</p> <p><i>Microbiological criteria (3.4)</i>  <u>Total count CFU/g or CFU/ml</u> is n=5, c=2, m= 10<sup>1</sup>, M=10<sup>5</sup>  <u>Escherichia coli, CFU/g or CFU/ml</u> n=5, c=2, m= 10, M=10<sup>2</sup></p> <p><i>These differences are not expected to be relevant in practice as compliance with EU rules of general process hygiene will lead to compliance with Chinese standards.</i></p>

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<b>Chinese standard</b>	<b>Notable deviations from relevant EU regulations<sup>12</sup></b>
GB 31602-2015 - dried sea cucumbers	The standard defines organoleptic and quality criteria such as moisture or protein content and provides that Chinese standards related to residues and contaminants are applicable. No specific legislation has been laid down in the EU concerning sea cucumbers. However, all fishery products must comply with general organoleptic requirements and with applicable criteria related to biotic and abiotic contamination. Applicable standards related to protein or moisture content must be fulfilled but have no relevance for food safety.
GB 19643-2016 – Algae and algae products	<p>Chinese food safety standards provide specific criteria for algae such as kelp, seaweed, wakame, Sargassum fusiforme as well as freshwater algae, such as spirulina.</p> <p><i>Microbiological criteria (3.4) where:</i></p> <p>Total count (CFU/g): <math>n = 5, c = 2, m = 3 \times 10^4, M = 10^5</math></p> <p>Coli group (CFU/g): <math>n = 5, c = 1, m = 3 \times 20, M = 30</math></p> <p>Mould (mildew)<sup>b</sup> (CFU/g): <math>3 \times 10^2</math></p> <p><sup>b</sup> Only limited to the instant algae dry products.</p> <p>It is unclear whether these products are indeed exported from the EU to China.</p>

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## 2.7 Impact on the EU exporters

### Who will be impacted?

For manufacturers exporting food products to China before 1 January 2022, the registration process had to be launched before Decree 248 entered into force. For new exporters, the registration process has to be as described in the Decree 248.

Also, Chinese importers have additional responsibilities under the new law. They are now obliged to ensure that his supplier details are correct, including his producer registration number for export to China.

### Timeline

Products in the 4 following categories: meat and meat casing, aquatic products, dairy products and bee products are already regulated in the former regulation. The manufacturers who have exported related food to China may already be in the GACC's list. When operating in one of the other remaining 14 food categories, manufacturers that are not organised in the relevant trade associations can contact their competent supervisory authority for being included in the recommendation list. Manufacturers of products which are not included in those 18 food categories will be able to register themselves via the platform 'www.singlewindow.cn' without the recommendation. Before registration the manufacturers should get their 'Located Country (Region) Register Number' from their competent supervisory authority.

In general, all the cases will be reviewed on a case-by-case basis. There is no mandatory period required and the GACC does not guarantee any specific days to process the application.

However, based on the official guidelines, the GACC states that it will notify the overseas manufacturer or the competent authority of the country (region) within 20 business days from the date of receiving the application - if the application documents do not meet the legal form/requirements, or if the application was deemed to be incomplete.

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### Registration process in brief

<b>What are the application materials required under the recommendation for registration?</b>	The competent authority of the country (region) shall examine and inspect the manufacturer to be recommended for registration; after confirming that the manufacturer conforms with the registration requirements, the competent authority of the country (region) recommends the producer to the GACC for registration, and submits the application materials as described in the Decree.
<b>What are the relevant application materials required under the self-registration section?</b>	Overseas manufacturers of foods other than the 18 categories shall, by themselves or by agents, file applications for registration with the GACC and submit the application materials as described in the Decree.
<b>Scope of the information to be submitted</b>	Unless stated otherwise, the application materials for the manufacturer’s registration shall be submitted in Chinese or English.  The GACC will formulate all kinds of imported food overseas production enterprises registration applications and filling examples. Details can be found on the official website of the GACC.
<b>Inspection and evaluation</b>	The GACC entrusted institutions shall set up a review team to conduct evaluations and reviews of the overseas manufacturers applying for registration. The evaluation is conducted in forms of document review, video inspection, and/or on-site inspection. A review team is composed of two or more reviewers.  Overseas manufacturers of imported foods and the competent authorities of the country (region) shall assist the GACC in carrying out the aforementioned evaluation and review.
<b>Approval</b>	The GACC shall, based on its own evaluation and review, register the overseas manufacturers that meet the requirements, grant them individual Chinese registration numbers, and notify the competent authority of the country (region) or the overseas manufacturers in writing of the registration/decision.  The list of registered overseas manufacturers will be published by the GACC on its official website.

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## Annexes

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Annex 1 : List of Chinese authorities and their contact, internet links

Annex 2: Templates of required documents

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## Annex 1: References to websites regarding specific information -

Subject	Reference
Registering of operators in the value chain	<p>Official Competent Authority of Denmark:  <a href="https://www.mattilsynet.no/mat_og_vann/eksport_utenfor_EU_EO_S/eksport_av_fisk_av_sjomat/registrering_av_sjomatvirksomheter_for_eksport_til_kina.45167">https://www.mattilsynet.no/mat_og_vann/eksport_utenfor_EU_EO_S/eksport_av_fisk_av_sjomat/registrering_av_sjomatvirksomheter_for_eksport_til_kina.45167</a></p> <p>Official Competent Authority of Denmark:  <a href="https://www.foedevarestyrelsen.dk/Leksikon/Sider/Liste_over_foedevarevirksomheder_godkendt_til_eksport.aspx">https://www.foedevarestyrelsen.dk/Leksikon/Sider/Liste_over_foedevarevirksomheder_godkendt_til_eksport.aspx</a></p>
Conditions and Compliance checklist for 1 <sup>st</sup> registration and for changes and renewal of registration	<p>Official Competent Authority of Norway:  <a href="https://www.mattilsynet.no/mat_og_vann/eksport_utenfor_EU_EO_S/eksport_av_fisk_av_sjomat/registrering_av_sjomatvirksomheter_for_eksport_til_kina.45167">https://www.mattilsynet.no/mat_og_vann/eksport_utenfor_EU_EO_S/eksport_av_fisk_av_sjomat/registrering_av_sjomatvirksomheter_for_eksport_til_kina.45167</a></p> <p><a href="https://www.mattilsynet.no/mat_og_vann/eksport_utenfor_EU_EO_S/eksport_av_fisk_av_sjomat/oppdatering_regodkjenning_kina_alle_som_er_godkjent_i_kina_maa_soke_om_regodkjenning_saa_fort_som_mulig_og_innen_12122022.48393">https://www.mattilsynet.no/mat_og_vann/eksport_utenfor_EU_EO_S/eksport_av_fisk_av_sjomat/oppdatering_regodkjenning_kina_alle_som_er_godkjent_i_kina_maa_soke_om_regodkjenning_saa_fort_som_mulig_og_innen_12122022.48393</a></p> <p>Official Competent Authority of Denmark:  <a href="https://www.foedevarestyrelsen.dk/Leksikon/Sider/Eksport-til-Kina-generelt.aspx">https://www.foedevarestyrelsen.dk/Leksikon/Sider/Eksport-til-Kina-generelt.aspx</a></p>
Health Certificates for fishery products for export to China	<p>Official competent Authority of Norway:  <a href="https://www.mattilsynet.no/skiema/11100_kina_sunnhetsattest_kinesiskengelsk_201504_specimen.18806/binary/1.1.100%20Kina,%20sunnhetsattest,%20kinesisk-engelsk,%202015-04,%20specimen">https://www.mattilsynet.no/skiema/11100_kina_sunnhetsattest_kinesiskengelsk_201504_specimen.18806/binary/1.1.100%20Kina,%20sunnhetsattest,%20kinesisk-engelsk,%202015-04,%20specimen</a></p> <p>Official Competent Authority of Denmark:  <a href="https://www.foedevarestyrelsen.dk/Selvbetjening/Certifikater/Sider/forside.aspx#/Show/af7225b2-3ba3-4180-aaed-692c1a177a46">https://www.foedevarestyrelsen.dk/Selvbetjening/Certifikater/Sider/forside.aspx#/Show/af7225b2-3ba3-4180-aaed-692c1a177a46</a></p> <p><a href="file:///C:/Users/Bruger/Downloads/La+230-4090+aktiv.pdf">file:///C:/Users/Bruger/Downloads/La+230-4090+aktiv.pdf</a></p> <p>Official Competent Authority of Ireland:  <a href="https://www.sfpa.ie/What-We-Do/Trade-Market-Access-Support/Exports/Export-Information-by-Country/Exports-to-China">https://www.sfpa.ie/What-We-Do/Trade-Market-Access-Support/Exports/Export-Information-by-Country/Exports-to-China</a></p>

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## Annex 2: Templates of required documents

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The following templates are given as an example to illustrate the guide and the requirements presented in this document only.

It is highly recommended to check the Cifer registration website to access the latest versions of these documents:

[General Administration of Customs China - GACC CIFER System](#)

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## **Example of Application for Registration Renewal of Officially Recommended Overseas Manufacturers of Imported Aquatic Products**

<https://www.gacc.app/application/seafood-register>

This is an application for registration renewal required by the General Administration of Customs of the People's Republic of China (GACC) which must be provided by overseas manufacturers of exporting aquatic products to China. Please submit in Chinese or English, and the content of the application materials must be complete to avoid delays in the application process.

### **Part One The basic condition of manufacturer**

1.1 Name of the manufacturer:

1.2 Country/region where the manufacturer is located :

1.3 Address of production site (if the production site is moved, a new application for registration is required):

1.4 Registration number (refers to the registration number approved by the competent authority of the country/region. If the registration number is changed, a new application for registration is required):

1.5 Authority to approve registration :

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1.6 Date of establishment:

1.7 Date of reconstruction, and description of the reconstruction project (if applicable)

1.8 The type of manufacturers

- Processing manufacturer    Capture vessel    Fish carrier  
 Capture and factory vessel    Independent cold storage

1.9 Product category of registration

1.9.1 Type of raw material (if applicable)

- Farming    Wild

1.9.2 Product category

- Fish    Crustaceans    Mollusk  
 Echinoderm    Jellyfish    Aquatic plants  
 Amphibian    Cephalopod    Reptiles  
 Aquatic mammals    Aquatic products (Here the original font table is red)

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### 1.10 Processing method

- Refrigerated     Chilled     Dried     Salted  
 Smoked     Cooked     Shrimp oil/fish oil

1.11 Export trade situation in the past 2 years (countries or regions that have been exported, corresponding to the types of export products)

1.12 Products to be registered with China (specify the specific varieties of products to be exported to China, indicate the Latin scientific name, and provide product photos if you want to)

1.13 The time when the qualification for registration in China has been approved, the registration number, company type, registered product category, and processing method (if applicable) in China have been approved

1.14 Production and processing capacity (annual output/ton)

Annual production capacity (description according to product variety, year/ton):

1.15 Refrigeration and storage capacity (if used)

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Ice making capacity is \_\_ ton/day;

Cold storage (0-4°C) capacity is \_\_ cubic meters;

Refrigeration (-18°C) capacity is \_\_ cubic meters;

1.16 The quantity exported to China last year/ton (description according to product variety)

1.17 Water used for production and processing

Water source: public Enterprise's own water source

If it is the company's own water source, is the water disinfected or not:

Yes No(If applicable)

Disinfection treatment method of self-owned water source:

chlorination treatment ozone treatment others

(If applicable)

1.18 Human Resources

Staff number: \_\_ Number of management technicians: \_\_

1.19 Product processing technology

Specific product processing technology (Including specific process time, such as heat treatment time and temperature)

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1.20 Name, contact number, and email address of the legal representative (if the legal representative changes, a new registration is required)

1.21 The name, telephone number and email of contact person

1.22 Documents certifying identification of the manufacturer, such as the business license issued by the competent authority of the country/region, etc.

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## **Part Two Statement of the Manufacturer**

Hereby clarify that the above situation and the submitted materials are true and correct, the manufacturer has passed the self-inspection in accordance with the "Registration Conditions for Overseas Manufacturers of Imported Aquatic Products and Key Points of Comparison and Inspection", and that the manufacturer can meet the requirements of relevant Chinese laws and regulations and national food safety standards.

Name and position of the legal representative

Signature of legal representative and company seal      Date

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### **Part Three Confirmation by the competent veterinary authority**

After evaluation and review, it is hereby clarified that the above situation and the submitted materials are true and correct.

The manufacturer can meet the requirements of "Registration Conditions for Overseas Manufacturers of Imported Aquatic Products and Key Points of Comparison and Inspection", as well as relevant Chinese laws and regulations and national food safety standards.

Name and position of the person in charge

Signature of the person in charge and stamp of the competent authority

Date:

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## **Registration Conditions and Inspection Criteria for Manufacturers of Imported Aquatic Products**

Registration Number:

Name:

Address:

Date:

Notes:

1. According to the *Regulations on the Registration Administration of Overseas Manufacturers of Imported Food* (Decree No.243 of the General Administration of Customs), the sanitary conditions of overseas manufacturers of aquatic products applying for registration in China shall conform to Chinese laws, regulations, and standards, including the requirements of the Protocol on Inspection and Quarantine of Aquatic Products Exported to China. This table is to be used by the overseas competent authorities of imported aquatic products for their implementation of official inspections on manufacturers of aquatic products based on the listed main conditions, covering the inspection focuses. Meanwhile, it is also to be used by overseas manufacturers of aquatic products for their filling-out and submission of supporting materials based on the listed main conditions. In addition, self-evaluation prior to application may be carried out with reference to the inspection focuses.
2. Determination for compliance shall be made by the competent authorities and manufacturers according to the actual conditions.

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3. Submitted materials shall be truly filled out in Chinese or English. Attachments shall be numbered, accurately corresponding to those in the column of "Filling-Out Requirements and Supporting Materials". The list of supporting materials shall be attached.

4. "Aquatic product" means aquatic animal and plant products and products of their origin for human consumption, such as from jellyfish, mollusks, crustaceans, echinoderm, cephalophora, fish, amphibians, reptiles, aquatic mammals and algae , excluding live aquatic animals and propagating materials.

5. Manufacturers of aquatic products mean processing plants, warehouses, reefer fishing vessels, fishing carriers and factory vessels.

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
<b>1. Enterprise Overview</b>					
1. Overview	<p>1. Articles 94 and 96 of the <i>Law on Food Safety</i> of P.R. China;</p> <p>2. Articles 5, 6, 7 and 8 of the <i>Regulations on the Registration Administration of Overseas Manufacturers of Imported Food</i> (Decree No.248 of the General Administration of Customs);</p> <p>3. <i>Measures for the Administration of Food Safety for Import and Export</i> (Decree No.249 of the General Administration of Customs);</p> <p>4. Relevant inspection and quarantine requirements agreed between the competent authorities and the General Administration of Customs.</p>	1.1 Fill in basic information of overseas manufacturers of imported aquatic products.	<p>1. Information provided by the enterprises shall be truthful and consistent with that submitted by the competent authority of the exporting country as well as with the actual processing conditions.</p> <p>2. Aquatic products to be exported to China shall be within the product scope stipulated in relevant agreements, protocols and memorandums on inspection</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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			<p>and quarantine of aquatic products exported to China.</p> <p>3. Human resources (both of the private and official sectors) shall be capable to fulfill operation and official supervision requirements.</p> <p>4. Cold storage capacity shall be compatible with continuous processing and storage of frozen/fresh aquatic products.</p>		

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
<b>2. Enterprise Location and Workshop Layout</b>					
2.1 Site Selection and Plant Environment	<p>1. Articles 33 of the <i>Law on Food Safety</i> of P.R. China;</p> <p>2. Articles 3.1 and 3.2 of the <i>National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881);</p> <p>3. Articles 3.1 and 3.2 of the <i>National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).</p>	<p>2.1.1 Provide a plant layout, indicating identifications of different operation areas.</p> <p>2.1.2 Provide pictures of surrounding areas, indicating the periphery information (such as urban, rural, industrial, agricultural and residential areas).</p>	<p>1. The plant layout meets the needs of processing.</p> <p>2. The plant is free from pollution.</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	

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2.2 Workshop Layout	<p>1. Articles 33 of the <i>Law on Food Safety</i> of P.R. China;</p> <p>2. Article 4.1 of the <i>National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).</p> <p>3. Article 4.1 of the <i>National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).</p>	2.2 Provide a workshop layout, indicating people flow, product flow, water flow, process flow and different cleaning zones.	1. The workshop layout shall be reasonable to meet processing requirements and prevent cross contamination.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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			<p>1. The interior structure shall be easy to be maintained, cleaned or sanitized, using proper and durable materials.</p> <p>2. The ceilings, walls, windows, doors and floors shall be of reasonable structure, easy to be cleaned</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
2.3 Interior Structure and Materials	<p>1. Articles 33 of the <i>Law on Food Safety</i> of P.R. China;</p> <p>2. Article 4.2 of the <i>National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).</p> <p>3. Article 4.2 of the <i>National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).</p>	2.3 Provide photos of ceilings, walls, windows, doors and the floors, including a list of materials.	<p>and free from insanitary conditions.</p> <p>3. Materials shall be nontoxic, odorless, mold-resistant, easy to clean and not easy to fall off.</p>		

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
<b>3. Facility and Equipment</b>					
3.1 Processing Equipment	<p>1. Articles 33 of the <i>Law on Food Safety</i> of P.R. China;</p> <p>2. Article 5.2.1 of the <i>National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).</p> <p>3. Articles 5.2.1 of the <i>National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).</p>	3.1 Provide a list of main equipment and facilities and information of their design processing capacities	1. Production equipment shall be suitable for the production capacity.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3.2 Plumbing	1. Article 5.1.2 of the <i>National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).	3.2 Provide the water flow diagram for the workshop, indicating flow directions.	<p>1. The safety, pressure, volume and related requirements shall be met for operation.</p> <p>2. Food processing water and water without contact</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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			<p>with food (such as indirect cooling water, sewage and waste water) shall be conveyed in thoroughly separated pipes to prevent cross contamination. Pipes shall be clearly indicated for identification.</p> <p>3. Properly convey sewage without causing any standing water. Drainage shall not contaminate food or processing water.</p> <p>4. Drainage shall be from high clean zone to low clean zone.</p>		

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
3.3 Cleaning and Sanitizing facilities	1. Article 5.1.3 of the <i>National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).	3.3 Provide a list of facilities. On-site observation may be made.	1. The cleaning and sanitizing facilities shall be sufficient.  2. Prevent cross contamination caused by cleaning or sanitizing utensils	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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3.4 Personal Sanitary Facilities	1. Article 5.1.5 of the <i>National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).	Provide a workshop layout. On-site observation may be made.	<p>1. Dressing rooms shall be provided at the entrances of workshops. Personal belongings and outer garments shall be separated.</p> <p>2. Hand washing and sanitizing facilities as well as boot sanitizing facilities shall be provided at the entrances of workshops and where as necessary, compatible with processing volume. Manual taps shall not be used for hand cleaning facilities, which is equipped with hot water</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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			<p>as necessary. Hand washing methods shall also be illustrated by hand washing facilities.</p> <p>3. Adequate toilet facilities shall be provided as needed. They shall be in a sanitary condition, and equipped with hand washing facilities, without any direct connect with food processing, packing or storage areas.</p>		

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3.5 Lighting	1. Article 5.1.7 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).	Provide photos of lights. On-site observation may be made.	1. Provide adequate lighting without altering food colors. 2. Provide safety-type lights or take protection measures over exposed food or materials.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
3.6 Storage Facilities	<p>1. Article 24 of <i>the Implementation Rules of the Law on Food Safety</i> of P.R. China;</p> <p>2. Article 10 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).</p> <p>3. Articles 10.2 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).</p>	<p>3.6 Describe the temperature control requirements and monitoring methods if there is a cold storage. (where applicable)</p>	<p>1. Storage facilities shall meet the temperature requirements for storage.</p> <p>2. According to their natures, raw materials, semi-final products, final products, packaging materials and packing materials shall be stored in separate storage or areas, with clear identifications to prevent cross contamination.</p> <p>3. Proper distance from the walls and floors shall be kept during storage. Other stored articles shall not impede the</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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3.7 Temperature Control Facilities	1. Article 5.1.9 of the <i>National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).	3.7 Provide a list of facilities. On-site observation may be made.	sanitary condition in the storage.  1. Proper heating, cooking or freezing facilities as well as temperature monitoring facilities shall be equipped on the basis of processing characteristics.  2. Control and monitoring facilities for room temperature shall also be equipped as needs.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
<b>4. Water/Ice/Steam</b>					
4.1 Water/ice/steam for production and processing (if applicable)	<p>1. <i>The National Food Safety Standards-Hygienic Standards for Potable Water</i> (GB 5749)</p> <p>2. Articles 5.1.1 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941)</p> <p>3. Article 5.1.1 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).</p>	<p>4.1.1 Provide photos of private water system or secondary water supply facilities and explain whether there are food protection measures such as designated persons or locks (if applicable)</p> <p>4.1.2 Provide a monitoring plan for water used in processing and ice/steam (where applicable) in direct contact with food, including bacteriological testing items, methods,</p>	<p>1. The production water monitoring plan shall cover all water outlets in the plant.</p> <p>2. Whether the items and methods meet the requirements of <i>The National Food Safety Standards-Hygienic Standards for Potable Water</i> (GB 5749).</p> <p>3. Purification or sanitizing facilities should be equipped as needed, as well as storage facilities in non-contaminated zone.</p> <p>Sanitary control procedures</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> N/A</p>	

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
		<p>frequency, records, results and the latest 2 reports.</p> <p>4.1.3 Provide information about boiler additives used in the production of steam in direct contact with food, and explain whether they meet the requirements of food processing (if applicable).</p>	<p>shall be made and implemented for secondary water supply facilities and appropriate food protection measures shall be in place.</p> <p>4. Boiler additives used in the production of steam in direct contact with food shall meet the requirements of food processing.</p>		

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
<b>5. Raw Materials, Ingredients and Packaging Materials</b>					
5.1 Receiving	<p>1. Article 5 of <i>the Implementation Rules of the Law on Food Safety</i> of P.R. China;</p> <p>2. Article 7 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).</p> <p>3. Article 7 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).</p>	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.	<input type="checkbox"/> Yes  <input type="checkbox"/> No	
5.2 Sources	<p>1. Article 7.2 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).</p> <p>2. Raw materials, such as viscera, eggs, skin, fins, scales, bones, shells and other non-muscle tissues of aquatic animals,</p>	5.2.1 Provide the latest test report if the raw materials are of toxin-forming species or for products commonly eaten raw (if applicable).	1. Toxin tests shall be carried out on toxin-forming materials such as bivalve shellfish and puffer fish. Acceptance standards and treatment shall be followed	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

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	<p>shall conform to <i>the National Food Safety Standards- Fresh and Frozen Aquatic Products of Animal Origin</i> (GB 2733).</p> <p>3. Aquatic products of animal origin shall conform to <i>the National Food Safety Standards- Fresh and Frozen Aquatic Products of Animal Origin</i> (GB 2733).</p> <p>4. Algae products shall conform to the <i>the National Food Safety Standards- Algae and Algae Products</i> (GB 19643).</p> <p>5. Table 1 of <i>the National Food Safety Standards- the Maximum Levels of Pathogenic Bacteria in Food</i> (GB29921)</p> <p>6. Articles 3.6 and 3.7 of <i>the National Food Safety Standards- Aquatic Products of Animal Origin</i> (GB10136)</p>	<p>5.2.2 Provide official permits or licenses for the fishing area, time and species and describe fishing methods if raw materials are from fishing vessels (if applicable).</p> <p>5.2. Provide qualification of farms, if raw materials are from aquaculture (if applicable).</p>	<p>in accordance with relevant stipulations to ensure the safety of raw materials.</p> <p>2. Raw materials shall meet the requirements of relevant agreements, protocols, memorandums on inspection and quarantine of aquatic products exported to China.</p>		

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
5.3 Bivalve Shellfish (Where Applicable)	<p>1. Article 7.2 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941);</p> <p>2. Table 1 of <i>the National Food Safety Standards- the Maximum Levels of Pathogenic Bacteria in Food</i> (GB29921);</p> <p>3. Articles 3.6 and 3.7 of <i>the National Food Safety Standards- Aquatic Products of Animal Origin</i> (GB10136)</p>	<p>5.3.1 Provide a description of growing waters where shellfish are originated and the official permits for harvesters.</p> <p>5.3.2 Provide information about purification and treatment.</p> <p>5.3.2 Describe monitoring measures for shellfish toxins.</p>	<p>1. Bivalve shellfish shall be originated from the growing or harvesting waters approved by the control authority and purified as necessary. Farmers and harvesters shall be approved by the control authority.</p> <p>2. Routine testing on shellfish toxins shall be carried out to verify the safety.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
5.4 Food Additives (Where Applicable)	<p>1. Article 7.3 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).</p> <p>2. Articles 7.3 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic</i></p>	5.4 List of food additives used (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.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
	<p><i>Products Production</i> (GB 20941).</p> <p>3. The National Food Safety Standard - Standards for Uses of Food Additives (GB 2760)</p>				
5.5 Packaging Materials	<p>1. Article 33 of <i>the Implementation Rules of the Law on Food Safety</i> of P.R. China;</p> <p>2. Article 8.5 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).</p> <p>3. Articles 5 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).</p> <p>4. Relevant requirements from bilateral inspection and quarantine agreements, memorandums and protocols</p>	<p>5.5.1 Provide proof to demonstrate that both packaging and packing materials are suitable for aquatic products.</p> <p>5.5.2 Provide model labels for finished products to be exported to China.</p>	<p>1. Packaging and packing materials do not affect food safety and product characteristics under specific storage and use conditions.</p> <p>2. Labels shall meet the requirements of bilateral inspection and quarantine agreements, memorandums and protocols.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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<b>6 Process Controls</b>					
6.1 Establishment and Implementation of Quality and Safety Management System	<p>1. Article 48 of <i>the Implementation Rules of the Law on Food Safety of P.R. China</i>;</p> <p>2. Article 8.1 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941);</p> <p>3. <i>Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Processing Plant</i> (GB/T 27341).</p>	<p>6.1.1 Provide flow chart, hazard analysis work sheet and HACCP plan of all products to be exported to China.</p> <p>6.1.2 Provide sample records for CCP monitoring, corrective actions and verification.</p>	<p>1. Biological, physical and chemical hazards shall be analyzed and effectively controlled in HACCP.</p> <p>2. Process flow shall be reasonable to prevent cross contamination.</p> <p>3. The establishment of CCPs should be scientific and feasible. Corrective actions and verification shall be appropriate.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

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6.2 Contamination Risk Controls	1. Article 8.1 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941); 2.2. Article 8.1 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).	6.2 Implementation of food safety management System	1. Processes, such as Raw material preparation, freezing, cooking, drying, smoking and salting, shall be segregated according to each steps and product characteristics to prevent cross contamination of people, materials and air flow. 2. Contamination shall be	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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			prevented by sewage or wastes on materials or products.		
6.3 Temperature Control	1 Article 8.2.2.1.4 to 8.2.2.1.6 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941); 2. Article 8.2.2.2.1 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941)( applicable to refrigerated aquatic products);	6.3.1 Provide information about thawing method, time and temperature control requirements of raw materials (if applicable).  6.3.2 Provide information about temperature control requirements and temperature monitoring equipment for processing workshops and storage warehouses. (applicable	1. Control thawing time and temperature.  2. Temperature controls shall be in place in the processing workshop for refrigerated aquatic products. Processed aquatic products shall be moved to the refrigerated environment as soon as possible. The refrigerating chamber shall be equipped with temperature indicators.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

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		to refrigerated aquatic products).			
6.4 Frozen Aquatic Products	1. Article 8.2.2.2.2 of of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941);	6.4.1 Provide information about freezing method, time and temperature control requirements of frozen aquatic products and their determination bases.  6.4.2 Provide information about temperature and time of cold treatment for aquatic products commonly eaten raw.	1. Based on the thickness, shape and production volume, freezing time and temperature are determined to ensure that products pass the maximum ice crystal generation zone as soon as possible.  1.Aquatic products commonly eaten raw shall go through sufficient cold treatment to destroy parasites harmful to humans.They shall be kept	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

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			<p>for 7 days at an ambient temperature below -20°C.</p> <p>3.Products shall be frozen to solid state at an ambient temperature of -35°C or below and kept for 15 hours at an ambient temperature of -35°C or below.</p> <p>4. Products shall be frozen to solid state at an ambient temperature of -35°C or below and kept for 24 hours at an ambient temperature of -20°C or below.</p>		

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6.5 Dried Aquatic Products (Where Applicable)	1. Article 8.2.2.2.3 of of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941);	6.5 Provide information about drying time and temperature, ambient humidity, water activity of finished products and packaging and storage methods.	1. Water activity of dried products shall be within a safe range.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
6.6 Salted Aquatic Products (Where Applicable)	1. Article 8.2.2.2.4 of of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941);	6.6 Provide information about sugar content/salinity.	1. Proper salinity shall be adopted to prevent the reproduction of non-halophilic bacteria.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
6.7 Canned Aquatic Products (Where Applicable)	1. Article 8.2.2.2.5 of of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941);	6.7.1 Provide information about sterilization temperature and time requirements for canned aquatic products of	1. Sufficient sterilization temperature and time shall be provided for canned aquatic products.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

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		<p>different specifications, and the latest sterilization/temperature records.</p> <p>6.7.2 Provide heat penetration and distribution reports for different specifications.</p>			

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
<b>7. Cleaning and Sanitizing</b>					
7.1 Cleaning and Sanitizing	1. Article 8.2.1 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881); 2. Article 8.2.1 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941);	7.1 Provide information about cleaning and sanitizing measures, including methods, frequency, and effect verification.	1. Cleaning and sanitizing measures shall be able to eliminate cross contamination and meet hygiene requirements.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7.2 Environmental Microbiological Monitoring	1. Articles 8.2.2.1.2 and 8.2.2.1.3 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).	7.2 Provide monitoring plan for microorganisms in the environment and products during production, including monitoring items, frequency, criteria and corrective measures for	1. The focus of monitoring shall cover areas where microorganisms are easy to hide and breed. 2. Selection of sampling sites. Add necessary sampling sites to the monitoring plan in case of	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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		positive results.	major maintenance, construction activities or worsen sanitary conditions. 3. Frequency for environment monitoring shall be adjusted according to test results and severity of contamination risks. 4. Corrective measures due to positive results.		

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
<b>8. Control of Chemicals, Waste and Pest</b>					
8.1 Chemicals Controls	1. Article 8.3 of of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881); 2. Article 8.3 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).	8.1 Brief description of the requirements for the use and storage of chemicals.	1. Prevent the contamination by chemicals.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
8.2 Waste Controls	1. Article 33 of <i>the Implementation Rules of the Law on Food Safety</i> of P.R. China; 2. Article 8.1.4 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).	8.2.1 Provide photos of edible product containers and waste containers in the workshop.  8.2.2 Describe the procedures of waste disposal.	1. Edible product containers and waste containers in the workshop shall be clearly identified and separated.  2. Waste shall be stored separately and disposed of in time to prevent contamination to production.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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8.3 Pest Controls	<p>1. Article 33 of <i>the Implementation Rules of the Law on Food Safety</i> of P.R. China;</p> <p>2. Article 6.4 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881).</p>	<p>8.3 Provide information about controls and distribution diagram. If controls are undertaken by a third party, provide its qualification.</p>	<p>1. Pest shall be excluded.</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	

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Item	Conditions and Reference	Filling-out requirements and supporting materials	Examination Focus	Compliance	Remarks
<b>9. Product Traceability</b>					
9 Traceability and Recall	<p>1. Article 33 of <i>the Implementation Rules of the Law on Food Safety</i> of P.R. China;</p> <p>2. Article 11 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881);</p> <p>3. Article 11 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).</p>	9. Describe traceability procedure in a brief manner and illustrate how to trace from finished products to raw materials with a batch number.	1. Traceability procedures shall be established to fulfill thorough tracking traceability from raw materials, processes to finished products.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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<b>10. Personnel Management and Training</b>					
10.1 Personnel Health and Hygiene Controls	<p>1. Article 45 of <i>the Implementation Rules of the Law on Food Safety</i> of P.R. China;</p> <p>2. Article 6.3 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881);</p> <p>3. Article 6.3 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).</p>	10.1 Provide information about health controls prior to employment and medical examination requirements.	<p>1. Personnel health management system shall be established and implemented.</p> <p>2. Employees shall have a medical examination and prove that they are suitable for working in food processing enterprises before employment. Training on sanitation shall be provided.</p> <p>3. Food handlers with an apparent illness which might impede food safety or open</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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			<p>lesions shall be excluded from any positions which might affect food safety.</p> <p>4. Personal health shall be kept prior to the entrance of food processing areas to prevent contamination. Employees shall wear outer garments and other personal protections properly, wash and sanitize hands according to the requirements.</p> <p>5. Non-food handlers shall not enter food processing areas. Identical sanitation requirements for food handlers shall be followed</p>		

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			under exceptional conditions for entrance.  2. Employees shall have regular physical examinations and keep records.		
10.2 Personnel Training	1. Article 44 of <i>the Implementation Rules of the Law on Food Safety</i> of P.R. China;  2. Article 12 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881);  3. Article 12 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941).	10.2 Provide annual training plans, contents, assessments and records for employees.	1. Training shall cover the contents of memorandums, agreements and protocols on inspection and quarantine of aquatic products exported to China, Chinese laws and standards, etc.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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<b>11. Self-inspection and Self-control</b>					
11. Finished Product Tests	<p>1. Article 9 of <i>the National Food Safety Standards-General Hygienic Standard for Food Production</i> (GB14881);</p> <p>2. Article 9 of <i>the National Food Safety Standards-Hygienic Standard for Aquatic Products Production</i> (GB 20941);</p> <p>3. <i>National Food Safety Standard - Fresh and Frozen Aquatic Products of Animal Origin</i> (GB 2733)</p> <p>4. <i>National Food Safety Standard - Aquatic Products of Animal Origin</i> (GB 10136)</p> <p>5. <i>National Food Safety Standard - Aquatic Flavouring</i> (GB 10133)</p> <p>6. <i>National Food Safety Standard - Algae and Algae Products</i> (GB 19643)</p>	<p>11.1 Provide information about testing items, indicators, methods and frequency for finished product.</p> <p>11.2 Provide qualification for either its own laboratory or entrusted third-party laboratories.</p>	1. Testing items of finished product meet the requirements of Chinese standards.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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	<p>7. <i>National Food Safety Standard - Standards for Uses of Food Additives (GB 2760)</i></p> <p>8. <i>National Food Safety Standard - Maximum Levels of Mycotoxins in Foods (GB 2761)</i></p> <p>9. <i>National Food Safety Standard - Maximum Levels of Contaminants in Foods (GB 2762)</i></p> <p>10. <i>National Food Safety Standard - Maximum Residue Limits for Pesticides in Food (GB 2763)</i></p> <p><i>Limited Concentrations of Radioactive Materials in Foods (GB 14882)</i></p> <p><i>National Food Safety Standard - Dried Sea Cucumber (GB 31602)</i></p>				

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<b>12. Food safety and sanitation management and operation of the protection system</b>					
12.1 Operation of Food Safety and Sanitation Management System	<p>1. Article 48 of 《the Regulations for the Implementation of the Food Safety Law of the People's Republic of China》 .</p> <p>2. Article 5 of 《the Regulations of the People's Republic of China on the Registration and Administration of Foreign Enterprises in Imported Food》 .</p> <p>3.8.1 in 《National Food Safety Standard, Hygienic Specification for the Production of Aquatic Products》 (GB 20941).</p> <p>4. 《Hazard Analysis and Critical Control Point (HACCP) System General Requirements for Food Production Enterprises》 (GB/T 27341).</p>	<p>12.1 Provide the company's quality manual and procedure files and records.</p> <p>12.2 Provide internal audit documents for the health quality system.</p> <p>12.3 Provide HACCP food safety management system documentation.</p> <p>12.4 Provide internal audit documents for HACCP food safety management system.</p>	<p>1. The compliance and effectiveness of food safety and hygiene management system and HACCP system regulations with on-site operation.</p> <p>2. Records shall be carried out in accordance with the requirements of the food safety and hygiene management system and related documents, and the completeness, accuracy and authenticity of the records shall be guaranteed.</p> <p>3. Establish and effectively implement evaluation</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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			<p>procedures for qualified suppliers.</p> <p>4.Establish and effectively implement sanitation control procedures in all links.</p> <p>5.Establish and effectively implement the whole process identification and traceability system.</p> <p>6.Establish and effectively implement a product recall system.</p> <p>7.Establish and effectively implement a control system for non-conforming products, including cause analysis, corrective</p>		

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			<p>measures and treatment measures.</p> <p>8.The effectiveness of the internal audit of the enterprise's food safety and sanitation management system and the HACCP system.</p> <p>9.Establish and effectively implement training for all types of employees and keep records.</p>		
12.2 Operation of food safety protection system	1.Article 5 of 《the Regulations of the People's Republic of China on the Registration and Administration of Foreign Enterprises in Imported Food》 .	12.2 Provide preventive control measures or safety protection plans for possible man-made contamination risks and possible emergencies in food.	<p>1.The enterprise establishes and effectively implements the written operating procedures of the protection system.</p> <p>2.Establish a food safety</p>	<input type="checkbox"/> yes <input type="checkbox"/> no	

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			<p>protection team and conduct regular drills.</p> <p>3.The key links of food safety protection have been verified.</p> <p>4.Establish emergency handling procedures for emergencies.</p>		

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<b>13. Declaration</b>					
13.1 Declaration	1. Articles9 of the Regulations on the Registration Administration of Overseas Manufacturers of Imported Food	13.1 Fill out the application for overseas manufacturers of imported aquatic products.	Signature of legal person and company seal	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13.2 Confirmation by Competent Authority	1. Articles 8 of the Regulations on the Registration Administration of Overseas Manufacturers of Imported Food	13.2Fill out the application for overseas manufacturers of imported aquatic products.	Signature of principal and seal of competent authority	<input type="checkbox"/> Yes <input type="checkbox"/> No	