EU ASIA COOPERATION
on (PHYTO-) SANITARY (SPS) and
FOOD SAFETY REGULATION

COMPARISON OF HYGIENE LEGISLATION AND FOOD SAFETY STANDARDS

For edible oils and fats, oilseeds, Edible grains / milled grain industry products and malt, Nuts and seeds

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CONTENT

MAIN ABBREVIATIONS

ALARA	As Low As Reasonably Achieveable
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)

INTRODUCTION

The objective of the study is to contribute to the facilitation of trade in oils, seeds and nuts 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 are laid down in the General Food Law (Regulation (EC) No 178/2002), the Hygiene Legislation (Regulation (EC) No 852/2004 and 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 oils, seeds and nuts 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.

Edible oil shipments must comply with the following requirements to enter the Chinese market: Edible oil shipments must be accompanied by phytosanitary certificates issued by the competent authority of the exporting country. Foreign oil exporters and Chinese oil importers must file their information at http: //ire.customs.gov.cn in order to have their shipments released by the customs. Vegetable oil produced from crops that are derived from agricultural biotechnology is also subject to AQSIQ Decree 62, the Administrative Measures for the Inspection and Quarantine of Entry-Exit GM Products. The Measures entered into force on May 24, 2004 and the latest revision was issued in April 2019. The Measures require importers to present an Agricultural Biotechnology Safety Certificate (import permit) and a File for Review of Agricultural GMO Label for customs clearance. On June 21, 2018, China released the national food safety standard Edible Vegetable Oil (GB 2716- 2018), which entered into force on December 21, 2018. Crude vegetable oil, edible vegetable oil, edible vegetable blend oil, and various edible vegetable oils used in frying food are subject to the standard. Edible oil products (such as edible hydrogenated oil, margarine, shortening, cocoa butter replacer, whipped cream, powdered oil) are not covered by the standard. In November 2016, China implemented the national food safety standard Edible Vegetable Oil Seeds (GB 19641-2015). The standard applies to oil seeds used in the production of edible vegetable oil.

To this study, a detailed evaluation of 38 Chinese National Food Safety Standards applicable to oils and seeds 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.

LIST OF CHINESE NATIONAL STANDARDS ASSESSED

GB 14881-2013	General Hygienic Regulation for Food Production
GB 4789.1-2016	Food microbiological examination- general rules
GB 29921-2013	Limit of pathogens in food products
GB/T 27341-2009	Hazard Analysis and Critical Control Point (HACCP) System - General requirements for food processing plant
GB 2761-2011	Maximum Levels of Mycotoxins in Foods
GB 2762-2017	Maximum levels of contaminants in foods
GB 2763-2021	Maximum residue limits for pesticides in food
GB 2760-2014	Uses of food additives
GB 5749	Drinking water quality
GB 2716-2018	National Food Safety Standard for Vegetable Oil
GB 19641-2015	National Food Safety Standards Edible Vegetable Oilseeds
GB 15196-2015	National Standards for Food Safety Edible Fats and Oils Products
GB 19300-2014	National Standards for Food Safety Nuts and seeds
GB/T 22165-2008	General standard for roasted seeds and nuts
GB/T 29647-2013	Good manufacturing practice of roasted nuts and seeds
GB 14880- 2012	Use of Nutritional Fortification Substances in Food
GB 10146-2015	Animal fats and oils for food use
GB 1886.65-2015	Food Additive Mono- and Diglycerol Fatty Acid Esters
GB 26400-2011	Food Additives Docosahexaenoic acid fats and oils (fermentation method)
GB 1886.178–2016	Food additive Polyglycerin fatty acid ester
GB 26401-2011	Food Additive Arachidonic Acid Oil (Fermentation Method)
GB 5009.254-2016	Determination of polydimethylsiloxane in animal and vegetable fats and oils
GB/T 5492-2008	Inspection of grain and oils— Identification of colour, odour and2taste of grain and oilseeds
GB/T 5494-2019	Inspection of grain and oils— Determination of foreign matter and unsound kernels of grain and oilseeds
GB 5491-85	Inspection of grain and oilseeds Methods for sampling and sample reduction
GB/T 5510-2011	Inspection of grain and oils— Determination of fat acidity value of grain and oilseeds
GB/T 14488.1-2008	Oilseeds—Determination of oil content
GB/T 14489.1-2008/ISO 665:2000	Oilseeds—Determination of moisture and volatile matter content
GB/T 10358-2008/ISO 771:1977	Oilseed residues—Determination of moisture and volatile matter content
GB/T 10360-2008/ISO 5500:1986	Oilseeds residues—Sampling
GB/T 5525-2008	Vegetable fats and oils—Method for identification of transparency, odour and flavour
GB/T 15688-2008	Animal and vegetable fats and oils— Determination of insoluble impurities content (ISO 663:2007,MOD)

GB/T 5532-2008	Animal and Vegetable fats and oils—Determination of iodine value (iso 3961:1996,MOD)
GB/T 5534-2008	Animal and Vegetable fats and oils—Determination of saponification value (iso 3657:2002,MOD)
GB/T 5533-2008	Inspection of grain and oils—Determination of soap content in vegetable oils
GB/T 5527-2010/ISO 6320:2000	Animal and vegetable fats and oils—Determination of refractive index (ISO 6320:2000,IDT)
GB/T 20795 – 2006	Determination of smoking point for vegetable fats and oils
GB 5009.236-2016	Determination of moisture and volatiles in animal and vegetable fats and oils

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 list of environmental contaminants for which limit values were defined in oils and seeds products or the water used in processing is not totally identical. 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. Furthermore, certain provisions of the Chinese Standards may hinder the access of EU oils and seed products- that meet the EU legislation - to the Chinese market. Provisions regarding labelling, pesticide MRLs, vitamins and minerals acceptable range of values, mixing of animal fats and others listed in this analysis must be taken into account by EU food business operators who wish to export their precuts 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 oils and seeds products are largely identical. EU legislation, as implemented by all food business operators and enforced by Member States and the EU Commission is in general consistent with applicable Chinese Food Safety Standards. Nevertheless, adherence to EU legal requirements will not ensure that seeds and oils products produced in the European Union fulfil the eligibility criteria of the People's Republic of China. EU oils and seeds producers must take into account a number of special provisions, set by the Chinese Standards. in order to meet the Chinese national food safety legislation.

1 SUMMARY COMPARISON

1.1 Chinese Food Safety Standards applicable to all food products

Subject	Evaluation result
1. **National standard 14881-2013** 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.
2. **National standard GB 4789.1-2016** 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. Nevertheless, as far as oils and especially vegetable fats are concerned, no microbiological limits are set by the EU legislation or the legislations of EU Member States. *In general, edible fats produced in the EU, in facilities meeting EU food safety legislation requirements, are expected to meet the microbiological criteria set in the Chinese Standard.*
3. **National standard 29921-2013** 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 Standard require testing for *Staphylococcus aureus*, while in the EU legislation coagulase positive *staphylococcae* are used as indicator) but overall the applicable food safety criteria are consistent.
4. **National standard GB/T 27341-2009 – Hazard Analysis and Critical Control Point (HACCP) System - General requirements for food processing plant** 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.	EU legislation provides that all establishments carrying out any stage of processing and distribution of food shall operate under HACCP principles. The Feed Hygiene Regulation 183/2005 is encouraging the development of sector guides for the application of HACCP Principles. Responding to this call, FEDIOL together with the European starch industry, Starch Europe, and the European biodiesel industry, EBB, have made the European Guide for the industrial manufacturing of safe feed materials. This Guide was endorsed by the Standing Committee on the Food Chain and Animal Health in June 2010 and the revised version in November 2014. EU Legislation sets rather similar but stricter criteria compared to the relevant Chinese Standard.

Subject	Evaluation result
5. **National standard GB 2761-2011** sets limits for certain mycotoxins i.e., Aflatoxin B1, Aflatoxin M1, Deoxynivalenol, Patulin, Ochratoxin A and Zearalenone in foods	In the Chinese National Standard limit values are defined as the maximum content of contaminants in food materials **and/or the edible part of the finished food products**. The edible part is defined as 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, nutshell, bones in meat/fish, shell of shellfish). The non-edible parts cannot be removed by non-mechanical means (such as refining of crude vegetable oil). The EU legislation (EU Regulation 2023/915) has similar measures for dried, diluted, processed and compound foodstuffs and imposes similar prohibitions on chemical detoxification that have similar consequences regarding the safety of final oils and seeds products. *The National Chinese Standard sets limits for Aflatoxin B1 in oils, whereas the EU Legislation has set similar limits for seeds and oils and for other substances such as the limits for Zearalenone in refined maize oil.* *EU legislation in general has different limits for a wide range of seeds, grains, nuts and oils from the respective Chinese standard. Hence EU food business operators intending to export nuts, seeds and oils products to China must ensure that they meet the requirements of this Chinese Standard.*
6. **National standard GB 2762-2017** 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 as the maximum content of contaminants in food materials **and/or the edible part of the finished food products**. The edible part is defined as 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). The non-edible parts cannot be removed by non-mechanical means (such as refining of crude vegetable oil). The EU legislation (EU Regulation 2023/915) has similar measures for dried, diluted, processed and compound foodstuffs and imposes similar prohibitions on chemical detoxification that have similar consequences regarding the safety of final oils and seeds products. In the Chinese National Standard limit values defined for contamination with nickel and chromium in oils and seeds products while in EU legislation no limits are set. The 'ALARA' Principle applies (as low as reasonably achievable). EU Legislation has a different approach as far benzo (a) pyrene PAH limits are concerned and stricter limits in place. PCB limits are also stricter in the EU. Therefore, fats and oils produced in the EU meet the relevant Chinese standards requirements but not vice versa. Likewise, the Chinese National Standard defines limits for Nickel for ***hydrogenated oil*** products while no such limits are laid down in EU legislation. Nevertheless, foods in the EU intended for consumers are required to contain less than 2g of industrial trans-fat (derived from partially hydrogenated oils) per 100g of fat. No such limit is set in Chinese Legislation.

Subject	Evaluation result
	Therefore, considering the hydrogenation process, EU products containing hydrogenated oil are expected to meet the limits set in the Chinese standard. *Nevertheless the relevant EU legislation has different limits for a wide range of substances in seeds, grains, nuts and oils from the respective Chinese standard. Hence EU food business operators intending to export nuts, seeds and oils products to China must ensure that they meet the requirements of this Chinese Standard.*
7. National standard GB 2763-2021 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, soybean oil 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. Regulation 396/2005 sets maximum residue levels (MRLs) for raw agricultural products, like oilseeds/oil fruits. According to this Regulation, MRLs also apply to processed products (like vegetable oils). In such cases, MRLs can be derived by applying a processing factor (reflecting the concentration or dilution caused by processing) to the MRL of the corresponding raw commodity. But Annex VI of Regulation 396/2005, which was scheduled to set specific processing factors, is today still empty. In absence of harmonized processing factors at EU level, Member States, as well as economic operators, may have a different understanding of MRLs applying to processed products which is a source of uncertainty and problems. ***This fact may hinder import of EU oil and fats products in the Chinese market.*** There is also a great number of discrepancies in the MRLs of the vast number of pesticides found in seeds and oils products that are regulated by the EU Regulation 396/2005 and the relevant Chinese Standard Therefore, EU food exporters of seeds and oils to the Chinese Markets should test the compliance of their products to the Chinese standard criteria. EU food business operators must ensure that oil and fats products exported to China meet the relevant Chinese Standard.
8. National standard GB 2760-2014 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. EU food business operators must ensure that only additives approved by Chinese Standards are used in products exported to China.
9. National standard GB 5749 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 conditions. Water used in processing of food products must be monitored and fulfil the quality criteria established. EU production facilities that meet EU Regulations meet the requirements of this Chinese standard.

1.2 Chinese Food Safety Standards specifically applicable to oils and seeds products

Subject	Evaluation result
10. **National standard GB 2716-2018** for Vegetable Oil specifies the required organoleptic, physical, and chemical characteristics of edible vegetable oils and sets labelling rules.	In EU food legislation limits are set for erucic acid in edible oils. No such limit is set by the Chinese National Standard. Labelling requirements set in Regulation 1169/2011 differ from the ones mentioned in the Chinese standard. Similar provisions regarding the organoleptic, physical, and chemical characteristics of edible vegetable oils can be found in national legislations of most EU Member States. Therefore, these minor discrepancies are considered formal rather than substantial and will not affect consumer risk. Nevertheless, EU food business operators must ensure that the labelling provisions set by the Chinese Standard are taken into consideration when labelling oil products exported to China.
11. National standard GB 19641-2015 National Food Safety Standards Edible Vegetable Oilseeds applies to oilseeds used to produce edible vegetable oils and provides limit values for ergot alkaloids and other toxic, harmful bacteria and plant seeds, such as mandarin seeds and pigmy bean seed. It also defines acceptable organoleptic characteristics and sets limits for mouldy grains concentrations.	EU limits for contamination (such as aflatoxin for example) that is caused by mouldy grains and EU limits for environmental contaminants are provided in different pieces of EU legislation. EU products that meet EU legislation are expected to meet the requirements of this Chinese standard. EU Legislation Limits for ergot alkaloids are far stricter than the ones of the Chinese Standard. Nevertheless, no limits are set in EU legislation for toxic seeds in oilseeds.\ Hence, EU food business operators must ensure that the toxic seed limits set by the Chinese Standard are taken into consideration when exporting oilseeds products exported to China.
12. **National standard GB 15196-2015** for Food Safety Edible Fats and Oils Products applies to edible oils and fats products such as edible hydrogenated oils, margarine (margarine), shortening, cocoa butter (cocoa-like butter), phytates, powdered fats and oils.	The Chinese standard sets limits for peroxide value and acidity in vegetable oils that are stricter than the relevant limits set in certain EU- Member States National Legislation. The organoleptic criteria set by the standard are identical to the ones set in certain EU- Member States National Legislation. Nevertheless, EU food business operators must ensure that the peroxide values limits set by the Chinese Standard are taken into consideration when exporting oil products to China.
13. National standard GB 19300-2014 for Food Safety Nuts and seeds applies to raw, dried, and cooked nuts and seeds. The Standard sets limits for organoleptic parameters, physical and chemical parameters, and microbiological parameters.	The Chinese Standard sets limits for mouldy grains that are not set by the relevant EU Legislation. Nevertheless, EU legislation sets limits for aflatoxin and mycotoxin and defines microbiological criteria (Annex I to Regulation (EC) No 2073/2005). Therefore, it can be reasonably expected that nuts and seeds products which meet EU legislation requirements also meet the requirements of the Chinese Standard.

Subject	Evaluation result
14. **National standard GB/T 22165-2008** for roasted seeds and nuts applies to the production, sale, and inspection of fried nut foods. The Standard sets limits for organoleptic parameters, physical and chemical parameters, and microbiological parameters. It also sets requirements for the labelling of the products and the packaging material	The limits set by the Chinese Standard are reasonably met by products that meet the relevant EU legislation. The Standard sets microbiological limits for margarine (vegetable fats) that are non-existent in EU legislation and EU-MS National Legislation. The Chinese Standard's' Labelling provisions for trans fats is less strict than the EU legislation. Hence, EU food business operators must ensure that oil and fats products exported to China meet the relevant Chinese Standards
15. **National standard GB/T 29647-2013** "Good manufacturing practice of roasted nuts and seeds" applies to the design, construction (modification and expansion), production management and quality management of nut and seed-based fried food production enterprises.	The EU legislation imposes stricter requirements compared to the corresponding standards in China. Consequently, it is reasonable to expect that roasted nuts and seeds production facilities complying with EU regulations will also satisfy the criteria outlined in this Standard.
16. **National Food Safety Standard GB 14880-2012** «for Use of Nutritional Fortification Substances in Food» specifies the fundamental purposes of nutritional fortification in foods, the requirements of using nutritional fortification substances, the selection requirements for fortifiable food categories and application requirements for nutritional fortification substances. This Standard is applicable to the application of nutritional fortification substances in foods.	The Chinese standard requires that the total amount of certain vitamins and mineral present in oils and fats are within a certain range of values. On the other hand, the relevant EU legislation (Regulation (EC) No 1925/2006), despite stating that the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold, does not exceed a certain limit, no limits or ranges have been set to this date. Hence, EU food business operators must ensure that oil and fats products exported to China meet the requirements of this Chinese Standard by adjusting vitamins and mineral levels within the range specified by the Standard.
17. **National Standard GB 10146-2015 "**Food Safety Standards Animal fats and oils for food use" applies to edible animal fats and oils and covers only edible lard, beef fat, lamb fat, chicken fat and duck fat. The Standard sets limits for organoleptic parameters, physical and chemical parameters, and microbiological parameters	The limit of the Chinese Standard for peroxide value is significantly lower than the EU limit set by Regulation 853/2004. The Standard sets also a limit for Malondialdehyde that does not exist in EU legislation. Furthermore, the Chinese Standard states that single species of edible animal fat should not be mixed with other fats and oils. *Hence, EU food business operators must ensure that oil and fats products exported to China meet the requirements of this Chinese Standard.*
18. **National Standard for Food Safety GB 1886.65-2015** "Food Additive Mono- and Diglycerol Fatty Acid Esters" applies to mono- and diglycerol fatty acid esters (oleic, linoleic, linolenic, palmitic, behenic, stearic, lauric) of food additives obtained by reaction of saturated or unsaturated fatty acids or oils with glycerol, with or without separation and purification and other processing.	The organoleptic criteria set by the Standard are identical to the EU legislation (Commission Regulation (EU) No 231/2012). Physical and Chemical parameters limits set in the Chinese Standard are far less extensive in scope and set less strict limits than the ones set by the respective EU legislation limits. Therefore, oil and seed products that meet EU legislation are certain to meet the criteria set by the Chinese Standard.

Subject	Evaluation result
19. **National Standards for Food Safety GB 26400-2011** "Food Additives Docosahexaenoic acid fats and oils (fermentation method)" applies to docosahexaenoic acid (DHA) oils and fats produced by biological fermentation using strains of Schizochytrium sp. or Ulkenia amoeboida or Crypthecodinium cohnii	A number of discrepancies were found between this Standard and COMMISSION IMPLEMENTING REGULATION (EU) 2021/1326, i.e. the corresponding EU Legislation. In general, the EU Regulation is stricter than the Chinese Regulation but in certain parameters, the Chinese Standard is stricter than the EU legislation. Furthermore, the Chinese Standard sets special storage conditions that are not present in the EU legislation. Hence, EU food business operators must ensure that DHA oils products exported to China meet the requirements of this Chinese Standard.
20. **National Standards for food safety GB 1886.178 – 2016** "National Food additive Polyglycerin fatty acid ester" applies to food additives Polyglycerin fatty acid esters derived from the reduction of glycerol into polyglycerol or polyglycerol, which is partially esterized with fat or fatty acids.	Limits set in EU legislation (COMMISSION REGULATION (EU) 2023/1329) are far stricter than the ones set in this Standard. Therefore, it is reasonable to expect that polyglycerine fatty acid esters complying with EU regulations will also satisfy the criteria outlined in this Standard.
21. **National Standard for Food Safety GB 26401-2011** Food Additive Arachidonic Acid Oil (Fermentation Method) applies to arachidonic acid (ARA) oils and fats produced by biological fermentation using Mortierlla alpina strain.	Several discrepancies were found between this Standard and the corresponding EU Legislation (Commission Decision of 12 December 2008 authorising the placing on the market of arachidonic acid-rich oil from Mortierella alpina as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council). In general, the EU Regulation is stricter than the Chinese Regulation but in certain parameters the Chinese Standard is stricter than the EU legislation. Furthermore, the Chinese Standard sets special storage conditions that are not present in the EU legislation. Hence, EU food business operators must ensure that ARA oils products exported to China meet the requirements of this Chinese Standard.
22. **GB 5009.254-2016** National Standard for Food Safety Determination of polydimethylsiloxane in animal and vegetable fats and oils specifies a method for the determination of polydimethylsiloxanes in animal and vegetable fats and oils. This standard applies to the determination of polydimethylsiloxanes in animal and vegetable oils and fats.	Since the beginning of its production and regulation, the additive E900 has been varying its permitted levels due to the increase in knowledge of its effects on health and the environment. Many studies have been carried out in animals and humans and, consequently, its levels of exposure and consumption have been adjusted according to health and food consumption patterns. PDMS was first evaluated as a food additive by the Joint FAO/WHO Expert Committee on Food Additives (JEFCA) in 1969 and again in 1974. Then, an acceptable daily intake (ADI) of 1.5 mg/kg of body weight (bw) was established based on a long-term toxicity study on rats performed in 1959, where no adverse effects were observed at exposition levels of 150 mg/kg bw per day . In 2008, the substance was placed back on the JECFA agenda, and the previously established ADI of 0–1.5 mg/kg of body weight was withdrawn, since a new study evaluated by the Committee showed E900 effects on the corneas of the tested animals. Based on this study, an additional safety factor of 2 was included to establish a temporary ADI of 0–0.8 mg/kg body weight [

Subject	Evaluation result
GB 5009.254-2016 (Cont'd)	In 2011, JECFA considered new studies and concluded that the ocular lesions were caused by local toxicity when the eyes of laboratory animals were exposed by contact to dimethylpolysiloxane, which would be present in feed or faeces, or even through grooming of contaminated fur. Therefore, the Committee re-established an ADI of 0–1.5 mg/kg bw per day In addition to this increase in the ADI from 0.8 to 1.5 mg/kg bw, the French Agency for Food, Environmental, and Occupational Health Safety (ANSES) re-evaluated the calculated exposure of PDMS based on updated human food intake patterns even to a lower value. This study, published a series of opinions on the use of various antifoaming agents as processing aids, including dimethylpolysiloxanes and emphasized that the previous database was extremely limited quantitatively and qualitatively. Therefore, updating values of human intake, due to the low use levels as a processing aid, exposure levels were determined to be low (from 0.2% to 22% percent of an ADI of 1.5 mg/kg bw per day), and the ANSES concluded there was no safety concern. Currently, the data on food consumption used to estimate the diet's exposure to dimethylpolysiloxanes are from the EFSA Comprehensive European Food Consumption database . As a rule of thumb, the amounts of PDMS in foodstuffs according to the existing regulations should not exceed, in general, of 10 mg/kg of the final product with concentrations ranging from 110 to 5 mg/kg depending on the food. These levels ensure an acceptable daily intake (ADI) below 1.5 mg/kg body weight, as it was established by the international Joint Expert Committee on Food Additives (JEFCA) [16]. This amount was limited with by the assumption of the standard diets studied in different countries and the fact that silicones do not biodegrade in living organisms and are not absorbed in the digestive tract. Finally, in 2020, the European Union Panel on Food Additives and Flavourings (FAF) of the EFSA provided an extensive re-evaluation of PDMS as a food additive and recommended what specifications should be updated to better describe the material used as the food additive E900 to ensure its safety of use for EU countries . In doing so, the current regulation by the EFSA Panel established an ADI of 17 mg/kg bw per day for dimethylpolysiloxane (E900) and withdrew the previous value of 1.5 mg/kg bw per day, established by its Scientific Committee of Food SCF in 1990 in accordance with the JEFCA value of 1974. However, together with this increase in the permitted level of E900, the Panel recommended to the European Commission that PDMS used as food additive should include additional information and chemicals restrictions. This information must include the range of the weight-average molecular weight (Mw) and number-average molecular weight (Mn) of the manufactured polymer used; the maximum amount of cyclopolysiloxanes and low molecular molecules of PDMS present in the mixture; assess the values of toxic metallic elements such as copper, (used as a catalyst in the industrial production) arsenic, lead, or mercury.

Subject	Evaluation result
GB 5009.254-2016 (Cont'd)	Following these guidelines, the name of dimethylpolysiloxanes was changed to the more accurate "poly(dimethylsiloxane)" (PDMS), and the authorized use of the substance is limited to linear polymers (without cyclic or branched structures) with molecular weights above 6.8 kDa and low levels or better total absence of impurities of toxic elements. With these restrictions, EFSA wants to avoid any absorption and adverse biological effects of PDMS, which are more associated with low-molecular-weight polymers, cyclic structures, and the presence of heavy metallic elements or impurities. The National Chinese Standard is similar to the relevant ISO standard used by several EU laboratories. EU fats and oils containing E900 that are compliant with EU legislation meet the relevant Chinese legislation on food additives.
23. **National standard GB/T 5492-2008** Inspection of grain and oils— Identification of colour, odour and taste of grain and oilseeds specifies the principles, apparatus, environment and laboratory, operating procedures and results for the identification of colour, odour and taste of grain and oilseeds. This standard applies to the identification of colour, odour and taste of commercial grains and oilseeds.	Specific organoleptic testing methods are not mentioned in the EU legislation. Nevertheless, the requirements of the Chinese Standard are expected to be met by the EU oilseeds producers that meet the requirements of the ESTA Standard (European Seed Treatment Assurance Quality Assurance System for Seed Treatment and Treated Seed) and the ISTA International Rules for Seed Testing. Grains and oils produced in establishments that meet EU food safety legislation (Regulation 852/2004) are expected to meet the requirements of this Standard.
24. National standard GB/T 5494-2019 Inspection of grain and oils— Determination of foreign matter and unsound kernels of grain and oilseeds specifies the apparatus and appliances, lighting requirements, sample preparation, operating procedures, calculation of results, etc. for the testing of impurities and imperfection content in grain and oilseeds. This standard applies to grain, oilseeds, impurities, imperfection content of the test	Specific testing methods are not mentioned in the EU legislation. Nevertheless, the requirements of the Chinese Standard are expected to be met by the EU oilseeds producers that meet the requirements of the ESTA Standard (European Seed Treatment Assurance Quality Assurance System for Seed Treatment and Treated Seed) and the ISTA International Rules for Seed Testing. Grains and oils produced in establishments that meet EU food safety legislation (Regulation 852/2004) are expected to meet the requirements of this Standard.
25. **National standard GB 5491-85** Inspection of grain and oilseeds Methods for sampling and sample reduction applies to the quality inspection of commercial grain and oilseeds.	Specific sampling methods are not mentioned in the EU legislation. Nevertheless, the requirements of the Chinese Standard are expected to be met by the EU oilseeds producers that meet the requirements of the ESTA Standard (European Seed Treatment Assurance Quality Assurance System for Seed Treatment and Treated Seed) and the ISTA International Rules for Seed Testing. Grains and oils produced in establishments that meet EU food safety legislation (Regulation 852/2004) are expected to meet the requirements of this Standard.

Subject	Evaluation result
26. National standard GB/T 5510-2011 Inspection of grain and oils— Determination of fat acidity value of grain and oilseeds specifies the terms and definitions, principles, reagents and materials, apparatus and equipment, operating procedures, calculation and representation of results, and precision for the determination of fatty acid values of grains and oilseeds. The Standard defines Fat acidity value as the number of milligrams of potassium hydroxide required to neutralise 100 g of free fatty acids in a dry matter specimen. Therefore, the Fat acidity value mentioned in the standard is the seed oil's saponification value (SV).	EU REGULATION (EU) 2022/2105 (rules on conformity checks of marketing standards for olive oil and methods of analysis of the characteristics of olive oil) requires the use of the IOC Method COI/T.20/Doc. No 34 Determination of free fatty acids, cold method). Olive oil Saponification values measured using the Chinese Standard method are expected to be in the same range of values measured estimated by using the IOC Method.
27.	
28. **National standard GB/T 14488.1-2008** Oilseeds— Determination of oil content specifies a method for the determination of the oil content of vegetable oilseeds and its principles. This method is applicable to the determination of the oil content of rapeseed, soybean and sunflower seeds used as industrial raw materials. However, this method does not preclude its use for determining the oil content of other vegetable oilseeds. Oil content (hexane extract) is defined as the mass fraction of the original or net sample obtained from the extraction of an oil using n-hexane or petroleum ether as the solvent under the conditions specified in this standard.	ISO 659:2009 specifies a reference method for the determination of the hexane extract (or light petroleum extract), called the "oil content", of oilseeds used as industrial raw materials. The procedure for sunflower seed is different from those for other seeds as it includes an additional moisture content determination after the seed has been ground to prepare the test sample. The method has been tested on rapeseed, soya beans and sunflower seed. This does not, however, preclude its applicability to other commercial seeds. If required, the pure seeds and the impurities can be analysed separately. In the case of groundnuts, the pure seeds, the total fines, the non-oleaginous impurities and the oleaginous impurities can be analysed separately. Oil content by nuclear magnetic resonance (NMR) is done according to the International Organization for Standardization, reference number ISO 10565:1992(E) Oilseeds—Simultaneous determination of oil and moisture contents—Method using pulsed nuclear magnetic resonance spectroscopy. A Bruker Mq10 Minispec NMR Analyzer calibrated with appropriated oilseed samples extracted with petroleum ether according to the ISO 659:2009 (Reference method). The NMR technique measures the resonance energy absorbed by hydrogen atoms in the liquid state of the sample, NMR methods give very accurate and precise results. This International Standard specifies a rapid method for the determination of the oil and water contents of commercial oilseeds using pulsed nuclear magnetic resonance (NMR). It is applicable to rapeseeds, soya beans, linseeds, and sunflower seeds with a water content less than 10 %. For seeds with higher water contents, drying is necessary before the oil content can be determined by pulsed NMR. This method has been tested with rapeseeds, soya beans, linseeds, and sunflower seeds. This does not, however, preclude its applicability to other commercial seeds whose oil is liquid at the temperature of measurement.

Subject	Evaluation result
	The reproducibility values are generally higher than those obtained by the drying method (ISO 665). EU food business operators estimate oil content in seeds, in laboratories that follow one of the ISO reference methods mentioned above. Vegetable oils' oil content values measured using the Chinese Standard method are expected to have a lower reproducibility value, than those obtained by using the IOC Method, used in several EU laboratories.
29. **National standard GB/T 14489.1-2008/ISO 665:2000 Oilseeds —** Determination of moisture and volatile matter content specifies a method for the determination of the moisture and volatile matter content of oilseeds.	Oil content by nuclear magnetic resonance (NMR) is done according to the International Organization for Standardization, reference number ISO 10565:1992(E) Oilseeds—Simultaneous determination of oil and moisture contents—Method using pulsed nuclear magnetic resonance spectroscopy. The NMR technique measures the resonance energy absorbed by hydrogen atoms in the liquid state of the sample, NMR methods give very accurate and precise results. This International Standard specifies a rapid method for the determination of the oil and water contents of commercial oilseeds using pulsed nuclear magnetic resonance (NMR). It is applicable to rapeseeds, soya beans, linseeds and sunflower seeds with a water content less than 10 %. For seeds with higher water contents, drying is necessary before the oil content can be determined by pulsed NMR. This method has been tested with rapeseeds, soya beans, linseeds and sunflower seeds. This does not, however, preclude its applicability to other commercial seeds whose oil is liquid at the temperature of measurement. The National Chinese Standard is identical to one of the relevant ISO standards used by several EU laboratories. Results have lower reproducibility value than the ones obtained by NMR METHODS USED IN SEVERAL EU LABORATORIES.
30. **National standard GB/T 10358-2008/ISO 771:1977** Oilseed residues—Determination of moisture and volatile matter content specifies a method for the determination of the moisture and volatile matter content of cake meal (other than composite products) after extraction of oil from oilseeds by pressing or leaching. This standard applies to the determination of the moisture and volatile matter content of cake meal (except composite products) after extraction of oil from oilseeds by pressing or leaching.	The National Chinese Standard is identical to the relevant ISO standard used by several EU laboratories.

Subject	Evaluation result
31. **National standard GB/T 10360-2008/ISO 5500:1986** Oilseeds residues—Sampling specifies the method for taking samples of oilseed cake meal. This standard applies to the taking of samples of all oilseed meal, whether in the form of meal, dough, or cake. Appendix C specifies the methods for taking samples of special types of oilseed meal. This includes certain substances that are not uniformly distributed, such as mycotoxins, castor seed hulls, toxic seeds, etc.	The National Chinese Standard is identical to the relevant ISO standard used by several EU laboratories.
32. **National standard GB/T 5525-2008** Vegetable fats and oils—Method for identification of transparency, odour and flavour specifies a method for the identification of the transparency, odour and taste of vegetable oils and fats. his standard applies to the identification of transparency, odour and taste of vegetable oils and fats.	As stated in the relevant EU legislation (Article 10 c of the COMMISSION DELEGATED REGULATION (EU) 2022/2104) indications of organoleptic characteristics defines referring to taste or smell may appear only for extra virgin and virgin olive oils. Only the organoleptic characteristics as defined in Annex IX to Regulation (EU) No 1308/2013 may appear on the label and only if they are based on an assessment carried out following the method referred to in Annex I, point 5, of Commission Implementing Regulation (EU) 2022/2105. This method is the IOC Method COI/T.20/Doc. No 15 (Sensory analysis of olive oil – Method for the organoleptic assessment of virgin olive oil) – except for its points 4.4 and 10.4. The definitions and ranges of results, which allow for indication of these organoleptic characteristics, are set out in Annex II of Regulation (EU) 2022/2104. Vegetable fats & oils produced in establishments that meet EU food safety legislation (Regulation 852/2004) are expected to meet the requirements of this Standard.
33. **National standard GB/T 15688-2008** Animal and vegetable fats and oils— Determination of insoluble impurities content (ISO 663:2007,MOD) specifies a method for the determination of the content of insoluble impurities in animal and vegetable fats and oils. This standard applies to animal and vegetable fats and oils. If soaps (in particular calcium soaps) or oxidised fatty acids are not to be calculated as insoluble impurity content, different solvents and methods of operation shall be used so that the determination of insoluble impurity content meets the relevant requirements.	The National Chinese Standard is identical to the relevant ISO standard used by several EU laboratories.
34. National standard GB/T 5532-2008 Animal and Vegetable fats and oils—Determination of iodine value (ISO 3961:1996,MOD) specifies a method for the determination of iodine values in animal fats and vegetable oils.	The National Chinese Standard is identical to the relevant ISO standard used by several EU laboratories.

Subject	Evaluation result
35. **National standard GB/T 5534-2008** Animal and Vegetable fats and oils—Determination of saponification value (ISO 3657:2002,MOD) specifies a method for the determination of the saponification value of animal and vegetable fats and oils. This standard applies to refined vegetable and animal fats and oils and crude oils and fats. This standard does not apply to products containing inorganic acids, unless the inorganic acids can be determined separately.	The National Chinese Standard is identical to the relevant ISO standard used by several EU laboratories.
36. **National standard GB/T 5533-2008** Inspection of grain and oils—Determination of soap content in vegetable oils National Standard GB/T 5533-2008 Inspection of grain and oils—Determination of soap content in vegetable oils specifies a method for the determination of soap content in vegetable oils and fats. This standard applies to the determination of the soap content of refined vegetable fats and oils. Soap content is defined as the amount of residual saponification in vegetable fats and oils after refining with alkali.	Similar analytical methods with that of the Chinese Standard are used in vegetable oil refineries across the EU.
37. **National standard GB/T 5527-2010/ISO 6320:2000** Animal and vegetable fats and oils—Determination of refractive index (ISO 6320:2000,IDT) specifies a method for the determination of the refractive index of animal and vegetable fats and oils.	The National Chinese Standard is identical to the relevant ISO standard used by several EU laboratories. It has to be noted though that ISO 6320:200 has been replaced by ISO 6320:2017. ISO 6320:2017 specifies a method for the determination of the refractive index of animal and vegetable fats and oils. Milk and milk products (or fat coming from milk and milk products) are excluded from the scope of the most recent relevant ISO standards.
38. **National standard GB/T 20795 – 2006** Determination of the smoke point of vegetable oils and fats specifies the terms and definitions, principles of determination, instrumentation, determination procedures and presentation of results for the determination of the smoke point of vegetable oils and fats. This standard applies to the determination of the smoke point of vegetable oils and fats	Similar analytical methods with that of the Chinese Standard are used in vegetable oil refineries across the EU.
39. **GB 5009.236-2016 National Standard for Food Safety** Determination of moisture and volatiles in animal and vegetable fats and oils specifies two methods for the determination of the moisture and volatile matter content in animal and vegetable fats and oils. The first method [sand bath (hot plate) method] is applicable to all animal and vegetable fats and oils; the second method (hot oven method) is only applicable to non-dry fats and oils with an acid value of less than 4 mg/g and is not applicable to lauric acid type oils (palm kernel oil and coconut oil)	Similar analytical methods with that of the Chinese Standard are used in vegetable oil refineries across the EU.

2 DETAILED ANALYSIS

2.1 General requirements for all food products

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

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
Scope 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.	**Article 1[1] Scope** 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; [1] **unless specified otherwise, Articles in this table refer to Regulation 852/2004**	
	Article 1 Scope (*cont*.) (e) guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance 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;	

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
	(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.	
2. Terms and Definitions Various terms are defined such as: Contamination, monitoring, contact surface, food processing location, etc.	**Article 2 Definitions** Various terms are defined such as: Food hygiene, establishment, contamination, processing, processed products, unprocessed products, etc.	
3. Site selection and plant surroundings 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. 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. 3.2 Plant surroundings 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. 3.2.2 The plant shall be arranged reasonably; each functional area shall be obviously divided with proper	**Regulation (EC) No 853/2004, Article 4** states that establishments handling products of animal origin shall not operate unless the competent authority has approved them following an on-site visit. **Article 4, 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. Annex I, II, 3 a) states: 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; **Article 4, 2.** 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:	**Guidance document Commission Notice 2016/C 278/01**, **Annex I, Examples of PRPs** **2.1 Infrastructure:** 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. *In the EU Guidance Document on the implementation of certain provisions of 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. *The requirements for approval are explained in detail in the EU Guidance Document on the implementation of certain provisions of Regulation*

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
separation or partition measures to prevent cross contamination. 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. 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. 3.2.5 The plant shall be equipped with proper drainage system. 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.	Food premises are to be kept clean and maintained in good repair and condition. **Regulation (EC) No 852/2004,** 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.	*(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).*
4. Plant and workshop **4.1 Design and layout** 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. 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. 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter I, 2. states: The layout, design, construction and size of food premises are to: (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; (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; (c) permit good food hygiene practices, including protection against contamination and, in particular, pest control; and (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.	

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
4.1.4 Inspection room in the plant shall be partitioned from the production area. 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.		
4.2 Internal structure and materials of the building 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. 4.2.2 Ceiling 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. 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. 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter II, 1 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. (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;	*For establishments producing food of animal origin additional requirements for internal structure and materials of the building are specified in more detail in **Regulation (EC) No 853/2004**.*
4.2.3 Wall 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 be nontoxic, odorless, mold-proof, difficult for shedding and easy for cleaning. 4.2.3.2 Wall, partition and ground junctions shall be reasonable in structure, easy for cleaning and effectively	(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 operators can satisfy the competent authority that other materials used are appropriate;	

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
avoid the accumulation of dirt, for example, the arrangement of smooth and accessible surfaces.		
4.2.4 Doors and windows 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. 4.2.4.2 Doors of clean operating area, quasi-cleaning operation area and other areas shall be able to timely be shut down. 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. 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.	(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; (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;	
4.2.5 Ground 4.2.5.1 Ground shall be made of nontoxic, odorless, anti-seepage and corrosion-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.	(a) floor 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 unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;	*More detailed requirements on this subject (ground) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.3:*** e) The presence of an indoor pool of water should be immediately addressed.
5 Facilities and Equipment **5.1 Facilities** 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	**Regulation (EC) No 852/2004,** 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.	*Potable water, clean seawater and clean water are defined in **Regulation (EC) No 852/2004, Article 2.*** (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).

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
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.	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 hazard to health or is likely to contaminate the food. 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.	
5.1.2 Drainage facilities 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. 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. 5.1.2.3 Outlet of drainage system shall be provided with appropriate measures to lower the risk of insect attack. 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.	**Regulation (EC) No 852/2004,** 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.	

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
5.1.2.5 Sewage shall be disposed of properly before discharge on order to meet relevant national requirements on sewage discharge.		
5.1.3 Cleaning and disinfection facilities Sufficient specialized cleaning facilities for food, tools and instruments and equipment shall be provided; where necessary, appropriate disinfection facilities shall be provided. Measures shall be taken to avoid cross contamination caused by tools and instruments for cleaning and disinfection.	**Regulation (EC) No 852/2004,** Annex II, Chapter I, 10: Cleaning agents and disinfectants are not to be stored in areas where food is handled. **Regulation (EC) No 852/2004,** 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.	**Regulation (EC) No 852/2004,** 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 accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.	

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
5.1.5 Personal hygienic facilities 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. 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. 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 the faucets that are matched with disinfection facilities, their switches shall be non-manual. 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter I, 9. Where necessary, adequate changing facilities for personnel are to be provided. **Regulation (EC) No 852/2004,** 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. **Regulation (EC) No 852/2004,** Annex II, Chapter I, 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. 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. Regulation 853/2004, Annex III, Section 1, Chapter 2 provides: Slaughterhouses must: • 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.	*More detailed requirements on this subject (changing room) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.1:*** 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.

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
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.	• The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.	
5.1.6 Ventilation facilities 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. 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. 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. 5.1.6.4 According to production requirements, where necessary, de-dusting facilities shall be installed.	**Regulation (EC) No 852/2004,** Annex II, Chapter I, 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. 6. Sanitary conveniences are to have adequate natural or mechanical ventilation	*More detailed requirements on this subject (ventilation) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.8:*** 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.
5.1.7 Lighting facilities 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. 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter I, 7. Food premises are to have adequate natural and/or artificial lighting.	*More detailed requirements on this subject (lighting) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.1:*** 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.

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5.1.8 Storage facilities 5.1.8.1 Storage facilities corresponding to quantity, storage requirements of products shall be provided. 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. 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. 5.1.8.4 Storing articles shall be kept a proper distance from wall and ground to contribute to ventilation and articles handling. 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter IX, 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. 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. **Regulation (EC) No 852/2004,** 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. **Regulation (EC) No 852/2004,** Annex II, Chapter I 10. Cleaning agents and disinfectants are not to be stored in areas where food is handled. **Regulation (EC) No 852/2004,** 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.	
5.1.9 Temperature control facilities 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. 5.1.9.2 According to production requirements, facilities for controlling room temperature may be arranged.	**Regulation (EC) No 852/2004, Article 4** 3. Food business operators shall, as appropriate, adopt the following specific hygiene measures: (c) compliance with temperature control requirements for foodstuffs; (d) maintenance of the cold chain;	

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	Regulation (EC) No 852/2004, Annex II, Chapter I 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.	
5.2 Equipment 5.2.1 Production equipment 5.2.1.1 General requirements Production equipment corresponding to productivity shall be provided and kept in order according to process flow to avoid cross contamination. 5.2.1.2 Materials 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. 5.2.1.2.2 Surface of equipment and tools and instruments contacting with food shall be made of smooth, nonabsorbent materials 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	**Regulation (EC) No 852/2004,** Annex II, Chapter V 1. All articles, fittings and equipment with which food comes into contact are to: (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; (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; **Regulation (EC) No 852/2004,** Annex II, Chapter II 1. 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. 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.	

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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.	**Regulation (EC) No 852/2004,** 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 air-borne 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; **Regulation (EC) No 852/2004,** Annex II, Chapter V: 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;	*More detailed requirements on this subject (equipment) are mentioned in* the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.1:** 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 cleaning and disinfection between use) for raw products and cooked products (chopping boards, knives, dishes, …). and **Annex I, 2.10:** 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, …).
5.2.2 Monitoring equipment The equipment used for monitoring, controlling and recording such as pressure gauge, thermometer and recorder shall be calibrated and maintained on regular basis.	**Regulation (EC) No 852/2004,** Annex II, Chapter I 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. **Regulation (EC) No 852/2004,** Annex II, Chapter V	*More detailed requirements on this subject (calibration) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.4 Technical maintenance and calibration:*** c) Calibration of monitoring devices (e.g. weighing scales, thermometers, flow meters) is of importance in controlling food safety and hygiene.

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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.	**Regulation (EC) No 852/2004,** 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 **Commission Notice 2016/C 278/01**, **Annex I, 2 Examples of PRPs, 2.4 Technical maintenance and calibration:** 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, …
Hygiene Management **6.1 Hygiene management system** 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 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. 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	**Regulation (EC) No 852/2004, Article 4** 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 general hygiene requirements laid down in Annex II… 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;	

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executive condition and effect shall be inspected periodically so that any problem can be corrected at once if it's found. 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.	(d) maintenance of the cold chain; (e) sampling and analysis. 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. **Regulation (EC) No 852/2004, Article 5** 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 acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; (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; 4 (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) 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).	*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.)* *In these guides requirements are explained in detail to enable application in that sector using simplified language and examples.*

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	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. **See also** *EU requirements equivalent to points 5.2.1.3, 5.2.2, 5.2.3 and in addition:* **Regulation (EC) No 852/2004,** 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.	
6.2 Hygiene management of plant and facilities 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. 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter I 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 air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations; **Regulation (EC) No 852/2004,** Annex II, Chapter V 1. All articles, fittings and equipment with which food comes into contact are to: (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; (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;	
6.3 Health management and hygienic requirement for food processing personnel 6.3.1 Health management for food processing personnel 6.3.1.1 Health management system for food processing personnel shall be established and implemented.	**Regulation (EC) No 852/2004,** Annex II, Chapter VIII 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.	*More detailed requirements on this subject (personnel, health status) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.9:***

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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. 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. 6.3.2 Hygiene requirements for food processing personnel 6.3.2.1 The personnel shall handle personal hygiene before entering food production site to avoid food contamination. 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. 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. 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 engaged in activities related to food production contacting food, tools and instruments or food equipment again. 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.	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.	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. *More detailed requirements on this subject (personnel, hygiene) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.9:*** 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, … 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. e) Eating, drinking and/or smoking rooms should be separated and clean. *More detailed requirements on this subject (visitors) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.9:*** g) The number of visitors should be minimized. Visitors should wear appropriate protective clothing, provided by the Food Business Operator.

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6.4 Insect pest control 6.4.1 The building shall be kept in perfect condition and tidy to prevent insect attack from intruding and breeding. 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. 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. 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 and instruments and packaging material shall not be contaminated. Pest control shall be recorded correspondingly. 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter I General requirements for food premises: 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: (c) permit good food hygiene practices, including protection against contamination and, in particular, pest control; **Regulation (EC) No 852/2004,** Annex II, Chapter IX 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). **Regulation (EC) No 852/2004,** Annex II, Chapter IX 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. 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.	*More detailed requirements on this subject (pest control) are mentioned in the* Guidance document **Commission Notice 2016/C 278/01, Annex I, 2.3 Pest control: focus on prevention:** a) External walls should be free of cracks or chinks, surroundings neat and clean and areas for cleaning accessible. 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.

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6.5 Waste disposal 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. 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.	**Regulation (EC) No 852/2004,** 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 accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.	
6.6 Work clothes management 6.6.1 The personnel shall wear work clothes when entering the operating areas. 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. 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter VIII 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.	*More detailed requirements on this subject (work clothes management) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.9:*** 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.

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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.		
7 Food Raw Materials, Food Additives and Food Related Products **7.1 General requirements** 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter IX 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.	
7.2 Food raw materials 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. 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. 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 are found to be abnormal, the food raw materials shall not be used and only the verified applicable ones shall be used.	**Regulation (EC) No 852/2004,** Annex II, Chapter IX 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. 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. 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). **Regulation (EC) No 852/2004,** Annex II, Chapter IV	

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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. 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. 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.	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. 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.	*More detailed requirements on this subject (first in, first out) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.10**.:* 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, …).
7.3 Food additives 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. 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. 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	**Regulation (EC) No 1333/2008, Article 4** 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. **Regulation (EC) No 852/2004,** Annex II, Chapter IV 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. **Regulation (EC) No 852/2004,** Annex II, Chapter IX 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.	***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.* *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.* *More detailed requirements on this subject (first in, first out) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.10**.:* d) Storage conditions at the establishment itself should take into account any instructions provided

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out"; where necessary, it shall be determined according to the characteristics of food additives.		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, …).
7.4 Food related products 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter IX 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 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.	
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.	**Regulation (EC) No 852/2004,** Annex II, Chapter IV 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.	
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".	**Regulation (EC) No 852/2004,** Annex II, Chapter IX 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.	*More detailed requirements on this subject (first in, first out) are mentioned in the Guidance document **Commission Notice 2016/C 278/01**, **Annex I, 2.10**.:* 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, …).

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
7.5 Others 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 measures for external packaging to lower the contamination risk.	**Regulation (EC) No 852/2004,** Annex II, Chapter II 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, washable corrosion-resistant and non-toxic materials… **Regulation (EC) No 852/2004,** 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.	**Commission Regulation (EC) No 1935/2004** provides general principles of safety and quality of all Food Contact Materials and sets out a harmonised legal EU framework.
8 Food Safety Control in Production Process **8.1 Contamination risk control of product** 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.	**Regulation (EC) No 852/2004, Article 5** 1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.	*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.*
8.2 Control of biological contamination **8.3 Control of chemical contamination** **8.4 Control of physical contamination**	**Regulation (EC) No 852/2004, Articles 4 and 5.** **Guidance document (Commission Notice 2016/C 278/01) Annex I and Annex II.**	*A detailed assessment of the requirements for the implementation of HACCP in EU legislation is provided below.*
8.5 Packaging 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. 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.	**Regulation (EC) No 852/2004,** 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.	

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
	4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.	
9 Inspection 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. 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. 9.3 The inspection room shall be equipped with sound management system to properly preserve the original record and inspection report of each inspection. Products sampling system shall be built up to timely keep sample. 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. 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.	**Regulation (EC) No 852/2004, Article 5** (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; The verification of effective self-controls is a key objective of official controls in food establishments: **Regulation (EU) 2017/625, Article 14** 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: (i) equipment, means of transport, premises and other places under their control and their surroundings; (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; (iii) cleaning and maintenance products and processes; (iv) traceability, labelling, presentation, advertising and relevant packaging materials including materials intended to come into contact with food; (c) controls on the hygiene conditions in the operators' premises; (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);	*Guidance document **Commission Notice 2016/C 278/01** provides that adequate infrastructure and resources must be provided to develop, organise and execute efficient self-controls.* 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 management who should consider itself owner of the HACCP plan and overall Food Safety Monitoring System.

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
	(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; (f) interviews with operators and with their staff; (g) the verification of measurements taken by the operator and other test results; (h) sampling, analysis, diagnosis and tests; (i) audits of operators; (j) any other activity required to identify cases of non-compliance.	
10 Storage and Transportation of Foods 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. 10.2 Suitable warehousing system shall be established and carried out. In case of any abnormality, it shall be timely handled. 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. 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter IX 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. 8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers. **Regulation (EC) No 852/2004,** Annex II, Chapter IV 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. 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.	

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
11 Product Recall Management 11.1 The product recall system shall be established based on relevant national regulations. 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. 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. 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.	**Regulation (EC) No 178/2002, Article 19** 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. 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.	
12 Training 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. 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.	**Regulation (EC) No 852/2004,** Annex II, Chapter XII Food business operators are to ensure: 1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity; 2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation *(= HACCP programme)* or for the operation of relevant guides have received adequate training in the application of the HACCP principles; and	

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
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. 12.4 Where the relevant laws, regulations and standards of food safety are updated, training shall be developed in time. 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.	3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.	
13 Management System and Personnel 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. 13.2 The management system of food safety shall correspond to the production scale, process level and variety characteristics of food and shall be constantly improved based on practical production and implementation experience. 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.	**Regulation 178/2002** Article 17 Responsibilities 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 the requirements of food law which are relevant to their activities and shall verify that such requirements are met.	Guidance document **Commission Notice 2016/C 278/01**, **Annex II, Heading 3: Preliminary activities** **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 management who should consider itself owner of the HACCP plan and overall Food Safety Monitoring System.
14 Record and Document Management **14.1 Record management** 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.		Guidance document **Commission Notice 2016/C 278/01**, **Annex II, Heading 10: Documentation and record keeping** 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

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
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. 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. 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. 14.1.1.4 The contents including name, batch, specification, quantity, recall reason and subsequent rectification program of recalled food shall be recorded truthfully. 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. 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. 14.2 The document management system shall be established for effective document management to ensure that documents at each relevant location are valid. 14.3 The advanced technology and means (electronic computer information system included) are encouraged to		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: — PRPs applied, working instructions, standard operational procedures, control instructions; — Description of the preparatory stages (before 7 principles); — Hazard analysis; — CCP (+/- PRPs) identification; — Critical limit determination; — Validation activities; — Corrective actions anticipated; — Description of planned monitoring and verification activities (what, who, when); — Record forms; — Modifications to the HACCP-based procedures; — Supporting documents (generic guides, scientific evidence, …). Record examples are: — Outcome of CCP monitoring activities; — Observed deviations and executed corrective actions; — 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

Chinese National standard GB 14881-2013	EU Regulation (EC) No 852/2004	Implementing rules, other remarks
be adopted to implement record and document management.		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. 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.

2.1.2 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
1. Scope This standard sets out the basic principles and requirements of microbiological test of food. This standard is applicable to microbiological test of food	**Article 1 Subject-matter and scope** 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.	
2. Basic Laboratory Requirements **2.1 Inspectors** 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 any color discrimination-involving examination.	**Directive 2004/10/EC, Article 1** 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. **Directive 2004/10/EC, Annex I, Section II Good laboratory practice principles** 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 necessary, provide training for these functions; (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; (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. 3. Facilities 3.1. General	**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** 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. *In addition, EU guidance documents are available for GLP:*

Chinese National standard GB 4789.1	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
2.2 Environment and facilities 2.2.1 The laboratory environment shall not affect the accuracy of the test results. 2.2.2 The laboratory area shall be clearly separated from the office area. 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. 2.2.4 The temperature, humidity, cleanliness, and illumination as well as noise level in laboratory shall meet the working requirements. 2.2.5 Food sample examination shall be conducted in clean area where shall be indicated with obvious signs. 2.2.6 The separation and identification of pathogenic micro-organism shall be carried out in Biosafety laboratory at Level II or higher level.	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. 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. 3.2. Test system facilities 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 organisms known to be or suspected of being biohazardous. 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. 3.3. Facilities for handling test and reference items 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. 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. 4. Apparatus, material, and reagents 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. 2. Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to standard operating procedures. Records of these activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of measurement. 3. Apparatus and materials used in a study should not interfere adversely with the test systems. 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.	- 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.

Chinese National standard GB 4789.1	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
2.3 Laboratory equipment 2.3.1 The laboratory equipment shall meet the requirements of the examination. See A.1 for common equipment. 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. 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. 2.3.4 The laboratory equipment shall be provided with daily monitoring or using records. **2.4 Examination supplies** 2.4.1 The examination supplies shall meet the requirements of the microbiological examination. The commonly used examination supplies are shown in A.2. 2.4.2 All examination supplies shall be kept clean and/or sterile before use. 2.4.3 The examination supplies requiring sterilizing shall be placed in specific containers or	The expiry date may be extended on the basis of documented evaluation or analysis. 5.2. Biological 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. 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 maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded. 3. Records of source, date of arrival, and arrival condition of test systems should be maintained. 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. 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. 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.	

Chinese National standard GB 4789.1	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
packaged/plugged with suitable materials (such as special packaging paper or aluminum-foil paper) to ensure the sterilization effect. 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. 2.4.5 The temperature, duration and effective life of sterilization for the sterilized examination supplies shall be recorded. **2.5 Culture media and reagents** The preparation and quality requirements of the culture media and reagents shall be in accordance with the provision specified in GB 4789.28. **2.6 Quality control strains** 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. 2.6.3 The preservation and transferring of standard strains shall be in accordance with the provision in GB 4789.28. 2.6.4 The strains separated in laboratory (wild strains) shall be regarded as the internal quality control strains in laboratory after identification.	6. Test and reference items 6.1. Receipt, handling, sampling and storage 1. Records including test item and reference item characterisation, date of receipt, expiry date, quantities received and used in studies should be maintained. 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. 3. Storage container(s) should carry identification information, expiry date, and specific storage instructions.	

Chinese National standard GB 4789.1	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
3. Sample Collections **3.1 Sampling principles** 3.1.1 Sampling should follow the principle of randomness and representativeness. 3.1.2 Sterile operation procedure shall be followed during sampling, so as to prevent all potential foreign contamination.	**Regulation (EC)No 2073/2005, Annex I, Chapter 3. Rules for sampling and preparation of test samples** 3.1 General rules for sampling and preparation of test samples 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. **Regulation (EC)No 2073/2005, Article 4** 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. 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.	
3.2 Sampling plan 3.2.1 Determine the sampling plan according to the examination objective, product characteristics, lot size, examination method and harmful levels of microorganisms, etc.		
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. 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.	**Regulation (EC) No 2073/2005, Annex I, Chapter 1. Food safety criteria** n = number of units comprising the sample; c = number of sample units giving values between m and M. **Chapter 2. Process hygiene criteria** **2.4 Fishery products** Interpretation of the test results The limits given refer to each sample unit tested.	**Regulation (EC) No 2073/2005, Annex I, Chapter 1. Food safety criteria** Interpretation of the test results 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: — satisfactory, if the following requirements are fulfilled: 1. the mean value observed is ≤ m

Chinese National standard GB 4789.1	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
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. 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 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 (≤100 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.	The test results demonstrate the microbiological quality of the process tested. *E. coli* in shelled and shucked products of cooked crustaceans and molluscan shellfish: — satisfactory, if all the values observed are ≤ m, — acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m, — unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M. Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish: — satisfactory, if all the values observed are ≤ m, — acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m, — unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M	2. a maximum of c/n values observed are between m and M 3. no values observed excess the limit of M. — 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 > M. Histamine in fish sauce produced by fermentation of fishery products: — satisfactory, if the value observed is ≤ the limit, — unsatisfactory, if the value observed is > the limit.
3.2.3 Sampling plan for different kinds of foods shall be implemented in accordance with the provisions of relevant food safety standards. 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. 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.	**Regulation (EC)No 2073/2005, Article 5** 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.	**Guidance document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs** of 13 November 2006 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 should choose the necessary sampling procedures according to the
3.3 Sampling methods of different kinds of food 3.3.1 Prepackaged food 3.3.1.1 The collected food samples shall be of the same batch, packaged individually and with appropriate number of		

Chinese National standard GB 4789.1	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
packages. The sampling size of each sample shall meet the requirements of microbiological indicator examination. 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. 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 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. 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. 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. 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 prevent the change of microorganism amount in sample.		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. **Guidance document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs** of 13 November 2006 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: Objective sampling 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. Selective sampling A planned strategy where the selection of the sample is from previously defined "high-risk" population groups. Samples are

Chinese National standard GB 4789.1	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
		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. 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. **Guidance document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs** of 13 November 2006 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 feeding stuffs – General rules for microbiological examinations.

Chinese National standard GB 4789.1	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
4. Examinations **4.1 Sample treatment** 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. 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. 4.1.3 The treatment of different food samples shall be in accordance with the provisions of examination methods in corresponding food safety standards. **4.2 Sample examination** Examination shall comply with the provisions of corresponding food safety standards.	**Directive 2004/10/EC, Annex I, Section II Good laboratory practice principles** **5.2. Biological** 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. 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 maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded. 3. Records of source, date of arrival, and arrival condition of test systems should be maintained. 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. 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. 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.	

Chinese National standard GB 4789.1	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
5. Biosafety and Quality Control **5.1 Laboratory biosafety requirement** It shall comply with the provisions in GB 19489. **5.2 Quality control** 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.	**Directive 2004/10/EC, Annex I, Section II Good laboratory practice principles** **2. Quality assurance programme** 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.	
6. Records and Reports **6.1 Records** All information such as phenomena, results and data observed during examination shall be recorded instantaneously and objectively. **6.2 Reports** The laboratory shall report the examination results accurately and objectively in accordance with the requirements specified in examination methods.	**Directive 2004/10/EC, Annex I, Section II Good laboratory practice principles** **3.4. Archive facilities** Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration. 10. Storage and retention of records and materials 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.	
7. Sample Disposal after Examination 7.1 The test sample can be disposed only when the examination results have been reported. 7.2 Bio-safety disposal shall be necessary for the sample detected with pathogens.	**Directive 2004/10/EC, Annex I, Section II Good laboratory practice principles** **3.5. Waste disposal** 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	

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

2.1.3 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
1. Scope 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.	**Article 1 Subject-matter and scope** 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.	
2. Application principles 2.1. Whether or not there are provisions of pathogen limits, food products manufacturers, processers, 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.	**Article 3 General requirements** 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.	
2.2. Samples should be taken in accordance with provisions of GB4789.1 and should be tested with methods listed in table one.	**Article 5 Specific rules for testing and sampling** 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.	See above for GB 4789.1
3. Index requirements Limit of Pathogens in food products is listed in table 1.	**Annex I, Chapter 1. Food safety criteria** **Annex I, Chapter 2. Process hygiene criteria** **2.4. Fishery products**	

Chinese National standard GB 29921	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
Table 1 **Aquatic Products** - cooked aquatic products - ready to eat raw aquatic products - ready to eat algae products *Salmonella*: n = 5, c = 0, m = 0	**Annex I, Chapter 1. Food safety criteria** 1.16 Cooked crustaceans and molluscan shellfish: *Salmonella*: 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: *Salmonella*: n = 5, c = 0, m = absence in 25 g (Products placed on the market during their shelf-life)	*Microbiological criteria for algae products are not mentioned in EU legislation.*
Vibrio parahaemolyticus: n=5, c =1, m = 100 MPN/g, M = 1000 MPN/g	1.25 Live bivalve molluscs and live echinoderms, tunicates and marine gastropods: *E. coli* (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) **Annex I, Chapter 2. Process hygiene criteria** **2.4. Fishery products** 2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish: *E. coli*: n = 5, c = 2, m = 1 cfu/g and M = 10 cfu/g (End of the manufacturing process)	*In EU legislation no specific criteria are set for Vibrio parahaemolyticus. E.coli is used as an indicator organism of faecal contamination.*
Staphylococcus aureus: n=5, c =1, m = 100 CFU/g, M = 1000 CFU/g	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. *E. coli* in shelled and shucked products of cooked crustaceans and molluscan shellfish: — satisfactory, if all the values observed are ≤ m, — acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,	*Staphylococcus aureus is a coagulase-positive staphylococcus*

Chinese National standard GB 29921	EU Regulation (EC) No 2073/2005	Implementing rules and remarks
	— unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M. Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish: — satisfactory, if all the values observed are ≤ m, — acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m, — unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.	
Note 1: Food category is used to define applicable scope of pathogen limit; it applies to this standard only. 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.		

2.1.4 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
1 Scope 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. **2 Normative References**	**Article 1 Scope** 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.	**Article 5 of the EU law** requires the implementation and maintenance of HACCP mandatory for **all food business operators except primary producers** (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). *The Chinese legislation refers to processing plants.* ***Three more Chinese standards** 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).* *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).*

Chinese National standard GB-27341	EU Regulation (EC) No 852/2004	Implementing rules and remarks
3 Terms and Definitions **3.1 Raw material** 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. **3.2 Potential hazard** Food safety hazard which may occur in case of no precaution. **3.3 Significant hazard** 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". **3.4 Operation limit** The operation index established in order to avoid deviation of monitoring index from critical limit. **3.5 Food defense plan** Measures established and implemented to protect food supply from deliberate biological, chemical or physical contamination or artificial damage.	**Definitions** In Regulation (EC) No 178/2002 definitions are listed in Article 2 for food and in Article 3 for: 'hazard' means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect; 'risk' means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard; '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; 'primary production' means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also 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.	*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.* In the guidance document (Commission Notice 2016/C 278/01) **Annex II, heading 5** 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. *Operation limit is an additional tool to assess the deviation noticed while monitoring the Critical limit.* In the guidance document (Commission Notice 2016/C 278/01) **heading 3** deals with **links between FSMS, PRPS, GHP, GMP and HACCP**. FSMS = food safety management system; PRPs = prerequisite programs; GHP = good hygiene practices; GMP = good manufacturing practices *These measures are equivalent to the food defense plan and have the same objective.*
4 HACCP System of Plant **4.1 General Requirements** The plant shall: a) Plan, implement, inspect and improve the HACCP system process, and provide the required resource. 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.	**Article 5** ***Hazard analysis and critical control points*** 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:	*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.* In the guidance document (Commission Notice 2016/C 278/01) **Annex II, heading 2** deals with: **General principles**

Chinese National standard GB-27341	EU Regulation (EC) No 852/2004	Implementing rules and remarks
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. 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.	(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 acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; (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). 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.	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 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.
4.2 Document Requirements 4.2.1 **HACCP system documents** shall include: a) Documented food safety guideline; b) HACCP manual; c) Documented procedure required in this standard;	3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production. 4. Food business operators shall:	In the guidance document (Commission Notice 2016/C 278/01) **Annex II, heading 10** deals with: **Documentation and record keeping** 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

Chinese National standard GB-27341	EU Regulation (EC) No 852/2004	Implementing rules and remarks
d) Documents required to guarantee the effective planning, operation and control of HACCP system process; e) Record required in this standard. 4.2.2 **HACCP manual** The plant shall prepare and maintain HACCP manual, at least covering: a) Scope of HACCP system, including the covered product or product category, operation step, site, and the relationship with other steps of food chain; b) Procedure document of HACCP system or the quotation of such document; c) Expression for HACCP system process and its interaction. 4.2.3 **Document control** Documents required for HACCP system shall be controlled. The documented procedure shall be prepared to specify the control on the following aspects: a) The document is approved prior to issuance so as to guarantee that it is sufficient, proper and effective; b) Where necessary, review and update the document and re-approve it; c) Ensure that changes and the current revision status of the document are identified; d) Ensure that relevant effective version of applicable document is available at application location; e) Ensure that the document is clear and easy for identification; f) Ensure that documents related to HACCP system are identified, with their distribution controlled; g) Prevent the unintended use of obsolete documents, properly mark the obsolete documents which shall be reserved. 4.2.4 **Record control**	(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; (b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times; (c) retain any other documents and records for an appropriate period.	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 business. Documents should be signed by a responsible reviewing official of the company.

Chinese National standard GB-27341	EU Regulation (EC) No 852/2004	Implementing rules and remarks
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. The record shall be maintained clear and easy for identification and retrieval.		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.
5 Management Responsibilities **5.1 Management Commitment** 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. **5.2 Food Safety Guideline** Top management shall focus on the consumer's edible safety, establish food safety guideline and food safety objective, and ensure food safety. **5.3 Responsibility, Authority and Communication** 5.3.1 **Responsibility and authority** 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.	*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).* *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. **Regulation 852/2005 Article 5** (on HACCP): 1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.	In the guidance document (Commission Notice 2016/C 278/01) **Annex II, heading 3** states: **Preliminary activities** **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 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 and control of critical points.
5.3.2 **Communication** In order to obtain necessary food safety information and guarantee the effectiveness of HACCP system, top management shall ensure that the plant has established,		In the guidance document (Commission Notice 2016/C 278/01) **heading 7. Training** states: Staff should be supervised and instructed and/or trained in food hygiene matters appropriate to their role, and

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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. **5.4 Internal Review** 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 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. **5.5 Management Review** 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.	**Annex II, Chapter XII to Reg 852/2004** **Training** Food business operators are to ensure: 1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity; 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 adequate training in the application of the HACCP principles; 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	those responsible for developing and maintaining the food safety management system should be suitably trained in the application of PRPs and HACCP principles. In the guidance document (Commission Notice 2016/C 278/01) **Annex II, heading 9** states: **Verification (and validation) procedures** The HACCP team should specify the methods and procedures to be used for determining if the HACCP-based procedures are working correctly. 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. 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. 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.

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6 Prerequisite Plan **6.1 General** 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 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.	**Article 4** states: **General and specific hygiene requirements** 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. 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. 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. **Annex II, Chapter XII** stipulates: **Training** Food business operators are to ensure: 1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity; 2. that those responsible for the development and maintenance of the procedure referred to in	In the guidance document (Commission Notice 2016/C 278/01) **Annex I** states: **Prerequisite programs (PRPs)** 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 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. PRPs must always be in place in any food business, including at primary production. The FBO should describe the applied PRPs, proportionate to the size and nature of the establishment, including a list of responsible person(s). Guidance document (Commission Notice 2016/C 278/01) **Annex I, 2 Examples of PRPs, 2.2 Cleaning and disinfection:** Cleaning and sanitation procedures are part of PRPs, including a description a) What, when and how cleaning and disinfection 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).
6.2 Human Resource Security Plan 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		

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equipped with necessary capacity; b) Assess the effectiveness of training provide or other measures taken; c) Maintain proper records of personnel education, training, skill and experience.	Article 5(1) of this Regulation or for the operation of relevant guides have received 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.	f) Visual checks on cleaning and sampling for analysis (e.g. hygienogram) should be used to control disinfection activities. **2.12 Working methodology** 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, … **Appendix I Glossary** Provides definitions for: FSMS, GHP, GMP, PRPs
6.3 Good Manufacture Practice (GMP) Plant shall establish and implement GMP according to food regulations and corresponding sanitary regulations.		In the guidance document (Commission Notice 2016/C 278/01) **Annex I** states: **Prerequisite programs (PRPs)** 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.
6.4 Sanitation Standard Operation Procedure (SSOP) Plant shall at least meet the following requirements when establishing and implementing SSOP: 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; b) Instruments, gloves or interior and exterior packaging materials contacting foods shall be clean, sanitary and safe;	**Annex II** to the Regulation provides detailed requirements under the heading: **General hygiene requirements for all food business operators, Chapter VII deals with water supply:** 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; 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. **Chapter V deals with equipment requirements** All articles, fittings and equipment with which food comes into contact are to:	In addition, the guidance document (Commission Notice 2016/C 278/01) **Annex I** lays down the: **Prerequisite programs (PRPs)** **2.8 Water and air control** 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. **2.1 Infrastructure (building, equipment)**

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	(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; (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; (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; (d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.	j) Equipment and monitoring/recording devices (e.g. thermometers) should be clean and the equipment suitable for contact with food products.
c) Protect foods free from cross contamination;	**Chapter IX Provisions applicable to foodstuffs** 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.	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 cleaning and disinfection between use) for raw products and cooked products (chopping boards, knives, dishes, …).
d) Ensure that hands of operators are cleaned and disinfected and the toilet facilities are clean;	**Chapter VIII Personal hygiene** 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. **Chapter I General requirements for food premises** 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.	**2.9 Personnel (hygiene, health status)** 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, … **2.1 Infrastructure (building, equipment)**

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e) Protect food safety free of hazard by lubricants, fuels, articles for cleaning and disinfecting, condensate and other chemical, physical and biological contaminants; f) Correctly label, store and use various toxic chemicals; g) Ensure the physical health and sanitation of the personnel contacting foods; h) Prevent and eliminate damage caused by rats and insects.	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; **Chapter IX Provisions applicable to foodstuffs** 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. **Chapter I General requirements for food premises** 10. Cleaning agents and disinfectants are not to be stored in areas where food is handled. **Chapter VIII Personal hygiene** 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.	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. **2.5 Physical and chemical contaminations from production environment** a) The frequency of the control of physical hazards (glass, plastic, metal, …) should be determined using a risk-based analysis (how big is the likelihood of occurrence in an establishment in question?). b) A procedure should be available explaining what to do in case of breakage of glass, hard plastic, knives, 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. d) Possible chemical hazards should only be dealt with by specialized, trained staff. Weighing scales for additives should be automatic. **2.9 Personnel (hygiene, health status)** 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.

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SSOP record shall be preserved.	**Chapter IX Provisions applicable to foodstuffs** 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). **Article 5, point 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 account of the nature and size of the food business; (b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times; (c) retain any other documents and records for an appropriate period.	**2.3 Pest control: focus on prevention** a) External walls should be free of cracks or chinks, surroundings neat and clean and areas for cleaning accessible. 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 *In the guidance document (Commission Notice 2016/C 278/01)* **Annex II, point 10** *specifies* **Documentation and record keeping***:* Recommended documentation includes: — PRPs applied, working instructions, standard operational procedures, control instructions. **Annex II, point 10** 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.
6.5 Safety and Sanitation Security System of Raw Material and Food Packaging Material Plant shall protect raw material and food packaging material free of food safety hazard, and shall establish and implement its safety and sanitation security system so as to meet the following requirements: a) Establish valid qualification conditions for raw material and food packaging material suppliers, and determine the supplier name list; b) Assess the capacity of raw material and food packaging material suppliers to provide product safety	Reg 178/2002 provides in Art 18: 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. **Commission Regulation (EC) No 1935/2004** provides general principles of safety and inertness	The guidance document (Commission Notice 2016/C 278/01) **Annex I, 2.10 Raw materials s**tates: 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. 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

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and sanitation, and carry out document review or site review for the supplier's food safety management system; 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 heath and sanitation of raw material and food packaging material where necessary; d) Establish control measures for food additives where necessary; e) Establish the supplier's assessment system, including elimination system for rejected suppliers.	for all Food Contact Materials and sets out a harmonised legal EU framework. 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.	extent of details on the PRPs and HACCP plan of the establishment itself 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. 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, …).
6.6 Maintenance Plan 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.	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 air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;	
6.7 Marking and Tracing Plan and Product Recall Plan 6.7.1 **Marking and tracing plan** 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:	**Regulation (EC) No 178/2002, Article 18** 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.	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

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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.	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 avail-able 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 shall be made available to the competent authorities on demand. 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.	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; (e) the name and address of the food business operator to whom the food is dispatched; (f) the name and address of the consignee (owner), if different from the food business operator to whom the food is dispatched; (g) a reference identifying the lot, batch or consignment, as appropriate; and (h) the date of dispatch. 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. 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.
6.7.2 **Product recall plan** 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: a) Ensure the responsibilities and rights of personnel starting and implementing product recall plan; b) Ensure relevant laws and regulations and related requirements which shall be complied with; c) Establish and implement recall measures for products under safety hazard effect; d) Establish analysis and disposal measures for recalled products; e) Periodic drill and verify its effectiveness. Implementation record for product recall plan shall be maintained.	**Regulation (EC) No 178/2002, Article 19** states: 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,	

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	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. 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. 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. 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.	
6.8 Emergency Plan Plant shall identify and determine potential food safety accident or emergency situation, 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	**Regulation (EC) No 178/2002, Article 17** states: 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	*Emergency plans are not part of food hygiene rules in the EU. If the safety of food products becomes compromised in a situation of disaster or emergency, food must not be placed on the market.*

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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.	law which are relevant to their activities and shall verify that such requirements are met.	
7 Establishment and Implementation of HACCP Plan **7.1 General** 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; 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.	**Regulation (EC) No 852/2004, Article 5** **Hazard analysis and critical control points** 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 acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; (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	

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	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). 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. 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. 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 account of the nature and size of the food business; (b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times; (c) retain any other documents and records for an appropriate period.	
7.2 Preliminary Steps 7.2.1 **Composition of HACCP team** 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&D, production process technology, equipment and facility		Guidance document **Commission Notice 2016/C 278/01**, **Annex II, Heading 3: Preliminary activities** **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

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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: a) Ensure that the process required for HACCP system is established, implemented and maintained; b) Report the effectiveness, suitability and updating or improving demand (if any) of HACCP system to top management; 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.		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 and control of critical points. The team may include specialists and technicians: — who understand the biological, chemical or physical hazards connected with a particular product group, — who have responsibility for, or are closely involved with, the technical process of manufacturing the product under study, — who have a working knowledge of the hygiene and operation of the process plant and equipment, — any other person with specialist knowledge of. microbiology, hygiene or food technology. 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).
7.2.2 **Product description** HACCP team shall identify and determine the applicable information (as listed below) required for hazard analysis in allusion to the product: a) Name, category, composition as well as biological, chemical and physical properties of raw material and food packaging material; b) Source, production, packaging, storage, transportation and delivery mode of raw material and food packaging material;		**3.2 Description of the product(s) at the end of process (called hereafter 'end product')** A full description of the end product should be drawn up, including relevant safety information such as: — Origin of ingredients/raw materials, which may help identify certain hazards, — composition (e.g. raw materials, ingredients, additives, possible allergens etc.),

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c) Reception requirement, reception mode and use mode of raw material and food packaging material; d) Name, category, composition as well as biological, chemical and physical properties of the product; e) Processing mode of the product; f) Packaging, storage, transportation and delivery modes of the product; g) Marketing mode and mark of the product; h) Other necessary information. Record of product description shall be maintained. 7.2.3 **Determination of intended use** HACCP team shall identify and determine the applicable information (as listed below) required for hazard analysis on the basis of product description: a) Consumption or use expectation of the customer on the product; b) Intended use, storage condition and warranty period of the product; c) Intended edible or use modes of the product; d) Intended customer of the product; e) Applicability of directly consumed product to vulnerable group; f) Unintended (but much more likely to occur) edible or use modes of product; g) Other necessary information. Record for intended use of the product shall be maintained. 7.2.4 **Establishment of flow diagram** 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: a) Each step and corresponding operation;		— structure and physico-chemical characteristics (e.g. solid, liquid, gel, emulsion, moisture content, pH, water activity, etc.), — processing (e.g. heating, freezing, drying, salting, smoking, etc. and to what extent), — packaging (e.g. hermetic, vacuum, modified atmosphere) and labelling, — storage and distribution conditions, including transport and handling — required shelf life (e.g. 'use by date' or 'best before date'), — instructions for use, — any microbiological or chemical criteria applicable. **3.3 Identification of intended use** 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. **3.4 Construction of a flow diagram (description of manufacturing process)** 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

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b) Sequence and interrelationship of such steps; c) Rework point and cycle point (where suitable); d) External process and outsourced content; e) Input point of raw material, auxiliary material and intermediate product; f) Discharge point of waste. The establishment of flow diagram shall be complete, exact and clear. 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. 7.2.5 **Confirmation of flow diagram** HACCP team personnel who are familiar with operation process shall carry out on-site verification for all operation steps under 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.		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: — plan of working premises and ancillary premises, — equipment layout and characteristics, — sequence of all process steps (including the incorporation of raw materials, ingredients or additives and delays during or between steps), — technical parameters of operations (in particular time and temperature, including delays), — flow of products (including potential cross-contamination), — segregation of clean and dirty areas (or high/low risk areas). **3.5 On-site confirmation of flow diagram** After the flow diagram has been drawn up, the HACCP team should confirm it on site during operating hours. Any observed deviation must result in an amendment of the original flow diagram to make it accurate.

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7.3 Hazard Analysis and Control Measures Preparation 7.3.1 **Hazard identification** HACCP team shall consider the following factors when analyzing the biological, chemical and physical hazards in processing step according to the food risk degree: a) Product, operation and environment; b) Safety and sanitation requirements for product, raw material and food packaging materials by the consumers, customers, laws and regulations; c) Monitoring and assessment results on edible and use safety of the product; d) Disposal, correction, recall and emergency plan of unsafe product; e) Historical and current data and food safety accidents on epidemiology, animal and plant epidemic situation or morbidity statistics; f) Scientific and technical literature, including hazard control guideline for relevant product; g) Effect of other step on the product within the scope of hazard identification; h) Artificial destruction and deliberate contamination. i) Experience. 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. Where any factor affecting the identification result is changed, HACCP team shall repeat the hazard identification. Records of hazard identification criterion and result shall be maintained. 7.3.2 **Hazard assessment** 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.	**Regulation (EC) No 178/2002, Article 3 (14):** 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 **Commission Notice 2016/C 278/01**, **Annex II, Heading 4. Hazard analysis (Principle 1)** **4.1 Listing of relevant hazards** 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). 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:

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Records of hazard assessment criterion and result shall be maintained.		— the likelihood of occurrence of hazards and severity of their adverse health effects; — the qualitative and/or quantitative evaluation of the presence of hazards; — the survival or multiplication of pathogenic micro-organisms and unacceptable generation of chemicals in intermediate products, end products, production line or line environment; — the production or persistence in foods of toxins or other undesirable products of microbial metabolism, chemicals or physical agents or allergens; — the contamination (or recontamination), of a biological (micro-organisms, parasites), chemical or physical nature, of raw materials, intermediate products or end products.
7.3.3 Establishment of control measures 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 document of control measures shall be maintained.		**4.2 Control measures** 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 *Salmonella* and *Listeria*.

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7.3.4 Hazard analysis sheet 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.		Control measures should be validated. Control measures should be supported by detailed procedures and specifications to ensure their effective implementation. *Documentation requirements are listed separately in the Guidance document* **Commission Notice 2016/C 278/01**, **Annex II, heading 10.**
7.4 Determination of Critical Control Point (CCP) 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 determine CCP However, the following factors shall be considered when adopting judgment tree: a) Judgment tree is only a tool contributing to the determine CCP, and cannot supersede professional knowledge; b) Judgment tree is used after hazard analysis and during determination of significant hazard; c) Subsequent processing step may be more effective to control hazard, and may be the preferred CCP which shall be selected; d) In processing, above I step may control I hazard. Where significant hazard or control measures are changed, HACCP team shall repeat the hazard analysis to judge CCP. 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.		Guidance document **Commission Notice 2016/C 278/01**, **Annex II, Heading 5. Identification of critical control points (CCP) (Principle 2)** 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. The identification of CCPs has two consequences for the HACCP team which should then: — 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; — establish and implement a monitoring system at each CCP. 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

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		manufacturing process in order to avoid, whenever possible, unnecessary CCPs. Training in the application of a method to identify CCPs is recommended. As illustrated in the Appendices, the hazard analysis may identify different levels of risks for each process step: — For lower risk levels it can be concluded that, if robust PRPs are in place, these PRPs are sufficient to control the hazards — 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)). — 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: — 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) — Control of blanching process for the deep freezing industry (time/temperature) 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. — 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.

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		— More severe incoming check upon reception of raw materials if supplier is not guaranteeing the desired quality/safety level (e.g. mycotoxins in spices). — Control of allergens by a sanitation program — For high level of risks, which are not controlled by PRPs or oPRPs, CCPs should be established.
7.5 Determination of Critical Limit 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.		Guidance document **Commission Notice 2016/C 278/01**, **Annex II, Heading 6. Critical limits at CCPs (Principle 3)** 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. 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. Critical limits should be validated and should have clear, specific values. 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.

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7.6 CCP Monitoring 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. 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. Where deviation from operation limit is indicated in monitoring, monitoring personnel shall timely take correction to prevent deviation from critical limit. Where deviation critical limit is indicated in monitoring, the monitoring personnel shall immediately stop the operation procedure, and timely take correction measures. Monitoring record shall be maintained.		Guidance document **Commission Notice 2016/C 278/01**, **Annex II, Heading 7. Monitoring procedures at CCPs (Principle 4)** 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. Observations or measurements must be able to detect loss of control at CCPs and provide information in time for corrective action to be taken. 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 knowledge and authority to carry out corrective actions when indicated. 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. The HACCP plan should describe the methods, the frequency of observations or measurements and the recording procedure for monitoring at CCPs: — who is to perform monitoring and checking, — when monitoring and checking is performed, — how monitoring and checking is performed. 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, … 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.

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7.7 Correction Measures for Establishment of Critical Limit Deviation Plant shall pre-establish correction measures for deviation of each critical limit of CCP for implementation upon deviation. 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. Correction personnel shall be familiar with product and HACCP plan, and shall be properly trained and authorized. 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. Correction record shall be maintained.		Guidance document **Commission Notice 2016/C 278/01**, **Annex II, Heading 8. Corrective actions (Principle 5)** For each CCP, corrective actions should be planned in advance by the HACCP team, so that they can be taken without hesitation when monitoring indicates a deviation from the critical limit. Such corrective actions should include: — proper identification of the person(s) responsible for the implementation of the corrective action, — means and action required to correct the observed deviation, — 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, — written record of measures taken indicating all relevant information (for example: date, time, type of action, actor and subsequent verification check). 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.
7.8 Confirmation and Verification for HACCP Plan Plant shall establish and implement confirmation and verification procedures for HACCP plan, so as to verify the integrity, suitability and effectiveness of HACCP plan. Confirmation procedure shall include effectiveness verification for all elements of HACCP plan. Confirmation shall be carried out before the implementation or after change of HACCP plan. Verification procedure shall include: criterion, method, frequency, personnel, content, result, measure and record of verification. 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.		Guidance document **Commission Notice 2016/C 278/01**, **Annex II, Heading 9. Verification (and validation) procedures (Principle 6)** 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 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. The frequency of verification should be sufficient to confirm that HACCP-based procedures are working effectively. The frequency of verification shall depend on

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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.		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. Verification procedures may include: — Audits of HACCP-based procedures and their records, — Inspection of operations (people compliance), — Confirmation that CCPs monitoring is implemented and maintained, — Review of deviations and product dispositions; corrective actions taken with regard to the product. 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: — check on the correctness of the records and analysis of deviations, — 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. 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, …).

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		Examples of changes that may require re-validation include: — change in raw material or in product, processing conditions (factory layout and environment, process equipment, cleaning and disinfection program), — change in packaging, storage or distribution conditions, — change in consumer use, — receipt of any information on a new hazard associated with the product. 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.
7.9 Maintenance of HACCP Plan Record 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: 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. 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. 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		Guidance document **Commission Notice 2016/C 278/01**, **Annex II, Heading 10. Documentation and record keeping (Principle 7)** 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 business. Documents should be signed by a responsible reviewing official of the company. Recommended documentation includes:

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signature; correction date; review signature and date of correction record. 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.		— PRPs applied, working instructions, standard operational procedures, control instructions; — Description of the preparatory stages (before 7 principles); — Hazard analysis; — CCP (+/- oPRPs) identification; — Critical limit determination; — Validation activities; — Corrective actions anticipated; — Description of planned monitoring and verification activities (what, who, when); — Record forms; — Modifications to the HACCP-based procedures; — Supporting documents (generic guides, scientific evidence, …). 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. Record examples are: — Outcome of CCP monitoring activities; — Observed deviations and executed corrective actions; — 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

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		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. 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).

2.1.5 National Standard GB 2761-2011 - Maximum Levels of Mycotoxins in Foods

Chinese National standard GB 2761-2011	EU Regulation (EC) No 2023/915	Implementing rules and remarks
1. Scope This standard sets limits for Aflatoxin B1, Aflatoxin M1, Deoxynivalenol, Patulin, Ochratoxin A and Zearalenone in foods.	**Regulation (EC) No on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006** **Article 2 General rules** 1. The food listed in Annex I shall not be placed on the market and shall not be used as a raw material in food or as an ingredient in food where it contains a contaminant at a level which exceeds the maximum level set out in Annex I. 2. Food complying with the maximum levels set out in Annex I shall not be mixed with food which exceeds these maximum levels. 3. The maximum levels set out in Annex I, unless otherwise specified in that Annex, shall apply to food as placed on the market and to the edible part of the food concerned. 4. In systems where cereal production and processing are integrated so that all incoming lots are cleaned, sorted and processed in the same establishment, the maximum levels shall apply to unprocessed cereals in the production chain at the stage before first-stage processing.	*The Chinese National Standard limit values are defined as the maximum content of contaminants in food materials and/or the edible part of the finished food products. The edible part is defined as 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, nutshell, bones in meat/fish, shell of shellfish). The non-edible parts cannot be removed by non-mechanical means (such as refining of crude vegetable oil).* *The EU legislation (EU Regulation 2023/915) has similar measures for dried, diluted, processed and compound foodstuffs and imposes similar prohibitions on chemical detoxification that have similar consequences regarding the safety of final oils and seeds products.* *The National Chinese Standard sets limits for Aflatoxin B1 in oils, whereas the EU Legislation has set similar limits for seeds and oils and for other substances such as the limits for Zearalenone in refined maize oil.* *EU legislation in general has different limits for a wide range of seeds, grains, nuts and oils from the respective Chinese standard. Hence EU food business operators intending to export nuts, seeds and oils products to China must ensure that they meet the requirements of this Chinese Standard.*

Chinese National standard GB 2761	EU Regulation (EC) No 2023/915	Implementing rules and remarks
2 Terminologies and definitions 2.1 Mycotoxin The toxic secondary metabolite produced by organisms of the fungi in the process of growth and reproduction. 2.2 Edible part The remaining part for edible use after mechanical processing, which remove the non-edible part (such as grain husk, fruit peeling, nuts cracking, removing bones in meat/fish, removing shell of shellfish). Note 1: removing the non-edible part shall not apply any non-chemical means (such as refining of crude vegetable oil); Note 2: quantity of the edible parts may vary when producing different products by different techniques using the same food materials. For example, the edible part could be 100% when processing cereal and whole-wheat flour from wheat, while the edible part is calculated by the actual flour extraction rate when producing wheat flour from wheat. 2.3 Limit Maximum level of mycotoxin in the edible parts of food materials and/or finished food products.	**Article 3 Dried, diluted, processed and compound food** 1. Where no specific Union maximum levels are set out in Annex I for food which is dried, diluted, processed or compound food (i.e. composed of more than one ingredient), the following aspects shall be taken into account when applying the maximum levels set out in Annex I to such food: (a) changes of the concentration of the contaminant caused by drying or dilution processes; (b) changes of the concentration of the contaminant caused by processing; (c) the relative proportions of the ingredients in the product; (d) the analytical limit of quantification. 2. Where the competent authority carries out an official control, the food business operator shall provide and justify the specific concentration, dilution or processing factors for the drying, diluting or processing operations concerned or the specific concentration, dilution or processing factors for the dried, diluted, processed or compound food concerned as well as the proportion of ingredients for mixing operations concerned. Where the food business operator does not provide the necessary concentration, dilution or processing factor or where the competent authority deems that factor inappropriate in view of the justification given, the competent authority shall itself define that factor, based on the available information and with the objective of maximum protection of human health. 3. Where no specific Union maximum levels for food for infants and young children are set out in Annex I, Member States may provide for stricter maximum levels for such food. **Article 4 Prohibition on detoxification** Food containing contaminants listed in Annex I shall not be deliberately detoxified by chemical treatments.	

Chinese National standard GB 2761	EU Regulation (EC) No 2023/915	Implementing rules and remarks
3 Principles of (Standard) Application 3.1 Regardless of existence of the mycotoxin limits, the food producers and processors shall take control measures to keep the mycotoxin content at the minimum level. 3.2 This standard lists the mycotoxins that may pose high risks to the public health, and the foods with the mycotoxin limits are foods that pose higher impact on consumers' dietary exposure. 3.3 Explanation of the Food Categories (Appendix A) is for defining scope of application of the mycotoxin limits, and is only applicable to this standard. When a mycotoxin limit is applied to a certain food category, all types of foods in the food category are subject to the limit unless otherwise specified. 3.4 Maximum levels of mycotoxins in foods are calculated by the edible parts of the food unless otherwise specified. 3.5 Maximum levels of mycotoxins in dried foods are converted by dehydration rate or the concentration rate. The dehydration rate or the concentration rate could be determined by analysis of the food, information provided by the producer, or other obtainable information/data.	Article 5Food to be subjected to sorting or other physical treatment before placing on the market for the final consumer or use as a food ingredient 1. Where a maximum level for a contaminant is set out in Annex I specifically as regards food to be subjected to sorting or other physical treatment before placing on the market for the final consumer or use as a food ingredient, such food may be placed on the market provided that: (a) it is not placed on the market for the final consumer or use as a food ingredient; (b) it complies with the maximum level set out in Annex I for that contaminant in that food to be subjected to sorting or other physical treatment before placing on the market for the final consumer or use as a food ingredient; and (c) it is labelled and marked in accordance with paragraph 2. 2. The label of each individual package and the original accompanying document of food referred to in paragraph 1, point (c), shall clearly show its use and bear the following information: 'Product shall be subjected to sorting or other physical treatment to reduce [name contaminant(s)] contamination before placing on the market for the final consumer or use as a food ingredient'. The consignment/batch identification code shall be indelibly marked on each individual package of the consignment and on the original accompanying document. 3. Food to be subjected to sorting or other physical treatment to reduce contamination levels shall not prior to this be mixed with food placed on the market for the final consumer or with food intended for use as a food ingredient. 4. Food which has been subjected to sorting or other physical treatment to reduce contamination levels may be placed on the market provided that the maximum levels set out in Annex I for food placed on the market for the final consumer or use as a food ingredient are not exceeded and that the treatment used has not resulted in the presence of other harmful residues.	

Chinese National standard GB 2761	EU Regulation (EC) No 2023/915	Implementing rules and remarks
4 Specifications **4.1 Aflatoxin B1** 4.1.1 Please refer to Table 1 for Aflatoxin B1 limits in foods. Table 1 Aflatoxin B1 limits in foods (μg/kg) Wheat, barley, other grains, Wheat flour, cereal, other husked grains, **Nuts and seeds 5.0** Paddy rice, brown rice, rice 10 Corn, corn flour (grits, flake) and corn products 20 Peanut and its products 20 All other cooked nuts and seeds 5.0 Vegetable oil and fat (with the exception of peanut oil, corn oil) 10 Peanut oil, corn oil 20	**ANNEX I** **Maximum levels for certain contaminants in food (μg/kg)** **Aflatoxin B1** (1.1.4) Groundnuts (peanuts) and other oilseeds, to be subjected to sorting or other physical treatment before placing on the market for the final consumer or use as an ingredient in food……8.0 (Sum of B 1 , B 2 , G 1 and G 2) 15.0 (1.1.5) Groundnuts (peanuts) and other oilseeds used as only ingredient or processed products from groundnuts (peanuts) and other oilseeds, placed on the market for the final consumer or use as an ingredient in food (limit is) 2.0 (Sum of B 1 , B 2 , G 1 and G 2) 4.0 (1.1.6) Tree nuts to be subjected to sorting or other physical treatment before placing on the market for the final consumer or use as an ingredient in food except products listed in 1.1.8 and 1.1.10 5.0 (Sum of B 1 , B 2 , G 1 and G 2) 10.0 (1.1.7) Tree nuts used as only ingredient or processed products from tree nuts, placed on the market for the final consumer or use as an ingredient in food except products listed in 1.1.9 and 1.1.11…… 2.0 (Sum of B 1 , B 2 , G 1 and G 2) 4.0 (1.1.8) Almonds, pistachios and apricot kernels to be subjected to sorting or other physical treatment before placing on the market for the final consumer or use as an ingredient in food (limit is) 12.0 (Sum of B 1 , B 2 , G 1 and G 2) 15.0	*Except groundnuts (peanuts) and other oilseeds for crushing for refined vegetable oil production. If groundnuts (peanuts) and other oilseeds with inedible shell are analysed, it is assumed, when calculating the aflatoxin content, that all the contamination is on the edible part.* *Except crude vegetable oils destined for refining and refined vegetable oils. If groundnuts (peanuts) and other oilseeds with inedible shell are analysed, it is assumed when calculating the aflatoxin content that all the contamination is on the edible part. In the case of food consisting of groundnuts (peanuts) and other oilseeds used as only ingredient or in the case of processed products consisting at least of 80 % from the groundnuts (peanuts) and other oilseeds concerned, the maximum levels as established for the corresponding groundnuts (peanuts) and other oilseeds apply also to those products. In other cases, Articles 3(1) and (2) apply.* *If tree nuts 'in shell' are analysed, it is assumed, when calculating the aflatoxin content, that all the contamination is on the edible part.* *If tree nuts 'in shell' are analysed, it is assumed, when calculating the aflatoxin content, that all the contamination is on the edible part. In the case of food consisting of tree nuts used as*

Chinese National standard GB 2761	EU Regulation (EC) No 2023/915	Implementing rules and remarks
	(1.1.9) Almonds, pistachios and apricot kernels, placed on the market for the final consumer or use as an ingredient in food limit is 8.0 (Sum of B 1 , B 2 , G 1 and G 2) 10.0 (1.1.10) Hazelnuts and Brazil nuts, to be subjected to sorting or other physical treatment before placing on the market for the final consumer or use as an ingredient in food 8.0 (Sum of B 1 , B 2 , G 1 and G 2) 15.0 (1.1.11) Hazelnuts and Brazil nuts, placed on the market for the final consumer or use as an ingredient in food 5.0 (Sum of B 1 , B 2 , G 1 and G 2) 10.0 (1.1.12) Cereals and products derived from cereals except products listed in 1.1.13, 1.1.18 and 1.1.19 2.0 (Sum of B 1 , B 2 , G 1 and G 2) limit is 4.0 (1.1.13) Maize and rice to be subjected to sorting or other physical treatment before placing on the market for the final consumer or use as an ingredient in food limit is 5.0	*only ingredient or in the case of processed products consisting at least of 80 % from the tree nuts concerned, the maximum levels as established for tree nuts apply also to those products. In other cases, Article 3(1) and (2) apply.* *If tree nuts 'in shell' are analysed, it is assumed, when calculating the aflatoxin content, that all the contamination is on the edible part.* *If tree nuts 'in shell' are analysed, it is assumed, when calculating the aflatoxin content, that all the contamination is on the edible part. In the case of food consisting of almonds, pistachios and apricot kernels used as only ingredient or in the case of processed products consisting at least of 80 % from the tree nuts concerned, the maximum levels as established for the corresponding tree nuts apply also to those products. In other cases, Article 3(1) and (2) apply.* *If hazelnuts 'in shell' are analysed, it is assumed, when calculating the aflatoxin content, that all the contamination is on the edible part.* *If hazelnuts 'in shell' are analysed, it is assumed, when calculating the aflatoxin content, that all the contamination is on the edible part. In the case of food consisting of hazelnuts and Brazil nuts used as only ingredient or in the case of processed products consisting at least of 80 % from the tree nuts concerned, the maximum levels as established*

Chinese National standard GB 2761	EU Regulation (EC) No 2023/915	Implementing rules and remarks
		for the corresponding tree nuts apply also to those products. In other cases, Article 3 *Including processed cereal products. Products derived from cereals relate to products containing at least 80 % cereal products.*
4.2 Aflatoxin M1 4.2.1 Please refer to Table 2 for Aflatoxin M1 limits in foods. Table 2 Aflatoxin M1 limits in foods No limits are set for vegetable oils, fats, seeds, nuts and grains	No limits are set for vegetable oils, fats, seeds, nuts and grains	
4.3 Deoxynivalenol 4.3.1 Please refer to Table 3 for Deoxynivalenol limits in foods. Table 3 Deoxynivalenol limits in foods Grains and grain products Corn, Corn flour (grits, flake), Barley, wheat, cereal, wheat flour…… 1000	(1.4.1) Unprocessed cereal grains except products listed in 1.4.2 and 1.4.3 1250 (1.4.2) Unprocessed durum wheat grains and oat grains 1750 (1.4.3) Unprocessed maize grains limit is 1750	*Except unprocessed maize grains intended to be processed by wet milling and except rice. The maximum level applies to unprocessed cereal grains placed on the market before first-stage processing* *The maximum level applies to unprocessed cereal grains placed on the market before first-stage processing* *Except unprocessed maize grains for which it is evident e.g. through labelling or destination, that they are intended for use in a wet milling process only (starch production). The maximum level applies to unprocessed maize grains placed on the market before first-stage processing* *The maximum level applies to unprocessed cereal grains placed on the market before first-stage processing*

Chinese National standard GB 2761	EU Regulation (EC) No 2023/915	Implementing rules and remarks
	(1.4.4) Cereals placed on the market for the final consumer, cereal flour, semolina, bran and germ as final product placed on the market for the final consumer except products listed in 1.4.7 and 1.4.8 750 (1.4.7.1) Maize flour not placed on the market for the final consumer 1250 (1.4.7.2) Other milling products of maize not placed on the market for the final consumer Limit is ……..750 (1.4.8) Baby food and processed cereal-based food for infants and young children Limit is 200	*Except rice and rice products* *At least 90 %, measured by weight, of the particles in the milling product have a size ≤ 500 µm* *Less than 90 %, measured by weight, of the particles in the milling product have a size ≤ 500 µm.* *Except rice products. The maximum level applies to the dry matter of the product as placed on the market.*
4.4 Patulin 4.4.1 Please refer to Table 4 for Patulin limits in foods. Table 4 Patulin limits in foods No limits are set for vegetable oils, fats, seeds, nuts and grains	No limits are set for vegetable oils, fats, seeds, nuts and grains	
4.5 Ochratoxin A 4.5.1 Please refer to Table 5 for Ochratoxin A limits in foods. Table 5 Ochratoxin A limits in foods Grains, Paddy rice in the brown rice basis, milled grain products limit is 5.0	(1.2.3) Pistachios to be subjected to sorting or other physical treatment before placing on the market for final consumer or use as an ingredient in food 10.0 (1.2.4) Pistachios placed on the market for final consumer or use as ingredient in foods Limit is 5.0	*If tree nuts 'in shell' are analysed, it is assumed, when calculating the ochratoxin A content, that all the contamination is on the edible part.* *If tree nuts 'in shell' are analysed, it is assumed, when calculating the ochratoxin A content, that all the contamination is on the edible part.*

Chinese National standard GB 2761	EU Regulation (EC) No 2023/915	Implementing rules and remarks
	(1.2.8) Sunflower seeds, pumpkin seeds, (water) melon seeds, hempseeds, soybeans 5.0	
	(1.2.9) Unprocessed cereal grains 5.0	*The maximum level applies to unprocessed cereal grains placed on the market before first-stage processing*
	(1.2.10) Products derived from unprocessed cereal grains and cereals placed on the market for the final consumer except products listed in 1.2.11, 1.2.12, 1.2.13, 1.2.23 and 1.2.24 3.0	*Including processed cereal products. Products derived from unprocessed cereal grains relate to products containing at least 80 % cereal products.*
	(1.2.11.3) other products containing oilseeds, nuts and/or dried fruits limit is 3.0	
	(1.2.24) Food for special medical purposes intended for infants and young children0.50	*The maximum level applies in the case of milk, milk products and similar products to the products ready to use (placed on the market as such or reconstituted as instructed by the manufacturer) and in the case of products other than milk, milk products and similar products to the dry matter*
4.6 Zearalenone 4.6.1 Please refer to Table 6 for Zearalenone limits in foods. Table 6 Zearalenone limits in foods Wheat, Wheat flour, Corn, Corn flour (grits, flake) limit is 60	(1.5.1) Unprocessed cereal grains except products listed in 1.4.2 and 1.4.3 limit is 100	*Except unprocessed maize grains intended to be processed by wet milling and except rice. The maximum level applies to unprocessed cereal grains placed on the market before first-stage processing*
	(1.5.2) Unprocessed maize grains 350	*Except unprocessed maize grains for which it is evident e.g. through labelling, destination, that it is intended for use in a wet milling process only (starch production). The maximum level applies to unprocessed maize grains placed on the market before first-stage processing (6).*

Chinese National standard GB 2761	EU Regulation (EC) No 2023/915	Implementing rules and remarks
	(1.5.3) Cereals placed on the market for the final consumer, cereal flour, semolina, bran and germ as final product placed on the market for the final consumer except products listed in 1.5.5, 1.5.6 and 1.5.8 Limit is 75	*Except rice and rice products.*
	(1.5.5) Maize placed on the market for the final consumer Maize-based snacks and maize-based breakfast cereals 100	
	(1.5.6.1) Maize flour not placed on the market for the final consumer 300	*At least 90 %, measured by weight, of the particles in the milling product have a size ≤ 500 µm.*
	(1.5.6.2) Other milling products of maize not placed on the market for the final consumer 200	*Less than 90 %, measured by weight, of the particles in the milling product have a size ≤ 500 µm.*
	(1.5.7) Refined maize oil 400	
	(1.5.8) Baby food and processed cereal-based food for infants and young children	*Except rice products. The maximum level applies to the dry matter of the product as placed on the market.*

2.1.6 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
1. Scope 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.	**Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs** **Article 1 General rules** 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	
2 Terminologies and definitions **2.1 Contaminants** 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. **2.2 Edible part** 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). Note 1: the non-edible parts cannot be removed by non-mechanical means (such as refining of crude vegetable oil); 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	**Council Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food, Article 1** 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.	

Chinese National standard GB 2762	EU Regulation (EC) No 1881/2006	Implementing rules and remarks
edible part is calculated by the actual flour extraction rate when producing wheat flour from wheat. **2.3 Limit** The maximum content of contaminants in food materials and/or the edible part of the finished food products.		
3 Principles of (Standard) Application 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. 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. 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. 3.4 Levels of contaminants in foods are calculated based on the edible parts of the food unless otherwise specified. 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.		
4 Specifications **4.1 Lead** 4.1.1 Please refer to Table 1 for lead limits in foods. Table 1 **Lead limits in foods**: limit (Pb) mg/kg Aquatic animal and its products Fresh, frozen aquatic animal (excluding fish, crustacean, bivalves) 1.0 (viscera removed) Fish, crustacean 0.5	**Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs,** Annex: maximum levels for certain contaminants in foodstuffs, Section 3: Metals **3.1 Lead** 3.1.8 Muscle meat of fish 0,30	

Chinese National standard GB 2762	EU Regulation (EC) No 1881/2006	Implementing rules and remarks
Bivalves 1.5 Aquatic products (excluding jellyfish products) 1.0 Jellyfish products 2.0 **4.2 Cadmium** Limit (in Cd basis) mg/kg Aquatic animal and its products Fresh, frozen aquatic animal Fish 0.1 Crustacean 0.5 Bivalves, gastropods, cephalopods, echinoderms 2.0 (viscera removed) Aquatic products Canned fish (excluding canned anchovy and canned sailfish) 0.2 Canned anchovy and canned sailfish 0.3 Other fish products (excluding anchovy and sailfish products) 0.1 Anchovy and sailfish products 0.3 **4.3 Mercury** Mercury limits in foods: limit (in Hg basis) mg/kg Aquatic animal and its products (excluding carnivorous fishes and its products) 0.5*	3.1.9 Cephalopods (without viscera) 0,30 Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster 0,50 Bivalve molluscs 1,50 **3.2 Cadmium** 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 (*Scomber* species), tuna (*Thunnus* species, *Katsuwonus pelamis*, *Euthynnus* species), bichique (*Sicyopterus lagocephalus*) 0,10 3.2.15.3 Muscle meat of the following fish: bullet tuna (*Auxis species*) 0,15 3.2.15.4 Muscle meat of the following fish: anchovy (*Engraulis species*), swordfish (*Xiphias gladius*) and sardine (*Sardina pilchardus*) 0,25 3.2.8 Crustaceans: muscle meat from appendages and abdomen. In case of crabs and crab-like crustaceans (*Brachyura* and *Anomura*) muscle meat from appendages 0,50 3.2.9 Bivalve molluscs 1,0 3.2.10 Cephalopods (without viscera) 1,0 **3.3 Mercury** 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 (*Brachyura* and *Anomura*) it applies to muscle meat from appendages. 0,5	

Chinese National standard GB 2762	EU Regulation (EC) No 1881/2006	Implementing rules and remarks
Carnivorous fishes and its products 1.0* * 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.	Muscle meat of the following fish: anglerfish (*Lophius species*), atlantic catfish (*Anarhichas lupus*), bonito (*Sarda sarda*), eel (*Anguilla* species), emperor, orange roughy, rosy soldierfish (*Hoplostethus* species), grenadier (*Coryphaenoides rupestris*), halibut (*Hippoglossus hippoglossus*), kingklip (*Genypterus capensis*), marlin (*Makaira* species), megrim (*Lepidorhombus* species), mullet (*Mullus* species), pink cusk eel (Genypterus blacodes), pike (*Esox lucius*), plain bonito (*Orcynopsis unicolor*), poor cod (*Tricopterus minutes*), Portuguese dogfish (*Centroscymnus coelolepis*), rays (*Raja* species), redfish (*Sebastes marinus*, *S. mentella*, *S. viviparus*), sail fish (*Istiophorus platypterus*), scabbard fish (*Lepidopus caudatus*, *Aphanopus carbo*), seabream pandora (*Pagellus* species), shark (all species), butterfish (*Lepidocybium flavobrunneum*, *Ruvettus pretiosus*, *Gempylus serpens*), sturgeon (*Acipenser* species), swordfish (*Xiphias gladius*), tuna (*Thunnus* species, *Euthynnus* species, *Katsuwonus pelamis*) 1,0	
4.4 Arsenic 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; otherwise, the inorganic arsenic should be tested again. 4.4.2 Testing methods: using methods provided in GB 5009.11.	**3.5 Arsenic (inorganic)** No EU limits defined	
4.5 Tin 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	**3.4 Tin (inorganic)** Canned foods other than beverages 200	

Chinese National standard GB 2762	EU Regulation (EC) No 1881/2006	Implementing rules and remarks
4.7 Chromium chromium limits in foods, limit (in Cr basis) mg/kg Aquatic animal and its products 2.0	No EU limits defined	*No limit values have been laid down for arsenic or chromium in fish or fishery products in EU legislation.* *The ALARA Principle aplies (as low as reasonably achieveable).*
4.9 Benzo[a]pyrene 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	**Section 6: Polycyclic aromatic hydrocarbons** maximum levels (µg/kg) **6.1.5** 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 (*Brachyura* and *Anomura*) it applies to muscle meat from appendages. 2,0 and 12,0 **6.1.6** Smoked sprats and canned smoked sprats (*Sprattus sprattus*); Smoked Baltic herring ≤ 14 cm length and canned smoked Baltic herring ≤ 14 cm length (*Clupea harengus membras*); Katsuobushi (dried bonito, *Katsuwonus pelamis*); bivalve molluscs (fresh, chilled or frozen); heat treated meat and heat treated meat products sold to the final consumer 5,0 and 30,0 **6.1.7** Bivalve molluscs (smoked) 6,0 and 35,0	*Benzo[a]pyrene (BaP) belongs to the group of compounds known as polycyclic aromatic hydrocarbons (PAHs).*
4.10 N-Nitrosodimethylamine 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		*No limits have been laid down for testing of notrosamines in fish or fishery products in EU legislation.* *The ALARA Principle aplies (as low as reasonably achieveable).*

Chinese National standard GB 2762	EU Regulation (EC) No 1881/2006	Implementing rules and remarks
4.11 Polychlorinated biphenyl 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 ***** Polychlorinated biphenyl is calculated by total of PCB28, PCB52, PCB101, PCB118, PCB138, PCB153 and PCB180.	**Section 5: Dioxins and PCBs** **5.3** Muscle meat of fish and fishery products and products thereof, 3,5 pg/g wet weight[1] 6,5 pg/g wet weight[2] 75 ng/g wet weight[3] with the exemption of: — wild caught eel — wild caught spiny dogfish (*Squalus acanthias*) — wild caught fresh water fish, with the exception of diadromous fish species caught 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 (*Brachyura* and *Anomura*) it applies to muscle meat from appendages. **5.4** 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[1] 6,5 pg/g wet weight[2] 125 ng/g wet weight[3] **5.4a** Muscle meat of wild caught spiny dogfish (Squalus acanthias) and products thereof 3,5 pg/g wet weight[1] 6,5 pg/g wet weight[2] 200 ng/g wet weight[3] **5.5** Muscle meat of wild caught eel (*Anguilla anguilla*) and products thereof 3,5 pg/g wet weight[1] 10 pg/g wet weight[2] 300 ng/g wet weight[3]	

Chinese National standard GB 2762	EU Regulation (EC) No 1881/2006	Implementing rules and remarks
	5.6 Fish liver and derived products thereof with the exception of marine oils referred to in point 5.7 -- pg/g wet weight[1] 20 pg/g wet weight[2] 200 ng/g wet weight[3] **5.7** Marine oils (fish body oil, fish liver oil and oils of other marine organisms intended for human consumption) 1,75 pg/g wet weight[1] 6 pg/g wet weight[2] 200 ng/g wet weight[3] [1] Sum of dioxins (WHO-PCDD/F-TEQ) [2] Sum of dioxins and dioxin-like PCBS (WHO-PCDD/F-PCB-TEQ) [3] Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180 (ICES – 6)	

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

Chinese National standard GB 2763	EU Regulation (EC) No 396/2005	Implementing rules and remarks
1. Scope 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.	**Regulation (EC) No 396/2005, Article 1, Subject matter** 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. **Article 2, Scope** 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.	
2 Normative reference 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) is also applicable to the testing of corresponding parameters.	**Regulation (EC) No 396/2005, Chapter II, Procedure for applications for MRL's, Articles 6 to 17.**	*Only three of the 194 Chinese testing methods mentioned in the national standard apply to animal 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".*

Chinese National standard GB 2763	EU Regulation (EC) No 396/2005	Implementing rules and remarks
3 Terms and definitions The terms and definitions below apply to this document. **3.1 Residue definition** 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. **3.2 Maximum residue limit (MRL)** 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). **3.3 Extraneous maximum residue limit (EMRL)** 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). **3.4 Acceptable daily intake (ADI)** 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).	**Article 3, Definitions** (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; (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; (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).	

Chinese National standard GB 2763	EU Regulation (EC) No 396/2005	Implementing rules and remarks
4 Technical requirements **4.540 (DDT)** 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	**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:** 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.	*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.*
4.544 (HCH) 4.544.1 Major purpose of use: insecticide. 4.544.2 ADI: 0.005 mg/kg bw. 4.544.3 Residue definition: sum of α-HCH, β-HCH, γ-HCH and δ-HCH. 4.544.4 Extraneous Maximum Residue Limit, mg/kg: Shall comply with provisions in the Table 544. Table 544: Extraneous Maximum Residue Limit, mg/kg, mg/kg: Aquatic products 0.1		*According to the Chinese National standard, aquatic products must be tested for the presence of the insecticide HCH, while no requirements for testing or monitoring for HCH of fish or fishery products have been laid down in EU legislation.* *Environmental contamination with HCH is generally very low.*
Appendix A The food categories and parts to be tested (Normative Appendix) Table A.1 The food category and parts to be tested: Animalderived food Aquatic products: the edible part, bone and scale removed		

2.1.8 National standard GB 2760-2014 – Uses of food additives

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
1. Scope This standard specifies the principles for application of food additives, allowed food additive varieties, scope of application, and maximum level or residue levels.	**Regulation (EC) No 1333/2008 on food additives, Article 2: Scope** 1. This Regulation shall apply to food additives.	
2 Definitions **2.1 Food Additive** 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. **2.2 Maximum Use Level** The maximum allowable adding level at the time of application of food additives. **2.3 Maximum Residue Level** The permissible residual level of a food additive or its decomposition products in final food products. **2.4 Processing Aid** 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. **2.5 International Numbering System (ins)** The international numbering of food additives, which is used in lieu of the description of complicated chemical structure names. **2.6 Chinese Number System (cns)** 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.	**Regulation (EC) No 1333/2008, Article 3: Definitions** (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 (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;	*For the definition of MRL see:* **Regulation (EC) No 396/2005, Article 3, Definitions** (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;

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
3 Principles for use of food additives **3.1 The use of food additives should observe the following basic requirements:** 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. **3.2 Food additives could be applied in the following cases:** a) To keep or improve the nutrition value of food itself; 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	**Article 6** 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: (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. 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: (a) preserving the nutritional quality of the food; (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.	

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
3.3 Quality standards of food additives Food additives used in accordance with this standard shall comply with corresponding quality standards. **3.4 Carry-over of principles** 3.4.1 In the following cases, food additives can be introduced into foods through ingredients (including food additives) : 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 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; 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. 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.	**Article 18** 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: (i) is permitted in the food additive, food enzyme or food flavouring in accordance with this Regulation; and (ii) has been carried over to the food via the food additive, food enzyme or food flavouring; and (iii) has no technological function in the final food; (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.	
4 Food category system 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.		

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
5 Provisions for use of food additives The use of food additives shall comply with the provisions in the appendix a.	**Article 15** Food additives shall not be used in unprocessed foods, except where such use is specifically provided for in Annex II.	
6 Flavoring substances The use of flavoring substances shall comply with the provisions of the appendix b.	**Regulation (EC) No 1334/2008, Annex I: Union list of flavourings and source materials**	
7 Food processing aid The use of food processing aids shall comply with the provisions of Annex C		*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.*
Appendix A Provisions for the use of food additives 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. **Tea polyphenol (TP)** 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	**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** *Contains lists for* **09.1.1 Unprocessed fish** 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. **09.1.2 Unprocessed molluscs and crustaceans** 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. **09.2 Processed fish and fishery products including molluscs and crustacean** 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.	

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
Phydroxy benzoates and its salts (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	**09.3 Fish roe** 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.	
Butylated hydroxyanisole (BHA) 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		***Butylated hydroxyanisole (BHA)** has in the EU legislation as E number: E320*
Butylated hydroxytoluene (BHT) 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	**E 321 Butylated hydroxytoluene (BHT)** 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.	
Neotame 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)		***Neotame** has in the EU legislation as E number: E961*

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
Monosodium fumarate 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 **Antioxidant of glycyrrhiza** CNS 04.008 INS – Function: antioxidant 09.03.02 Pickled fish and fish products 0.2 Max Level (g/kg) Note: as glycyrrhetic acid **Beta-carotene** 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 **Curdlan** 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 16.07 Other (artificial aquatic products, such as artificial abalone, artificial sea cucumber, artificial shellfish, etc.) Max level: GMP		***Carotenes** have in the EU legislation as E number: E 160a*

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
Paprika orange CNS 08.107 INS – Function: colour Frozen minced and creamed fish products (including fish balls) Max level: GMP **Paprika red** CNS 08.106 INS – Function: colour Frozen minced and creamed fish products (including fish balls) Max level: GMP		***Paprika extract*** *(and capsanthin, capsorubin) has in the EU legislation as E number: E 160c*
4-hexylresorcinol CNS 04.013 INS 586 Function: antioxidant Fresh aquatic products (shrimp only) Max Level: GMP Note: Residue ≤1mg/kg	**E 586 4-hexylresorcinol 2** Maximum level (mg/l or mg/kg as appropriate) Restrictions/exceptions: only in fresh, frozen or deep-frozen crustacean meat. Listed under 09.1.2 Unprocessed molluscs and crustaceans *(see lists mentioned above)*.	
Phosphoric acid, disodium dihydrogen pyrophosphate, tetrasodium pyrophosphate, calcium dihydrogen phosphate, potassium dihydrogen phosphate, diammonium hydrogen phosphate, dipotassium hydrogen phosphate, calcium hydrogen phosphate (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 Function: humectant, bulking agent, Acidity regulator, stabilizer, coagulant, anticaking agent 09.02.01 Frozen aquatic products 5.0 Max Level (g/kg) Note: Singly or in combination, Max level calculated by PO43-	**E 338-452 Phosphoric acid — phosphates — di-, tri- and polyphosphates** 5 000 Maximum level (mg/l or mg/kg as appropriate) The maximum level is expressed as P_2O_5 Restrictions/exceptions: only frozen and deep-frozen fish fillets. **E 338-452 Phosphoric acid** — phosphates — di-, tri- and polyphosphates 1 000 Maximum level (mg/l or mg/kg as appropriate) The maximum level is expressed as P_2O_5 Restrictions/exceptions: only canned crustaceans products; surimi and similar products.	

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
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- 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- 09.05 Canned fish products 1.0 Max Level (g/kg) Note: Singly or in combination, Max level calculated by PO43- **Aluminium potassium sulfate**, **aluminium ammonium sulfate** 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 ≤ 500mg/kg (as Al in instant jelly fish) **Maltitol and maltitol syrup** 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) **Propyl gallate (PG)** 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	**E 338-452 Phosphoric acid** — phosphates — di-, tri- and polyphosphates 5 000 Maximum level (mg/l or mg/kg as appropriate) The maximum level is expressed as P_2O_5 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 fishery products including molluscs and crustaceans *(see lists mentioned above)*.	***Maltitols** have in the EU legislation as E number: E 965.* ***Propyl gallate** has in the EU legislation as E number: E 310.*

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
Rosemary extract CNS 04.017 INS – Function: antioxidant 02.01.02 Animal fats (including lard, tallow, fish oil, and other animal fats) 0.3 g/kg	**E 392 Extracts of rosemary** 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.	
Pullulan CNS 14.011 INS 1204 Function: glazing agent, thickener 09.03 Pre-processed fish and fish products 30.0 Max Level (g/kg)		***Pullulan** has in the EU legislation as E number: E 1204.*
Nisin CNS 17.019 INS 234 Function: preservative Fully preserved fish and fish products (can be directly consumed) 0.5 Max Level (g/kg)		***Nisin** has in the EU legislation as E number: E 234.*
Rtemisia gum (sa-hao seed gum) CNS 20.037 INS – Function: thickener 09.02.03 Frozen minced and creamed fish products (including fish balls) 0.5 Max Level (g/kg)		
Sorbic acid, potassium sorbate 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	**E 200-203 Sorbic acid — sorbates** 1 000 Maximum level (mg/l or mg/kg as appropriate) Restrictions/exceptions: aspic **Sorbic acid — sorbates; Benzoic acid — benzoates** 200 Maximum level (mg/l or mg/kg as appropriate) Restrictions/exceptions: only salted, dried fish	

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
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	**Sorbic acid — sorbates; Benzoic acid — benzoates** 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. **Sorbic acid — sorbates; Benzoic acid — benzoates** 6000 mg/l or mg/kg Restrictions/exceptions: only cooked *Crangon crangon* and *Crangon vulgaris*. **Sorbic acid — sorbates; Benzoic acid — benzoates** 2000 mg/l or mg/kg Restrictions/exceptions: only semi-preserved fish products including fish roe products.	
Sorbitol and sorbitol syrup 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		***Sorbitols** have in the EU legislation as E number: E 420.*
Sodium diacetate CNS 17.013 INS 262ii Function: preservative Fully preserved fish and fish products (can be directly consumed) 1.0 g/kg		
Diacetyl tartaric acid ester of mono (di) glycerides (DATEM) CNS 10.010 INS 472e Function: emulsifier, thickener 09.0 Aquatic products (excluding fresh aquatic products) 10.0 g/kg		***Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids** have in the EU legislation as E number: E 472e.*

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
Tertiary butylhydroquinone (TBHQ) 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 **Aspartame** 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 **Stabilized chlorine dioxide** 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 **Phytic acid (inositol hexaphosphoric acid), sodium phytate** CNS 04.006 INS – Function: antioxidant Fresh aquatic products (shrimp only) Max Level (g/kg): GMP ≤20mg/kg	**E 951 Aspartame** 300 mg/l or mg/kg Restrictions/exceptions: only sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs. **E 962 Salt of aspartame-acesulfame** 200 mg/l or mg/kg Restrictions/exceptions: only sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs.	***Tertiary butylhydroquinone (TBHQ)*** *have in the EU legislation as E number: E 319.*

Chinese National standard GB 2760	EU Regulation (EC) No 1333/2008	Implementing rules and remarks
Antioxidant of bamboo leaves CNS 04.019 INS – Function: antioxidant Aquatic products (including fish, crustaceans, shellfish, mollusks, and echinode, and their processed products) 0.5 g/kg 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. 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). 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. A.6 The "function" item in the aforementioned Tables are the main functions of the additive for reference in use.		

2.1.9 National standard GB 5749 – Drinking water quality

Chinese legislation: National standard GB 5749	EU legislation: Council Directive 98/83/EC	Implementing rules and comparative evaluation
1. Scope **GB 5749-2006** **Standards for Drinking Water Quality** 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.	**Scope** This Directive applies to the quality of water intended for human consumption in all food chain.	Chinese Standards and European Legislation pursue the same objectives and limit values defined are largely identical. 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.

Chinese legislation: National standard GB 5749	EU legislation: Council Directive 98/83/EC	Implementing rules and comparative evaluation
3 Terms and Definitions **3.1 Drinking water** Water and domestic water for people to live. **3.2 Type of water supply** 3.2.1 Central water supply 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. 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. 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). 3.2.4 Non-central water supply Getting water directly from the water source by dispersive residents with no or just simple facilities. **3.3 Regular indices** The index that can reflect the basic drinking water quality. **3.4 Non-regular indices** Drinking water quality indices that need to be adopted according to the region, time or special circumstances.	**Definitions** **Council Directive 98/83/EC, Article 2** 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 satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form; 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.	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.
4. Hygiene requirements for drinking water 4.1 The quality of drinking water should meet the following basic requirements to ensure the safety of users. 4.1.1 Pathogenic microorganisms should not be contained in the drinking water.	**Council Directive 98/83/EC, Article 4 General obligations:** 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	

Chinese legislation: National standard GB 5749	EU legislation: Council Directive 98/83/EC	Implementing rules and comparative evaluation
4.1.2 Chemicals in drinking water should not be harmful to human health. 4.1.3 Radioactive substances in drinking water should not be harmful to human health. 4.1.4 Sensory properties of drinking water should be good. 4.1.5 Drinking water should be through sterilization processing. 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. 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. 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. 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.	this Directive, water intended for human consumption shall be wholesome and clean if it: (a) is free from any micro-organisms and parasites and from any substances which, in 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. **Article 5: Quality standards** 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. **Article 6: Point of compliance** 1. The parametric values set shall be complied with: … (d) in the case of water used in a food-production undertaking, at the point where the water is used in the undertaking. **Annex II Monitoring:** 1. Monitoring programmes for water intended for human consumption must: (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; (b) provide information on the quality of the water supplied for human consumption to demonstrate that the obligations set out in Articles 4 and 5, and the parametric values laid down in Annex I, are being met; (c) identify the most appropriate means of mitigating the risk to human health.	

Chinese legislation: National standard GB 5749	EU legislation: Council Directive 98/83/EC	Implementing rules and comparative evaluation
	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: (a) collection and analysis of discrete water samples; or (b) measurements recorded by a continuous monitoring process. In addition, monitoring programmes may consist of: (a) inspections of records of the functionality and maintenance status of equipment; and/or (b) inspections of the catchment area, water abstraction, treatment, storage and distribution infrastructure. 3. Monitoring programmes may be based on a risk assessment as set out in Part C. 4. Member States shall ensure that monitoring programmes are reviewed on a continuous basis and updated or reconfirmed at least every 5 years	
6. Hygiene requirements for centralized water supply unit The Sanitation requirements of centralized water supply unit should refer to Hygienic Standard for the Drinking Water Centralized Supply Unit promulgated Ministry of Health.	See above. Monitoring programmes must ensure that water complies with the standards set forth at all points throughout the distribution network.	
7. Hygiene requirements for secondary water supply 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.	See above. Monitoring programmes must ensure that water complies with the standards set forth at all points throughout the distribution network.	
8. Hygiene requirements for health security products related to drinking water 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.	**Council Directive 98/83/EC, Article 4 General obligations:** Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean.	

Chinese legislation: National standard GB 5749	EU legislation: Council Directive 98/83/EC	Implementing rules and comparative evaluation
8.2 Water transport and distribution equipment, protective materials and treatment materials of drinking water should not pollute drinking water.		
9. Water quality monitoring **9.1** Water quality detection of the water supply unit **9.1.1** 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. **9.1.4** 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. **9.1.5** 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. **9.2** Water quality monitoring of health supervision **9.2.1** 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. **9.2.2** 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. **9.2.3** Water quality monitoring scope, project, frequency of health supervision should be determined by the health administrative department at or above the local municipal.	See above. Monitoring programmes must ensure that water complies with the standards set forth at all points throughout the distribution network.	

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

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		
Main indicators	**EU limits**	**GB 5749-2006 limits**
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 CaCo3) 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
Fluoride (F)	1.5 mg/l	1.0 mg/l
Nitrate (NO3) (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

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				
Main indicators	**EU limits**		**GB 5749-2006 limits**	
Giardia	Not mentioned		< 1 per 10l	
Cryptosporidium	Not mentioned		< 1 per 10l	
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 α	0.5 Bq/l
	Total indicative dose	0.10 mSv/year	Total radioactivity β	1 Bq/l

2.2 Specific requirements for seed and oil products

2.2.1 GB 2716-2018 National Food Safety Standard for Vegetable Oil

Chinese Legislation Main Points	Relevant EU Legislation Description	Relevant EU GMP Guides
Sensory Requirements	Regulation 852/2004	National EU MS State Legislations have similar sensory requirements
Physical & Chemical Indices such as: Peroxide values Acid value Polar component (frying oil) Gossypol cotton seed oil	No limits for gossypol, peroxide values and polar components exist in EU legislation	
GB 2763 on pesticides	Pesticides EU Legislation is mainly Regulation 396/2005 that sets maximum residue levels (MRLs) for raw agricultural products, like oilseeds/oil fruits. According to this Regulation, MRLs also apply to processed products (like vegetable oils). In such cases, MRLs can be derived by applying a processing factor (reflecting the concentration or dilution caused by processing) to the MRL of the corresponding raw commodity. But Annex VI of Regulation 396/2005, which was scheduled to set specific processing factors, is today still empty. In absence of harmonized processing factors at EU level, Member States, as well as economic operators, may have a different understanding of MRLs applying to processed products which is a source of uncertainty and problems.	FEDIOL has strived to have a pragmatic approach on processing factors for vegetable oils and fats that is legally set in the legislation (Annex VI of Reg. 396/2005). This is to ensure a harmonized enforcement of MRLs in the various EU Member States as well as a common understanding between economic operators. In order to address the absence of legally set processing factors in the meantime, FEDIOL has developed and used since 2007 an approach on processing factors for fat soluble pesticides in crude vegetable oils and fats, already recognised in several Member States (see FEDIOL position). A research project was also run to substantiate this approach. Proper storage management is strongly advocated as it is one of the ways to guarantee the safety and quality of oilseeds, the lack of residue tolerances for the use of post-harvest and storage treatments on oilseeds can lead to incidental MRL exceedances. Indeed, cross-contamination from treated cereals to oilseed may happen during storage. FEDIOL is committed to solving this problem by raising awareness along the supply chain and with storage managers across the EU. As a result of a concerted action of oilseed trading and processing companies, along with storekeepers, co-ordinated by MVO , FEDIOL, COCERAL, Het Comité and UNISTOCK, a brochure on pesticide management has been developed.

Chinese Legislation Main Points	Relevant EU Legislation Description	Relevant EU GMP Guides
GB 2762 on contaminants	The basic principles of EU legislation on contaminants in food are laid down in Council Regulation 315/93/EEC	
	On glycidyl esters (GE), risk management discussions led to the setting of EU maximum levels (MLs) entering into force in 2018 (see Regulation (EU) 2018/290).	MCPD ESTERS AND GLYCIDYL ESTERS Review of mitigation measures Revision 2015 by FEDIOL
GB 2761 on mycotoxins	European Union measures (establishment of maximum levels) have been taken for the following contaminants: • mycotoxins (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, citrinine, ergot sclerotia and ergot alkaloids) • plant toxins (erucic acid, tropane alkaloids, hydrocyanic acid, pyrrolizidine alkaloids, opium alkaloids, Δ9-THC) • metals (lead, cadmium, mercury, arsenic, inorganic tin) • halogenated persistent organic pollutants (dioxins, dioxin-like PCBs, non dioxin-like PCBs; perfluoroalkyl substances: PFOS, PFOA, PFNA, PFHxS) processing contaminants (polycyclic aromatic hydrocarbons (PAH): benzo(a)pyrene, sum of 4 PAHs; 3-monochloropropane-1,2-diol (3-MCPD), glycidyl fatty acid esters) other contaminants (nitrates, melamine, perchlorate)	FEDIOL List of Foodstuffs as meant in the FEDIOL Code of Practice for the transport in bulk of oils into or within the European Union

Chinese Legislation Main Points	Relevant EU Legislation Description	Relevant EU GMP Guides
GB 2760 GB 14880	Regulation (EC) No 1333/2008 on Food Additives requires that food additives are subject to safety evaluation by EFSA before they are permitted for use in the EU. In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by EFSA. A programme for the re-evaluation of food additives already permitted in the EU before 20 January 2009 was set up under Regulation 257/2010. Under this programme, food additives go through a new risk assessment by EFSA, which includes an assessment of consumer exposure to additives through the diet. Interested parties are invited to provide data on usage level of additives in food.	In this context, FEDIOL regularly provides information on the use of additives of relevance for the oils and fats sector.
	Food Allergens are regulated by EU Regulation 1169/2011 on the provision of food information to consumers and its annex II Allergenicity is one of the key areas where the oils and fats industry has put a lot of efforts and research over the years to guarantee the safety in the production of refined oils and fats. Peanut-, nut- and soybean- oils have been put under scrutiny in 2003 due to the known allergenicity of its raw materials. While the non-allergenicity of refined peanut oil has not be accepted by the European Food Safety Authority in 2004, the non allergenicity of refined soybean oil was scientifically established by clinical trials both in Europe and the US, acknowledged by EFSA in 2007 and is part of EU law. As such, fully refined soybean oil and fat and the product thereof - in so far as the process that they have undergone is not likely to	

Chinese Legislation Main Points	Relevant EU Legislation Description	Relevant EU GMP Guides
	increase the level of allergenicity assessed by EFSA for the relevant product from which they originated - are excluded from allergen labelling.	
	• Reg. 852/2004 on the hygiene of foodstuffs • Commission Regulation (EU) n°579/2014 granting a derogation from certain provisions of Annex II to Regulation 852/2004 of the European Parliament and of the Council as regards the transport of liquid oils and fats by se Shipping of vegetable oils and fats into Europe by sea voyage benefits from specific conditions. It is permitted in bulk tanks, in which substances included in a positive list (acceptable previous cargoes) were transported. Strict criteria were established by the Scientific Committee for Food to define the list of acceptable previous cargoes. These criteria were reconfirmed by EFSA in 2009. In addition, the lining of the ship tanks can determine in some cases whether the immediate previous cargo or the three previous cargoes have to be on the positive list. For ocean carriers, only the immediate previous cargo needs to comply with the positive list (see details in 14COD152 Annex 2). Strict cleaning procedures are also defined by the sector (see 07COD138). For road transport, train and barges, the transport of oils and fats is food dedicated. The definition of food acceptable as previous cargo has been defined by the oils and fats sector in a short list of recommended substances in order to guarantee an optimal cleaning of the tanks (see 14COD152 Annex 1).	• **Transport in bulk of oils into or within the European Union (14COD152)** ○ **Annex 1-FEDIOL list of foodstuffs**, ○ **Annex 2- Practical guide to previous cargoes**) • **Cleaning of bulk road tankers and tank containers for direct food use (07COD138)** **ENFIT Guideline**

Chinese Legislation Main Points	Relevant EU Legislation Description	Relevant EU GMP Guides
4 The single variety edible vegetable oil should not be added other oil. 4.2 The blended vegetable oil products should be named "Edible Vegetable Blend Oil." 4.3. Labels of edible vegetable blend oil should indicate the percentages of different edible vegetable oils. 4.4. Labels of edible vegetable blend oil may indicate the name and content of fatty acid composition with more than 2% (percentage in the total fatty acid quantity); format and requirements should follow the Annex A.	Labelling: Regulation 1169/2011 on food information to consumers governs today the labelling of all food products on the market, including the nutrition labelling. It integrates former Directives 2000/13 and 90/496. New set of rules on nutrition information entered into force in December 2016. The following elements have to be included in the nutrition declaration on all food packages: • the energy value and the amounts of fat, • saturates, • carbohydrate, • sugars, • protein • and salt. As far as vegetable oils and fats are concerned, such food labelling can also be supplemented by the following elements such as amounts of mono-unsaturated or polyunsaturated.	The information per portion is particularly relevant for foods where consumption per eating occasion is much less than 100g, as is the case for vegetable oils for which a typical portion of 10g, corresponding to an easily measurable soup spoon, has been determined by the European oil sector. FEDIOL Guidance on the labelling requirements for the ingredient listing of vegetable oils and fats as per Regulation (EU) 1169/2011: category name, implications for QUID, hydrogenation
Compared to the measures adopted by other countries, China didn't form regulations to limit the TFA content in all prepackaged food but only in baby food. According to the national standards listed below, it is forbidden to use hydrogenated oil and fat in both infant formula and complementary baby food. Edible oil and fat products processed by the hydrogenation process should be marked with the content of trans fatty acids, and the test method should be carried out according to GB/T 22507.	Trans Fatty Acids Among the fatty acids, some of them are called "trans fatty acids or TFA". "Trans fatty acids" refers to fatty acids with at least one non-conjugated (namely interrupted by at least one methylene group) carbon-carbon double bond in the trans configuration (Regulation 1169/2011).	FEDIOL statement – Rules for Defining the Country of Origin (COO) for vegetable oils and fats

2.2.2 National standard GB 19641-2015 National Food Safety Standards Edible Vegetable Oilseeds

Chinese National standard GB 19641	Relevant EU Legislation	Relevant EU GMP Guides
1. Scope This standard applies to oilseeds for the production of edible vegetable oils. 2 Terms and definitions 2.1 Mouldy grains A granule that is visibly mouldy and injures the embryo or endosperm or cotyledons and has no edible value	The **Feed Hygiene Regulation 183/2005** is encouraging the development of sector guides for the application of HACCP Principles. Responding to this call,.	FEDIOL together with the European starch industry, Starch Europe, and the European biodiesel industry, EBB, have made the **European Guide for the industrial manufacturing of safe feed materials**. This Guide was endorsed by the Standing Committee on the Food Chain and Animal Health in June 2010 and the revised version in November 2014
Sensory requirements	**No provisions regarding sensory requirements found in EU legislation** **Nevertheless contaminates due to mouldy grains such as mycotoxins are regulated**	
Physical and chemical indicators **Mandarin and other toxic plants seeds**	The EU Regulations does not stipulate criteria for mandarin and toxic plants seeds	
Ergots <0.05%	The EU maximum levels for ergot alkaloids and ergot sclerotia in certain cereals and cereal products have been published in Regulation (EU) 2021/1399. For unprocessed cereals (except maize, rice and rye), the ergot sclerotia content is lowered to 0.02%. For rye, the level must not exceed 0.5 mg/kg.	
3.4 Contaminant limits Contaminant limits shall comply with the provisions of GB 2762. **3.5 Pesticide residue limits and veterinary drug residue limits** 3.5.1 Pesticide residue limits shall comply with the provisions of GB 2763.	**See Analysis in 1.2.1**	
3.8 Food additives The use of food additives shall comply with the provisions of GB 2760.	See 1.2.1	

2.2.3 National Standard GB 15196-2015 for Food Safety Edible Fats and Oils Products

Chinese National standard GB15196	Relevant EU Legislation Description	National EU MS Legislation /Relevant GMP Guides
1. Scope This standard applies to edible oils and fats products such as edible hydrogenated oils, margarine (margarine), shortening, cocoa butter (cocoa-like butter), phytates, powdered fats and oils.	See Analysis in 1.2.2	
4. Technical requirements **4.2 Sensory requirements**	**No provisions regarding sensory requirements were found in EU Legislation**	
4.3 Physical and chemical index Acid Value Peroxide Value	**No provisions regarding acid value and peroxide value were found in EU Legislation**	Peroxide and acid value limits are set in certain EU- Member States National Legislation that are higher than the limits of the Chinese Standard.
4.4 Contaminant limits Contaminant limits shall comply with the provisions of GB 2762.	**See Analysis in 1.2.1**	
4.5 Pesticide Residue limits	**See Analysis in 1.2.1**	
4.6 Microbiological limits	**Limits identical to the limits of EU Regulation 2073/2005**	
3.6 Food additive The usage of food additive shall conform to the stipulations in GB 2760.	**See Analysis in 1.2.1**	See discussion of GB 2760

3 LEGAL FRAMEWORK FOR THE IMPORTATION OF SEED &OIL PRODUCTS

The Chinese national import control system for seed and oil 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 food1.

[1] 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.

3.1 Decree 248 – Registration of manufacturers of imported foods

3.1.1 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 registration2.

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.

3.1.2 Registration through the competent authority

The OMs of that shall be registered through the competent authority are producers of the following foods3:

- 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

2 Decree 248 Article 6

3 Decree 248 article 7

For producers of oils and oilseeds 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 farms, packaging facilities, processing establishments and warehouses.

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 trough the competent authority[4].

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

Step	Activity	Supporting documentation
1	OM apply for registration by the Competent authority of the country	-
2	Competent authority of the country[5] 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 https:// cifer.singlewindow.cn	Required Application Materials: - Letter of recommendation by the competent authority of the country/region - Application from the OM (or in case of several OMs, list of the OM and their applications) - Documents certifying the identification of the OM - Statement that the producer recommended by the competent authority of the country/region comply with requirements of Decree 248. - Reports of examinations/ inspections/review conducted by the competent authority of the country/ region to relevant manufacturers. 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

[4] Reference is made to Danish Competent authority website providing a list from February 202 as an example.

[5] 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

Step	Activity	Supporting documentation
5	GACC Review Team conduct review including: - document review, - video inspection, - and/or on-site inspection.	The submitted application documents.
6	Based on satisfactory 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 not satisfactory, the registration will be rejected	Notification to the competent authority in both cases.

3.1.3 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.

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;

3.2 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[6], 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[7].

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)8.

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;
- 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.

6 Decree 249 article 9

7 Decree 249 article 3

8 and determine corresponding inspection and quarantine requirements based on the results of the assessment and examination ????

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 9a list of designated ports and designated supervision zones for conducting of import controls.

[9] *Article 24 of Decree 248*

3.3 Conditions and Key Points of Control Inspection for Registration of Overseas Production Enterprises of Imported Edible Oils and Oil Seeds

Registration No.:

Enterprise Name:

Address:

Date of Filling:

Notes:

1. In accordance with the Provisions of the People's Republic of China on the Administration of Registration of Overseas Imported Food Production Enterprises (Decree No. 248 of the General Administration of Customs), the overseas edible oils and oil seeds production enterprises applying for registration with China shall establish effective food safety and hygiene management and protection system to ensure that the food exported to China complies with the relevant laws and regulations of China and the national food safety standards, and meets the relevant inspection and quarantine requirements agreed upon by the General Administration of Customs and the competent authorities of the countries (regions) where they are located. This form is for the foreign edible oils and oil seeds to conduct official inspection on edible oil and oil seeds production enterprises according to the listed main conditions and basis and against the inspection points. At the same time, edible oil and oil seeds production enterprises shall fill in and submit information to support the application form according to the listed main conditions and basis, and can also conduct self-inspection against the inspection points for self-evaluation before applying for registration.

2. Foreign competent authorities and foreign edible oil and oil seeds production enterprises must make a truthful judgment of conformity according to the actual situation of the control inspection.

3. The submitted materials shall be truly filled out in Chinese or English. The Appendix shall be numbered, and their numbers and contents shall accurately correspond to the item numbers and contents in the column of "Filling Requirements and Supporting Materials". The list of supporting materials shall be attached.

4. Edible oils refer to the single products or mixtures of vegetable oils prepared from edible vegetable oil seeds for processing or consumption as well as vegetable oils processed in one or several ways in refining and extraction. Oil Seeds refer to the kernels of oil seeds vegetables used to squeeze edible vegetable oil, such as Arachis hypogaea for oil and sesame seeds.

Items	Conditions and bases	Filling requirements and supporting materials	Key points for review	Conformity determination	Remarks
1. Enterprise Overview					
1.1. Enterprise Overview	1. Articles 5, 6, 7, and 8 of the Provisions of the People's Republic of China on the Administration of Registration of Overseas Imported Food Production Enterprises (Decree No. 248 of the General Administration of Customs) 2. Relevant Inspection and Quarantine Protocol signed between the competent authority of the applicant country and the General Administration of Customs.	1.1.1 Fill out the: 1. form of basic information of overseas production enterprises of imported edible oils and oil seeds; and 1.1.2An enterprise shall provide the production and operation information in the past 2 years (or information since the establishment of the enterprise in case of establishment for less than 2 years), including the production capacity, annual actual output (by variety), export volume (if any, by variety and country), etc.	1. Enterprises should truthfully fill in the information. The basic information should be consistent with that submitted by the competent authority of the exporting country and with the actual production and processing. 2. The edible oils and oil seeds to be exported to China shall conform to the product scope stipulated in relevant agreements, protocols, and memorandums on inspection and quarantine.	□ Conforming □ Non-conforming	
1.2Management system	1. Articles 5, 6, 7, and 8 of the Provisions of the People's Republic of China on the Administration of Registration of Overseas	1.2Enterprises shall provide management system documents in terms of phytosanitary prevention and control, food safety management, personnel management, chemical use, raw material acceptance, storage	The enterprise shall establish and effectively implement management procedure documents covering but not limited to the phytosanitary prevention and control, food	□ Conforming □ Non-conforming	

	Imported Food Production Enterprises (Decree No. 248 of the General Administration of Customs) 2. Relevant Inspection and Quarantine Protocol signed between the competent authority of the applicant country and the General Administration of Customs.	management, finished product export inspection, recall of unqualified products, traceability management, etc.	safety management, personnel management, use of chemicals, acceptance of raw materials, warehouse management, an inspection of the finished product for export purposes, recall of nonconforming products, and traceability management.		
1.3 Management organization	1. Articles 5, 6, 7, and 8 of the Provisions of the People's Republic of China on the Administration of Registration of Overseas Imported Food Production Enterprises (Decree No. 248 of the General Administration of Customs) 2. Protocol on Inspection and Quarantine of Edible Grains Exported to China signed by the competent authority of the applicant country and the General	1.3 Provide the information on the personnel assigned by the enterprise management organization and the departments or posts related to phytosanitary and food safety management.	The enterprise shall set up a department or post responsible for the management of plant health and food safety, and shall have management personnel with the background of these professions.	□ Conforming □ Non-conforming	

	Administration of Customs.				
2. Enterprise Location and Workshop Layout					
2.1 Site Selection and Plant Environment	1. Articles 3.1 and 3.2 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881) 2. Article 3.2 in the National Food Safety Standard— Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955)	2.1.1 Provide a plant plan, indicating the names of different operation areas. 2.1.2 The ground used for stacking and drying oil seeds shall not pollute food vegetable oil seeds, such as asphalt ground.	1. The plant layout meets the needs of production and processing. 2. There is no pollution source around the plant.	□ Conforming □ Non-conforming	
2.2 Workshop Layout	1. Article 4.1 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881) 2. Articles 4.2 and 4.3 in the National Food Safety Standard— Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB	2.2 Provide workshop plan. The edible oil filling area shall be separated from other operation areas to prevent cross contamination.	1. There shall be no factors that may cause contamination to products around the growing area of the enterprise	□ Conforming □ Non-conforming	

	8955)				
3. Facility and Equipment					
3.1 Production and Processing Equipment	1. Article 5.2.1 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881) 2. Article 5.4 in the National Food Safety Standard—Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955)	3.1 Provide a list of main production equipment and facilities and design production processing capacity.	1. The enterprise should be equipped with production and processing equipment suitable for the production and processing capacity.	□ Conforming □ Non-conforming □ NA	
3.2 Storage Facility	Article 10 of National Food Safety Standards General Hygienic Regulation for Food Production (GB 14881) 2. Article 5.4, 5.5, 5.6, and 5.7 in the National Food Safety Standard—Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955)	3.2 Provide information on storage tank, warehouse or goods yard.	1 Enterprises shall establish relatively independent and closed storage facilities suitable for production. The temperature, humidity, sanitation, and other conditions in the storage facilities shall be suitable for product storage.	□ Conforming □ Non-conforming □ NA	
4. Water/Ice/Steam					
4.1 Water/ice/steam	1. National Food Safety Standard—Standard for	4.1.1 Provide the required materials for steam condensation used in edible	The enterprise shall inspect the water quality of production water	□ Conforming □ Non-conforming	

for production and processing (if applicable)	Drinking Water Quality (GB 5749) 2. Article 5.2 in the National Food Safety Standard—Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955) 3. Articles 5.1. of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881)	oil processing in direct contact with the product. (If applicable)	(if used) to ensure it meets safety requirements.	□ NA	
5. Raw and Auxiliary Materials and Packaging Materials					
5.1 Acceptance of Raw and Auxiliary Materials	1. Article 7 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881)	5.1 Provide the acceptance measures, acceptance criteria, acceptance records, and harm-elimination records of raw materials.	1. The enterprise shall carry out plant quarantine and plant safety inspection of raw materials, or take necessary harm-elimination measures before they are delivered to the factory.	□ Conforming □ Non-conforming	
5.2 Source of Raw Materials	1. Table 1 in the National Food Safety Standard—Limit of Pathogens in Food Products (GB 29921)	5.2.1 Provide the evidentiary material for the compliance of raw materials. 5.2.2Provide materials to demonstrate that the raw materials purchased for the enterprise's production shall come from any area without the reporting	1. The raw materials used shall meet the requirements stipulated in Chinese laws and regulations, national food safety standards, relevant agreements, protocols, and memorandums on inspection	□ Conforming □ Non-conforming	

	2. National Food Safety Standards - Standard for the Use of Food Additives (GB 2760) 3. National Food Safety Standard - Limit of Mycotoxins in Foods (GB 2761) 4. National Food Safety Standard - Limit of Contaminants in Foods (GB 2762) 5. National Food Safety Standard - Maximum Residue Limits for Pesticides in Food (GB 2763) 6. National Food Safety Standard—Vegetable Oil (GB 2716) 7. National Food Safety Standard—Edible Vegetable Oil Seeds (GB 19641) 8. Regulations on Administration of Agricultural Genetically Modified Organisms Safety	of quarantine pests under close supervision of the Chinese government, and raw material suppliers shall have the qualification required by the local regulations. 5.2.3 Raw material types are genetically modified or non-genetically modified. Provide relevant evidentiary materials.	and quarantine, and other provisions. 2. Whether the enterprise has established raw material conformity assessment and implemented traceability management for the purchased raw materials in accordance with the requirements of the agreement.		

	9. Measures for the Administration on the Inspection and Quarantine of the Genetically Modified Organism Entering and Exiting the Territory				
5.3 Packaging Materials	1. Article 8.5 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881) 2. Article 7.4 in the Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955)	5.3.1 Provide proof that the inner and outer packaging materials are suitable for product packaging. 5.3.2 Provide label styles for finished products to be exported to China. (If applicable)	1. Packaging materials do not affect food safety and product characteristics under specific storage and use conditions. 2. Packaging labels shall meet the requirements of bilateral inspection and quarantine agreements, memorandums, and protocols.	□ Conforming □ Non-conforming □ NA	
6 Production and Processing Control					
6.1 Operation of food safety and hygiene control system	1. Article 8 of National Food Safety Standards General Hygienic Regulation for Food Production (GB 14881) 2. Article 8.1 in the National Food Safety Standard—Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955)	6.1.1 Provide the manufacturing process flow, indicate the critical control points (CCP) and the hazard control measures being taken. 6.1.2 If the HACCP system is adopted, provide hazard analysis worksheet and HACCP Schedule, CCP monitoring record, deviation correction record, and verification record sample sheet (if applicable).	1. The production and processing technology and flows and major relevant process parameters of the enterprise shall be scientific and standardized to ensure product safety. Moreover, special hazard control measures shall be taken, or critical control points (CCP) shall be set, for any and all processes crucial to controlling safety risk.	□ Conforming □ Non-conforming □ NA	

	3. Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Processing Plant (GB/T 27341).				
6.2 Temperature Control	1. Article 7.3 in the National Food Safety Standard—Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955)	6.2.1 Temperature and moisture records during storage	1. Silos and storage tanks storing bulk raw materials shall be placed by separate warehouses and tanks according to different varieties and different quality grades. The temperature and moisture shall be inspected and recorded for oil seeds during storage.	□ Conforming □ Non-conforming □ NA	
6.3 Use of food additives and nutritional fortification substances (if applicable)	1. Article 7.3 of National Food Safety Standards General Hygienic Regulation for Food Production (GB 14881) 2. Article 7.2 in the National Food Safety Standard— Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955) 3. National Food Safety Standards - Standard for the Use of Food Additives (GB 2760)	6.3 List of food additives and nutritional fortification substances used in production and processing (including designation, application, the volume of addition, etc.) (if applicable)	1. The food additives and nutritional fortification substances used in the production conform to China's regulations on the use of food additives.	□ Conforming □ Non-conforming □ NA	

	4. National Food Safety Standard for the Use of Nutritional Fortification Substances in Foods (GB 14880)				
7.Cleaning and Sanitizing					
7.1. Cleaning and Sanitizing	1. Article 8.2.1 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881)	7.1 Provide cleaning and disinfection equipment, washing and disinfectants adapted to production (provide lists) and provide use records and storage records.	1. Cleaning and disinfection measures should be able to eliminate cross contamination and meet hygiene requirements.	□ Conforming □ Non-conforming	
8 Safety risk control					
8.1Chemical Pollution Control	1. Article 8.3 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881) 2. Article 8.4 in the National Food Safety Standard—Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955) 3. National Food Safety Standard - Limit of Contaminants in Foods (GB 2762)	8.1.1 Provide food safety risk control measures and relevant monitoring records for heavy metals, pesticide residues, and food additives (if used) in the product. 8.1.2 Records of monitoring the key process parameters during the processing of edible oils and their products	1. Ensure compliance with the requirements of China and of the country of origin. 2. Monitoring of process parameters	□ Conforming □ Non-conforming □ NA	

	4. National Food Safety Standard—Maximum Residue Limits for Pesticides in Food (GB 2763) 5. National Food Safety Standards - Standard for the Use of Food Additives (GB 2760) 6. National Food Safety Standard for the Use of Nutritional Fortification Substances in Foods (GB 14880) 7. National Food Safety Standard—Vegetable Oil (GB 2716) 8. National Food Safety Standard—Edible Vegetable Oil Seeds (GB 19641)				
8.2 Physical contamination control	1. Article 8.4 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881) 2. Article 8.5 in the National Food Safety Standard— Specification for	8.2 Provide control measures for foreign matter.	1. Screens, filters, metal detectors, etc. shall be equipped to control foreign matters, formulate operating specifications, and conduct monitoring effectively. The source of foreign matter found shall be analyzed in a timely	□ Conforming □ Non-conforming	

	Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955)		manner and relevant control measures shall be taken.		
8.3 Biocontamination control	1. National Food Safety Standard - Limit of Mycotoxins in Foods (GB 2761) 2. National Food Safety Standard—Limit of Pathogens in Food Products (GB 29921)	8.3 Provide the control measures for microbial risks in the product as well as the relevant monitoring records.	1. The product complies with the requirements of China and the country of origin.	□ Conforming □ Non-conforming □ NA	
8.4 Disease-prone vector control	1. Article 6.4 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881) 2. Articles 6.2 and 7.3 in the National Food Safety Standard—Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955)	8.4.1 Vector control measures against mosquitoes, mice, and other vectors established by enterprises throughout all production processes 8.4.2 Photos of the installed protective facilities such as screens, rat guards, air curtains, etc. in the closed production and storage places such as filling workshops and warehouses 8.4.3 Pest inspection records of oil seeds during storage, and corresponding treatment measures taken for mildew and worm-eaten found	1. Insect and rat pests such as mosquitoes and flies shall be avoided to affect production safety and health. 2. Pest records of the oil seeds during storage	□ Conforming □ Non-conforming	

8.5 Waste Management	1. Article 6.5 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881)	8.5 Provide waste management system and relevant disposal records.	1. Edible product containers and waste storage containers in the workshop shall be clearly marked and distinguished. 2. Waste should be stored separately and disposed of in time to avoid pollution to production.	□ Conforming □ Non-conforming □ NA	
9. Product Traceability					
9.1 Traceability and Recall	1. Article 11 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881)	9.1. Describe the product traceability procedure in a brief manner and take the batch number of a batch of finished products as an example to illustrate how to trace raw materials from finished products.	1. Traceability procedures should be established to realize the two-way traceability of the whole chain from raw materials, production, and processing processes to finished products.	□ Conforming □ Non-conforming	
9.2Warehouse - in and out management	1. Article 11 and 14.1 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881)	9.2 Provide product warehouse-in and warehouse-out management.	1 Products shall be inspected before entering the warehouse, and the records of incoming inspection, storage, and delivery shall be well maintained and kept for at least 2 years.	□ Conforming □ Non-conforming	
10. Personnel Management and Training					
10.1 Personnel Health and Hygiene Management	1. Article 6.3 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881)	10.1 Provide pre-employment health management and medical examination requirements for employees.	1. Employees should have a medical examination and prove that they are suitable for working in food processing enterprises before employment.	□ Conforming □ Non-conforming	.

			2. Employees shall have regular physical examinations and keep records.		
10.2 Personnel Training	1. Article 12 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881)	10.2 Provide annual training plans, contents, assessments and records for employees.	1. The training shall cover relevant inspection and quarantine memorandums, agreements and protocols, Chinese regulations and standards, etc.	□ Conforming □ Non-conforming	
10.3 Requirements for management personnel	1. Article 13.3 of National Food Safety Standards - General Hygienic Regulation for Food Production (GB 14881)	10.3 Provide the training records of management personnel on the relevant provisions of the laws and regulations on phytosanitary and food safety of the country/region where the exported products are located and of China and conduct on-site sampling inspection and Q&A when necessary.	1. The business competence of the production and management personnel of the enterprise shall be adapted to the post requirements, familiar with the relevant provisions of phytosanitary and food safety laws and regulations in the country/region where it is located and China, and the requirements of the protocol and the Specification concluded by the two sides. 2. Have qualifications and capabilities suitable for their work.	□ Conforming □ Non-conforming	
11. Self-inspection and Self-control					
11 Product inspection	1. Article 9 of National Food Safety Standards - General Hygienic	11.1 Provide the items, indicators, inspection and quarantine methods,	1. The enterprise shall carry out plant quarantine, food safety, and other tests on the products,	□ Conforming □ Non-conforming	

	Regulation for Food Production (GB 14881) 2. Article 9 in the National Food Safety Standard—Specification for Production Hygiene of Edible Vegetable Oil and Its Product (GB 8955) 3. National Food Safety Standard—Vegetable Oil (GB 2716) 4. National Food Safety Standard—Edible Oil Products (GB 15196) 5. National Food Safety Standard—Edible Vegetable Oil Seeds (GB 19641) 6. National Food Safety Standards - Standard for the Use of Food Additives (GB 2760) 7. National Food Safety Standard for the Use of Nutritional Fortification Substances in Foods (GB 14880) 8. National Food Safety Standard - Limit of Mycotoxins in Foods (GB 2761)	and frequency of plant quarantine and food safety inspection. 11.2 If the enterprise has its own laboratory, please submit the laboratory capability and qualification certificates; if the enterprise entrusts a third-party laboratory, please provide the qualification certificates of the entrusted laboratory. 11.3 Inspection and testing records	ensuring that the results of tests meet the requirements of China. The test records shall be kept for no less than 2 years. 2. The enterprise shall be capable of inspecting and testing the phytosanitary and food safety or may entrust a qualified institution with such inspection and testing.		

	9. National Food Safety Standard - Limit of Contaminants in Foods (GB 2762) 10. National Food Safety Standard - Maximum Residue Limits for Pesticides in Food (GB 2763) 11. National Food Safety Standard—General Rules of Pre-packaged Food Labels (GB 7718) 12. National Food Safety Standard—General Rules for Nutrition Labeling of Prepackaged Foods (GB 28050) 13. National Food Safety Standard—Limited Concentrations of Radioactive Materials in Foods (GB 14882)				
12 Pest Control					
12.1 Prevention and control of quarantine pests of concern to China	Bilateral inspection and quarantine memorandum, agreement, and protocol	12.1 Provide the list of quarantine pests of concern to China and the monitoring system and records.	1. The enterprise shall take effective measures during production and storage to prevent products from being infected by harmful organisms, monitor the quarantine pests of concern to	□ Conforming □ Non-conforming □ NA	

			China, and keep the monitoring records for at least 2 years.		
12.2 Identification of Pests	Bilateral inspection and quarantine memorandum, agreement, and protocol	12.2 Provide the records of pests found during production and storage as well as the records of identification made by itself or entrusted professional institutions.	1. The enterprise shall be capable of identifying pests found during the processing of production and storage or entrust a professional organization with the identification, and establish work records, which shall be kept for no less than 2years.	□ Conforming □ Non-conforming □ NA	
12.3 Pest control	Bilateral inspection and quarantine memorandum, agreement, and protocol	12.3 Provide the records of implementation of pest control measures in production and storage areas.	1. The enterprise shall implement pest control measures in production and storage areas on a regular basis or when necessary. Relevant control measures shall be documented, and the records shall be kept for at least 2 years.	□ Conforming □ Non-conforming □ NA	
12.4 Fumigation treatment (if necessary)	Bilateral inspection and quarantine memorandum, agreement, and protocol	12.4 Provide the fumigation treatment method as well as the qualification of the fumigation institution and personnel.	1. Fumigation treatment method shall meet the requirements of China, and the institution and personnel conducting fumigation shall have relevant qualifications or conditions.	□ Conforming □ Non-conforming □ NA	
13. Statement					
13.1 Declaration by Enterprise	1. Articles 8 and 9 of the Provisions of the People's Republic of China on the Administration of Registration of Overseas		1. Signature of legal person and company seal	□ Conforming □ Non-conforming	

	Imported Food Production Enterprises (Decree No. 248 of the General Administration of Customs)				
13.2 Confirmation by Competent Authority	1. Articles 8 and 9 of the Provisions of the People's Republic of China on the Administration of Registration of Overseas Imported Food Production Enterprises (Decree No. 248 of the General Administration of Customs)		1.Signature of principal and seal of competent authority	□ Conforming □ Non-conforming	

3.4 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.

Registration process in brief

What are the application materials required under the recommendation for registration?	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.
What are the relevant application materials required under the self-registration section?	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.
Scope of the information to be submitted	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.
Inspection and evaluation	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.
Approval	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.