EuropeAid 139908/DH/SER/MULTI Contract: PI/2019/409-971/	EU-Asia Cooperation on (Phyto-) Sanitary (SPS) and Food Safety Regulation in China, India, Indonesia, Malaysia, Philippines, South Korea, Thailand, Vietnam
Ref: C02-2020	**REPORT: COMPARISON OF EU LAW VERSUS CHINESE LAW CONCERNING HYGIENE AND FOOD SAFETY OF DAIRY PRODUCTS**

A comparison of hygiene legislation and Food Safety Standards applicable to dairy products in the People's Republic of China and in the European Union

Project Activity C:	**Preparation of Guides for Applicants**
Task:	**C07-10 – 2022**
Specific ToRs approved on:	**17 August 2022**
Date of submission of the report:	**17 March 2023**
Version:	**FINAL DRAFT**

The content of this report reflects only the views of the consultant and not that of the European Commission.

INDEX

LIST OF NATIONAL STANDARDS ASSESSED

GB 16568-2006 - National food safety standard - Sanitary specification for dairy farm

GB/T 20014.8-2013 - National food safety standard - Good agricultural practice - Part 8: Dairy control points and compliance criteria

GB 14881 - General Hygiene Practice for food production

GB 12693-2010 - National food safety standard - Good manufacturing practice for milk products

GB 27341 - Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Processing Plant

GB/T 527342-2009 - National food safety standard - Hazard analysis and critical control point (HACCP) system - Requirements for dairy processing plant

GB 19301-2010 - National food safety standard – Raw milk

GB 19644-2010 - National food safety standard – Milk powder

GB 11674-2010 - National food safety standard – Whey powder and whey protein powder

GBT 5413.2-1997 - National food safety standard - Milk powder and formula foods for infant and young children - determination of whey protein

GB 25190-2010 - National food safety standard - Sterilized milk

GB 19645-2010 – National food safety standard - Pasteurized milk

GB 19302-2010 – Fermented milk

GB 19646-2010 – National food safety standard - Cream, butter and anhydrous milkfat

GB 25191-2010 – National food safety standard - Modified milk

GB 13102-2010 - National food safety standard **–** Evaporated milk, sweetened condensed milk and formulated condensed milk

GB 4789.18–2010 - National food safety standard - Food microbiological examination: Milk and milk products

GB/T 21732-2008 - National food safety standard - Milk beverages

GB 31638-2016 - National food safety standard - Casein

GB 5420–2021 - National food safety standard - Cheese

GB 25192-2022 - National food safety standard – Cheese and cheese products

GB/T 21704-2008 - National food safety standard - Determination of non-protein-nitrogen content in milk and dairy products

GB 2760-2015 Maximum levels of additives allowed in dairy products

GB 2761-2017 Maximum levels of mycotoxins allowed in dairy products

GB 2762-2017 Maximum levels of contaminants allowed in dairy products

GB 2763-2019 - National food safety standard - Maximum residue limits of pesticides

GB 29921 - National food safety standard - Maximum Residue Limit of Pathogens in Prepackaged Food

PROJECT BACKGROUND AND INTRODUCTION

The overall objective of the project is to contribute to the facilitation of trade in livestock products between the European Union and the People's Republic of China by a systematic comparison of hygiene and food safety standards applicable to these products. By identifying matching provisions – as well as 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.

The focus of this particular study is on dairy products.

European Union (EU) Regulations pertinent to food hygiene in general and dairy products in particular are laid down in the General Food Law (Regulation (EC) No 178/2002), the Hygiene Legislation (Regulations (EC) No 852, No 853 and Regulation (EU) 2017/625 on official controls and other official activities and the respective implementing rules, for example on microbiological criteria applicable to food (Regulation (EC) 2073/2005). In addition, various guidelines assist food business operators with implementing the legislative requirements, which are published as Commission notices (Commission Notice 2016/C 278/01 and Commission Notice 2020/C 199/01).

The basic legislation in China pertinent to food hygiene and safety of dairy products is laid down and published in 27 relevant Food Safety Standards that were examined in detail. The present document compares EU legislation applicable to the production of dairy products with the respective legal requirements of the People's Republic of China.

RESULTS AND CONCLUSIONS

The EU food law and Chinese food safety standards pursue the same objective and identify very similar end points. Process controls based on HACCP principles are mandatory for all food business operators and provide the core element of food safety controls for milk and dairy products in both regulatory systems. Limit values for biotic and abiotic contaminants are largely identical.

The Chinese food law includes numerous provisions for individual product categories such as milk powder, whey protein, sterilized milk etc., while the EU legislation addresses a broad range of products through a single legal act. Also methodological questions are frequently addressed in detail, while the EU legislation is less prescriptive and generally refers to internationally established methods. Both regulatory approaches are suitable to guarantee reliable analyses and are, therefore, considered equivalent. EU legislation is adapted to technical progress more easily, as any update of ISO standards automatically becomes legally binding without formal legislative and administrative procedures. Chinese standards often contain technical, physico-chemical and organoleptic criteria to identify certain products, which are addressed in the EU through the agricultural market order. These formal and legalistic differences are not relevant for the hygiene and safety of milk or dairy products exported to China. Obviously, food business operators must ensure that products exported to China comply with quality criteria and labelling rules applicable, but these questions are not relevant for the recommendation of their registration by competent authorities under GACC Decree 248.

The comparison of the microbiological limits applicable to dairy products shows few differences between the Chinese and the European requirements. While in the EU separate criteria were defined for process controls and market surveillance (process hygiene criteria and food safety criteria), in China only one set of criteria exists. However, in both systems very similar indicators of microbial contamination must be monitored and very similar limits must be observed. No criteria exist in EU legislation for mould in cheese, cheese products or fermented products. This occasionally causes trade issues and food business operators must ensure that products exported to China – in particular camembert-type cheeses - fulfil this requirement.

Also the list of pesticide residues and environmental contaminants for which limit values were defined for milk and dairy products 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.

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

TABULATED COMPARISON OF MAIN ELEMENTS OF CHINESE AND EU STANDARDS

Subject	Evaluation result
GB 16568-2006 - Sanitary specification for dairy farm	Minor differences exist in prescribed storage temperatures for fresh (raw) milk (6°C in EU law, 4°C in the Chinese national standard). This minimal difference will not affect the hygiene of the product. More relevant is the strict compliance with the requirements in practice.
GB/T 20014.8-2013 - Good agricultural practice, part 8 dairy control points and compliance criteria	Same conclusion as for GB 16568.
GB 14881 - General Hygiene Practice for food production	Chinese general food safety requirements with regard to process hygiene are fully addressed by applicable EU legislation. Legally authorized establishments that produce or process dairy products in the EU fulfil applicable Chinese hygiene standards.
GB 12693-2010 - Good manufacturing practice for milk products	All provisions of the standard are matched by similar rules that are applicable in the EU.
GB 27341 - Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Processing Plant	Chinese general requirements related the Hazard Analysis and Critical Control Points in food production are fully addressed by applicable EU legislation and guidance. Legally authorized establishments that produce or process dairy products in the EU fulfil Chinese HACCP standards.
GBT 527342 – 2009 - Hazard analysis and critical control point (HACCP) system - Requirements for dairy processing plant	All provisions of the standard are matched by similar rules that are applicable in the EU.
GB 19301-2010 – Raw milk	A minor difference in microbial characteristics was identified. In the Chinese national standard the limit for total number of colonies is ≤ 200 000 CFU/g (ml), while the EU legislative requirement is for raw cows' milk a plate count at 30° C (per ml) of ≤ 100 000 CFU/g (ml) is provided plus and a somatic cell count (per ml) of ≤ 400 000. Milk produced according to EU standards will fulfill Chinese criteria.
GB 19644 – 2010 – Milk powder	The microbiological criteria of the EU laid down in Regulation 2073/2005 include Enterobacteriaceae while Chinese standard select Coliform bacteria as model organism to identify faecal contamination. The criterion for Enterobacteriaceae in EU legislation is usually slightly stricter. It can be concluded that milk produced according to EU standards will fulfill Chinese criteria.

GB 11674-2010 Whey powder and whey protein powder	Same minor differences in microbiological criteria as discussed above.
GBT 5413.2-1997 - Milk powder and formula foods for infant and young children - determination of whey protein	EU legislation does not lay down a method for the determination of the casein to whey protein content in infant formulae and milk powders, however the EU food law provides that internationally established, validated methods must be used. This discrepancy s not considered relevant.
GB 25190-2010 - Sterilized milk	All provisions of the standard are matched by similar rules that are applicable in the EU.
GB 19645-2010 – Pasteurized milk	Same minor differences in microbiological criteria as discussed above.
GB 19302-2010 – Fermented milk	Same minor differences in microbiological criteria as discussed above. There is no criterion in EU legislation concerning the presence of mould in fermented milk. Food business operators must ensure that products exported to China fulfil this requirement.
GB 19646-2010 – Cream, butter and anhydrous milkfat	There are no criteria for mould in cream, butter or anhydrous milkfat in EU legislation.
GB 25191 – 2010 – Modified milk	All provisions of the standard are matched by similar rules that are applicable in the EU.
GB 13102 - 2010 – Evaporated milk, sweetened condensed milk and formulated condensed milk	All provisions of the standard are matched by similar rules that are applicable in the EU.
GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	All provisions of the standard are matched by similar rules that are applicable in the EU. Same minor differences in microbiological criteria as discussed above.
GB/T 21732-2008 Milk beverages	EU legislation does not provide a definition or specific rules for milk beverages. However, all provisions of the standard are matched by similar rules that are applicable in the EU for dairy products.
GB 31638-2016 – Casein	No microbiological criteria are defined specifically for casein in EU legislation. According to EU legislation, casein is a dairy product and, accordingly, pertinent microbial limits apply. These are consistent with Chinese food safety standards.
GB 5420 – 2021 - Cheese	All provisions of the standard are matched by similar rules that are applicable in the EU.
GB 25192 – 2022 - Cheese and cheese products	No criteria for mould in cheese and cheese products exist in EU legislation. This occasionally causes trade issues with camembert-type cheeses. Food business operators must ensure that products exported to China fulfil this requirement.

GB/T 21704-2008 – Determination of Non-Protein-Nitrogen content in milk and dairy products	EU legislation does not exist for non-protein nitrogen in milk and dairy products
GB 2760-2015 - principles for application of food additives	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.*
GB 2761-2017 Maximum levels of mycotoxins in food	Limit values applicable in the EU for Aflatoxin M1 are stricter than Chinese food safety standards.
GB 2762-2017 Maximum levels of contaminants in foods	In the Chinese National Standard specific limit values are defined for contamination with mercury, arsenic, chromium and nitrite in while in EU legislation the 'ALARA' Principle applies (as low as reasonably achieveable). These discrepancies are considered formal rather than substantial and will not affect consumer risk.
National standard GB 2763-2021 maximum residue limits of pesticides.	Chinese National standards define fewer MRLs in dairy products than EU legislation. Among the MRLs defined in both reulations, very few discrepancies were identified which are not considered relevant and will not affect consumer risk.
GB 29921 Maximum Residue Limit of Pathogens in Prepackaged Food	The provisions of the standard are matched by similar rules that are applicable in the EU.

DETAILED ANALYSIS

1 National standard GB 16568 - Sanitary specification for dairy farm

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
Scope This standard specifies the requirements for the environment and facilities of dairy farms, animal hygiene conditions, requirements for the introduction of cows, feeding hygiene, feeding management, staff health and hygiene, milking hygiene, hygiene for fresh milk preparation, storage and transport, immunisation and disinfection and monitoring, and decontamination. This standard applies to all dairy farms and the cows they keep. Other dairy farmers (points) are referred to for implementation.	**Regulation (EC) No 852/2004, Article 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; (e) guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with	The EU Commission has prepared a **Commission notice (2022/C 355/01)** to be used as a guidance document for food business operators to facilitate and harmonise the implementation of the EU requirements on PRPs and HACCP-based procedures by providing practical guidance. It will help food business operators to implement EU requirements after establishment of specific adaptations and without prejudice to their primary responsibility in matter of food safety.

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
	food hygiene rules and with the application of the HACCP principles; (f) it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment; (g) it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard. This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.	
3. Environment and facilities **3.1 Site** Dairy farms should be established on flat, dry terrain, with good water quality, sufficient water sources and no harmful pollution sources, and away from schools, public places, residential areas, protected areas of drinking water sources and areas requiring special protection under national and local laws and regulations.	**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. **Annex I, II** states: 2. As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo. 3. Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate Community and	**Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP** **3.1 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. This should also be considered for primary production (fields). *In the EU Guidance Document on the implementation of certain provisions of*

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
3.2 Layout and facilities 3.2.1 The farm should be divided into a management area and a production area, and be located upwind. The veterinary room, the isolation room for sick cattle and the manure treatment area should be located in the downwind direction. 3.2.2 The production area should be separated from the clean and dirty paths, with the dirty path downwind.	national legislative provisions relating to the control of hazards in primary production and associated operations, including: 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; **Regulation (EC) No 852/2004, Annex I, II, 4** states: Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate: (a) to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner; (b) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels; (c) as far as possible to ensure the cleanliness of animals going to slaughter and, where necessary, production animals;	*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. **Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP 3.1 Infrastructure:** b) Lay-out should strictly separate between contaminated (low care) and clean areas (high care) (or separation in time and suitable cleaning in between); suitable arrangements of rooms should be made for one-direction production flow and cooled rooms or heating facilities should be insulated.

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
	(f) as far as possible to prevent animals and pests from causing contamination; (h) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the competent authority;	
3.2.3 Roads within the farm area should be hard, level and free from stagnant water. The area outside the barn, exercise yard and roads should be green. 3.2.4 The barn should face south, be strong and durable, be spacious and bright, have good drainage, be well ventilated, be able to effectively discharge damp and dirty air, have facilities to prevent heat in summer, and the floor and walls should be made of materials that are easy to clean and disinfect. The ground at the entrance of the production area is equipped with a disinfection pool of not less than 3.8m, 3.0m and 0.1m in length, width and depth respectively, and personnel should enter the production area through the disinfection channel, which should have ground disinfection and UV disinfection facilities.	**Regulation (EU) 2016/429, Chapter 3, Section 1, Article 10 ("Animal Health Law")** 1. Operators shall: (b) where appropriate, take such biosecurity measures regarding kept animals, and products under their responsibility, as are appropriate for: (i) the species and categories of kept animals and products; (ii) the type of production; and (iii) the risks involved, taking into account: — geographical location and climatic conditions; — local circumstances and practices; 4. The biosecurity measures referred to in point (b) of paragraph 1 shall be implemented, as appropriate, through: (a) physical protection measures, which may include: (i) enclosing, fencing, roofing, netting, as appropriate;	**Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP** **3.1 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. This should also be considered for primary production (fields).

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
	(ii) cleaning, disinfection and control of insects and rodents; (b) management measures, which may include: (i) procedures for entering and exiting the establishment for animals, products, vehicles and persons; **Regulation (EC) No 852/2004, Annex I, II, 4** (g) to store and handle waste and hazardous substances so as to prevent contamination;	
3.2.5 The farm area should be equipped with cattle manure and urine treatment facilities, after treatment should be in line with the provisions of GB7959, the discharge of sewage out of the field must comply with the relevant provisions of GB 8978.		
3.2.6 Changing rooms, toilets, showers and rest rooms must be provided in the farm area. The changing rooms should be equipped with wardrobes according to the number of people. Toilets should have flushing devices, non-manual switch hand washing facilities and hand washing detergent.	(e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;	**Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP** **3.1 Infrastructure:** g) The specific clothes changing room(s) should be clean and ordered, not used as a refectory or a smoking room. A separation between normal clothing, clean work clothing and used work clothing should be facilitated. 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 and strategically placed signs informing about the obligation, when applicable, to remove protective clothing before using the toilets.

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
3.2.7 The site must have a microbiological and product quality inspection room appropriate to the production capacity and equipped with the necessary instruments and equipment for the work and with After training by the animal epidemic prevention and supervision institutions to assess the certification of the inspectors. 3.2.8 Special storage rooms and cabinets must be set up for dangerous goods in the farm, where toxic and harmful substances are stored and marked with a conspicuous "harmful" label. In the use of dangerous goods need to be approved by the special management and under the strict supervision of designated personnel use. **3.3 Field supply and drainage system** 3.3.1 There should be sufficient water for production in the site, water pressure and water temperature should meet the requirements of production, water quality should be in line with the provisions of NY5027. If equipped with water storage facilities, there should be anti-pollution measures, and regular cleaning and disinfection.	(i) to take account of the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health; (j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation. (d) to use potable water, or clean water, whenever necessary to prevent contamination;	i) Hand washing facilities should be positioned conveniently between toilets/changing rooms and the food handling area, not excluding the possible need for additional wash hand basins in production areas near work stations; disinfectants, soap and towels for single use should be available; installations blowing warm air should only be present in rooms without food and non-hand-operable taps are desirable. f) Clearly defined storage facilities should be available for raw material, and receptacles for food and packaging materials. Only products that may be added to food (e.g. additives) should be stored in the area with the food, excluding common storage with toxic products (e.g. pesticides). **Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP** **3.10 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.

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
3.3.2 The farm area should have a good drainage system and should not pollute the water supply system.		
4 Animal health conditions Dairy farms must obtain the Animal Epidemic Prevention Certificate issued by the animal epidemic prevention and supervision institution before engaging in the production and operation of dairy cattle.	Dairy farms must fulfill among others the requirements mentioned in **Regulation (EC) No 852/2004, Regulation (EC) No 853/2004, Annex III, Section IX and Regulation (EU) 2016/429 ("Animal Health Law").**	
5 Requirements for the introduction of dairy cattle 5.1 Cows that have passed the statutory quarantine and obtained a Certificate of Animal Quarantine Conformity should be introduced and reported to the local animal epidemic prevention and supervision agency prior to introduction and upon arrival. 5.2 Introduced cows should be kept in quarantine for 45 d and observed to be disease free before they are allowed to enter the production area.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum – primary production** 1. Raw milk and colostrum must come from animals: (a) that do not show any symptoms of infectious diseases communicable to humans through milk and colostrum; (b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and colostrum and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder; (c) that do not have any udder wound likely to affect the milk and colostrum;	

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
	(d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC; (e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed. 4. Raw milk and colostrum from any animal not complying with the appropriate requirements of points 1 to 3, and in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC, must not be used for human consumption. 5. The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in point 1 or 2 (*refers to brucellosis and tuberculosis*) must be effective to avoid any adverse effect on other animals' milk and colostrum.	
6 Feeding hygiene **6.1 Feed and feed additives** 6.1.1 The use of feed and feed additives should comply with the requirements stipulated in	**Regulation (EC) No 183/2005, Annex I, Primary production, part A:** 3. Feed business operators shall meet the obligations set out in points 1 and 2 by complying with appropriate Community and national	**Regulation (EC) No 999/2002, Article 7:** 1. The feeding to ruminants of protein derived from mammals is prohibited.

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
NY5032 and the feeding of ruminant-derived meat and bone meal is prohibited. 6.1.2 All kinds of forage should be clean and free from impurities. The transfer of forage from infected areas is strictly prohibited. Where possible, forage should be disinfected in a non-polluting manner.	legislative provisions relating to the control of hazards, including: (i) measures to control hazardous contamination such as that arising from the air, soil, water, fertilisers, plant protection products, biocides, veterinary medicinal products and handling and disposal of waste, and (ii) measures relating to plant health, animal health and the environment that have implications for feed safety, including programmes for the monitoring and control of zoonoses and zoonotic agents. **Regulation (EC) No 852/2004, Annex I, II, 4**	
6.2 Use of veterinary drugs The use of veterinary drugs should comply with the requirements of NY5030.	Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate: (j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.	**Regulation (EU) 2019/6** on veterinary medicinal products
6.3 Drinking water hygiene The requirements of NY5027 should be met. Drinking pools should be cleaned and water changed regularly.	(d) to use potable water, or clean water, whenever necessary to prevent contamination;	
7 Feeding management	**Regulation (EC) No 183/2005, Annex I, Primary production, part A:**	

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
7.1 Before feeding, forage should be cut short, discard soil, remove foreign matter and prevent pollution; root and tuber feeds should be cleaned and chopped to prevent freezing in winter. 7.2 Feed according to feeding regulations, do not stack troughs, do not empty troughs, do not feed mouldy, spoiled and frozen forage feed. 7.3 Wash the troughs, floors and walls of the barn every day to remove bedding, dirt and manure. The manure and dirt should be transported to the manure storage yard in time after the cleaning work. The manure of cattle in the exercise yard should be cleaned daily and collected in the manure storage yard. 7.4 Dairy farms should strengthen the veterinary epidemic prevention and management of dairy cattle rearing in accordance with the provisions of NY5047. The farm should regularly exterminate mosquitoes, flies and rats, remove weeds, and disinfect regularly with liquid that does not directly touch the cows and milk-holding utensils; annual inspection and deworming of parasitic diseases should be carried out in conjunction with the prevalence of local parasitic diseases; mastitis tests should be carried out regularly on cows and effective treatment should be given to sick cows. When a	4. Where appropriate, feed business operators shall take adequate measures, in particular: (a) to keep clean and, where necessary after cleaning, to disinfect in an appropriate manner, facilities, equipment, containers, crates and vehicles used for producing, preparing, grading, packing, storing and transporting feed; (b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, feed; (c) to use clean water whenever necessary to prevent hazardous contamination; (d) to prevent, as far as possible, animals and pests from causing hazardous contamination; (e) to store and handle wastes and hazardous substances, separately and securely, so as to prevent hazardous contamination; (f) to ensure that packaging materials are not a source of hazardous contamination of feed; **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum – primary production** 1. Raw milk and colostrum must come from animals:	

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
suspected epidemic is found, it shall be dealt with and reported in accordance with the Animal Epidemic Prevention Law of the People's Republic of China and relevant regulations. 7.5 No other livestock or poultry shall be kept on the farm and other livestock or poultry shall be prevented from entering the farm.	(a) that do not show any symptoms of infectious diseases communicable to humans through milk and colostrum; (b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and colostrum and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder; (c) that do not have any udder wound likely to affect the milk and colostrum; (d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC; 5. The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in point 1 or 2 must be effective to avoid any adverse effect on other animals' milk and colostrum. **Regulation (EC) No 852/2004, Annex I, II, 4** Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:	

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
7.6 Dairy farms should regularly carry out clinical health checks on cattle in accordance with the technical requirements stipulated in GB16549.	(f) as far as possible to prevent animals and pests from causing contamination; (h) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the competent authority; **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum – primary production** I, 1. Raw milk and colostrum must come from animals: (a) that do not show any symptoms of infectious diseases communicable to humans through milk and colostrum; (b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and colostrum and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;	
8 Staff health and hygiene 8.1 The staff of the farm should undergo annual health checks and obtain a health certificate before they are allowed to work. The relevant	**Regulation (EC) No 852/2004, Annex I, II, 4** Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:	**Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP** **3.11 Personnel** a) Personnel should be aware of hazards from gastro-intestinal infections, hepatitis and wounds

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
departments in the farm shall establish health records of the staff. 8.2 Those suffering from one of the following diseases shall not be engaged in forage and fodder acquisition, processing, feeding, milking and control work: - Dysentery, typhoid, curvular bacillosis, viral hepatitis and other infectious diseases of the digestive tract (including pathogen carriers). - Active tuberculosis, brucellosis. - Septic or exudative skin diseases. - Other diseases affecting human and animal health. 8.3 Milkers must not milk until they have sustained cuts and other open trauma to the hands. 8.4 Breeders and milkers must wear work clothes, a work cap and work shoes (boots) when working. Milkers must not wear ornaments or cosmetics at work and must trim their nails regularly. 8.5 The working cap, work clothes and working shoes (boots) of the breeder and milking staff shall be washed frequently and disinfected before use; public places such as changing rooms, shower rooms, rest rooms and toilets shall be cleaned, washed and disinfected frequently.	(e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks; **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum – primary production** **II, C - staff hygiene** 1. Persons performing milking and/or handling raw milk and colostrum must wear suitable clean clothes. 2. Persons performing milking must maintain a high degree of personal cleanliness. Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk and colostrum to wash their hands and arms.	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. b) Hands should be washed regularly (and disinfected if necessary), as a minimum, before starting work, after using the lavatory, after breaks, after rubbish disposal, after coughing or sneezing (in a disposable paper or, if no alternative, into your elbow), after handling of raw materials, between tasks, etc. Disposable gloves used hygienically can be effective in preventing cross contamination when handling ready-to-eat foods. Hands must be washed thoroughly before and after use. Gloves must be used only once and should be changed between tasks to prevent cross contamination. c) Hair covers (and beard snoods) should be considered and appropriate clothing with high degree of cleanliness, minimum of pockets, absence of jewelry and watches. The use by workers of clothing or items of clothing with different colors is recommended in different microbiological risk areas.

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
		d) Protective clothing should preferably not be worn when using the toilets or when wheeling the rubbish bins onto the street. e) Eating, drinking and/or smoking rooms should be separated and clean. f) First aid kits should be easily accessible and available for immediate use. g) The number of visitors should be minimized and visits should follow the conditions set by the FBO so as not to compromise the food safety. Visitors should at least wash hands and wear appropriate protective clothing, provided by the FBO.
9 Milking hygiene **9.1 Hand milking** 9.1.1 Brush and rinse the cow. 9.1.2 Remove faeces from the cow's bed and fix the cow's tail. Wash with warm water at 40°C to 45°C and use a clean towel to dry the udder. 9.1.3 When milking, the first and second milk should be discarded and the cow should be prevented from contaminating the milk with urine or faeces. 9.1.4 After milking the cow's teats should be disinfected one by one with a medicinal bath. 9.1.5 Milking should be done in the order of healthy cows first and then sick cows.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum – primary production** **II, B Hygiene during milking, collection and transport** 1. Milking must be carried out hygienically, ensuring in particular: (a) that, before milking starts, the teats, udder and adjacent parts are clean; (b) that milk and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and	

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
9.1.6 Milk from sick cows, especially milk from cows with mastitis or milk that has not passed the rest period after the use of antibiotics, should be stored separately and handled separately. 9.1.7 Milk holding utensils must be thoroughly cleaned and disinfected before and after use.	colostrum presenting such abnormalities is not used for human consumption; (c) that milk and colostrum from animals showing clinical signs of udder disease are not used for human consumption otherwise than in accordance with the instructions of a veterinarian; (d) the identification of animals undergoing medical treatment likely to transfer residues to the milk and colostrum, and that milk and colostrum obtained from such animals before the end of the prescribed withdrawal period are not used for human consumption; and (e) that teat dips or sprays are used only after authorisation or registration in accordance with the procedures laid down in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market;	
9.2 Machine milking 9.2.1 Milking machines should be kept in good condition when in use. Milk storage tanks and milking machines should be disinfected before use, cleaned in time after use and placed according to operational regulations. 9.2.2 Cows should be checked for disease before milking. Sick cows, especially those suffering	(f) that colostrum is milked separately and not mixed together with raw milk. *Legislation applies as mentioned for hand milking*	**Commission staff working document** Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin (SANCO/10098/2009 Rev. 3): **5.11. Automatic milking installations**

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
from mastitis or those that have not passed the rest period after using antibiotics, should not be milked on the machine and should be switched to hand milking and the milk squeezed out should be stored separately and handled separately. 9.2.3 Wash udder and teats with warm water and dry with disposable paper towels before milking. 9.2.4 Disinfect the teats with a disinfectant spray after milking.		Traditionally the milker checks the milk from each animal by visual inspection. Other methods achieving similar results may be used. Other methods are necessary if milking is performed using fully automated milking installations. In particular, it would be good practice that automatic milking installations should be able to detect abnormal milk automatically and separate it from the human consumption supply. An internationally recognised ISO standard concerning the requirements for automated milking installations has been developed and includes the methods used to check for organoleptic or physico-chemical abnormalities in the milk (ISO 20966:2007).
10 Fresh milk handling, storage and transport hygiene 10.1 Fresh milk should be stored in a single room, isolated from the barn, and protected from dust, flies and rodents. 10.2 Fresh milk must be filtered through a filter or multiple layers of gauze before it is put into containers for storage and should be cooled to 0°C-4°C within 2 hours.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum – primary production** **II, B Hygiene during milking, collection and transport** 2. Immediately after milking, milk and colostrum must be held in a clean place designed and equipped to avoid contamination. (a) Milk must be cooled immediately to not more than 8° C in the case of daily collection, or not more than 6° C if collection is not daily;	*The minimal difference in prescribed storage temperature will not affect the hygiene of the product. More relevant is the strict compliance with the requirements in practice.*

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
10.3 The hygiene of milk tankers or drums used to transport fresh milk should comply with the relevant provisions in GB12693. 10.4 The quality of fresh milk from the time it is extruded to the time it is processed to prevent contamination should conform to the provisions of NY5045.	(b) Colostrum must be stored separately and immediately cooled to not more than 8° C in the case of daily collection, or not more than 6° C if collection is not daily, or frozen. 3. During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk and the colostrum must not be more than 10° C. 4. Food business operators need not comply with the temperature requirements laid down in points 2 and 3 if the milk meets the criteria provided for in Part III and either: (a) the milk is processed within two hours of milking; or (b) a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises. *Requirements for vaccination of (listed) diseases is laid down in* **Regulation (EU) 2016/429 ("Animal Health Law")**	
11 Immunisation and disinfection 11.1 Immunisation of cows should be carried out in strict accordance with national regulations. However, cows should not be immunised against brucellosis.		**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum – primary production** **I Health requirements** 2. (a) In particular, as regards brucellosis, raw milk and colostrum must come from:

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
11.2 A sound disinfection system should be established on dairy farms. Disinfection shall be carried out in accordance with the provisions of NY/T 5049. **12 Monitoring and decontamination** 12.1 Dairy farms shall be subject to regular annual monitoring by animal epidemic	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum – primary production** **II, A requirements for premises and equipment** 3. Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and must be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials. 4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once a day, containers and tanks used for the transport of milk and colostrum must be cleaned and disinfected in an appropriate manner before re-use. **Regulation (EC) No 852/2004, Annex I, III: record-keeping** 7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the	(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is free or officially free of brucellosis;

Chinese National Standard GB 16568	EU legislation	Implementing rules and comparative evaluation
prevention and supervision institutions at or above the county level in accordance with the law. Cows and their products found to be positive for tuberculosis, brucellosis and other diseases shall be firmly destroyed. 12.2 The animal epidemic prevention and supervision agency shall issue a health certificate to cows that do not show any abnormality in the clinical examination and pass the monitoring. 12.3 A cow health file should be established on each cow on the dairy farm, recording the cow's health, medication, immunisation and monitoring status.	nature and size of the food business. Food business operators are to make relevant information contained in these records available to the competent authority and receiving food business operators on request. 8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on: (a) the nature and origin of feed fed to the animals; (b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods; (c) the occurrence of diseases that may affect the safety of products of animal origin; (d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health; and (e) any relevant reports on checks carried out on animals or products of animal origin.	

2 National standard GB/T 20014.8-2013 - Good agricultural practice, part 8 dairy control points and compliance criteria

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4 Requirements **4.1 Registration** 4.1.1 Dairy farms should obtain the relevant permits and registration documents, and dairy breeds should be registered with the national or industry-authorised authorities in a uniform manner. 4.1.2 Dairy farms should obtain a Raw Milk Acquisition Permit in accordance with the provisions of the Regulations on the Supervision and Administration of Dairy Products Quality and Safety. The means of transport and the transport and purchase handover form shall be issued by the local animal husbandry and veterinary authorities as "Raw Milk Permit" and "Raw Milk Transport and Purchase Handover Form".	**Regulation (EC) No 852/2004, Article 6** 2. In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment. **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum- primary production** Food business operators producing or, as appropriate, collecting raw milk and colostrum must ensure compliance with the requirements laid down in this Chapter. **I. Health requirements for raw milk and colostrum production** **II. Hygiene on milk and colostrum production holdings** **III. Criteria for raw milk and colostrum** **Chapter II: requirements concerning dairy and colostrum-based products**	*No permit is necessary for dairy farms in the EU as long as the requirements (registration, hygiene, animal welfare) are fulfilled.*

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4.2 Feed 4.2.1 Dairy farms should be counselled on nutrition and scientific feeding 4.2.2 A suitable feeding plan is established and implemented and reviewed more than twice a year. 4.2.3 The dairy cow's diet should not contain drugs and feeds of animal origin other than milk and its products, which are prohibited by relevant national policies and regulations. 4.2.4 Feeding systems should provide sufficient feeding space for cattle of different ages and weights. Feeding on the ground inside the enclosure is not permitted.	**Council Directive 98/58/EC** (concerning the protection of animals kept for farming purposes), **Annex point 14.** Animals must be fed a wholesome diet which is appropriate to their age and species and which is fed to them in sufficient quantity to maintain them in good health and satisfy their nutritional needs. No animal shall be provided with food or liquid in a manner, nor shall such food or liquid contain any substance, which may cause unnecessary suffering or injury. 15. All animals must have access to feed at intervals appropriate to their physiological needs. 16. All animals must have access to a suitable water supply or be able to satisfy their fluid intake needs by other means. 17. Feeding and watering equipment must be designed, constructed and placed so that contamination of food and water and the harmful effects of competition between the animals are minimised.	*Good agricultural practice is generally explained for the food business operators in various guides to good practice. Some examples on milk production and/or feeding of dairy cattle:* 1. Branschriktlinjer för hygienisk mjölkproduktion (= Swedish national guide on good practice for hygienic milk production published in 2018) 2. Branschriktlinjer för hygienisk produktion av mjölkprodukter (= Swedish national guide on good practice for hygienic production of milk products published in 2017). 3. Guia de Boas Práticas de Alimentação Animal na Exploração Pecuária (= Portuguese national guide on good practice for animal feeding at the farm level published in 2009). 4. Industry Guide to Good Hygiene Practice Milk and Dairy Products (British national guide on good practice published in 2010). 5. Handboek 37 melkveehouderij 2018/19 (published by ZuivelNL and Wageningen University). 6. Hygienecode zuivel (= Dutch national guide on good practice published in 2011).
4.3 Housing and facilities **4.3.1 General rules**	**Regulation (EC) No 852/2004, Annex I** *lays down general hygiene rules for primary production.* **Regulation (EC) No 852/2004, Annex II** *lays down more detailed hygiene rules for food premises.*	**Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP** **3.1 Infrastructure:**

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4.3.1.1 The floor of the barn should be stable and non-slip, and its resting area floor should be free of leaking joints. 4.3.1.2 All aisles should be well maintained to minimise injury to cows. 4.3.1.3 Horned and hornless cows should be kept in separate groups. 4.3.1.4 Calves should be dehorned 4.3.1.5 The barn should be well ventilated and the temperature and humidity should be appropriate. 4.3.1.6 The barn should be warm in winter and cool in summer, should have a good manure and	**Council Directive 98/58/EC** (concerning the protection of animals kept for farming purposes), **Annex point 8.** Materials to be used for the construction of accommodation, and in particular for the construction of pens an equipment with which the animals may come into contact, must not be harmful to the animals and must be capable of being thoroughly cleaned and disinfected. 9. Accommodation and fittings for securing animals shall be constructed and maintained so that there are no sharp edges or protrusions likely to cause injury to the animals. 21. No animal shall be kept for farming purposes unless it can reasonably be expected, on the basis of its genotype or phenotype, that it can be kept without detrimental effect on its health or welfare. 10. Air circulation, dust levels, temperature, relative air humidity and gas concentrations must be kept within limits which are not harmful to the animals.	c) Non-slippery floors should be constructed with waterproof, non-absorbent material, and should be washable and without fissures. Walls should be likewise at least up to appropriate height. It is also recommended that walls and floors are in light colors that facilitate visual hygiene assessment. **Recommendation concerning cattle** (adopted by the Council of Europe on 21 October 1988) **Article 17, 1.** Procedures resulting in the loss of a significant amount of tissue, or the modification of bone structure of cattle shall be forbidden, and in particular: b. dehorning by other means than the surgical removal of the horns;

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
urine removal system and the resting area should be kept dry. 4.3.1.7 The barn and its facilities are easily cleaned and disinfected 4.3.1.8 Cows not housed should be provided with adequate, dry lying and free-range areas. 4.3.1.9 Cows should not be affected by the external environment 4.3.1.10 The barn should be thoroughly cleaned at least once a year 4.3.1.11 Cattle yard facilities such as ventilation equipment should be cleaned regularly.	**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. **Council Directive 98/58/EC** (concerning the protection of animals kept for farming purposes), **Annex point 12.** Animals not kept in buildings shall where necessary and possible be given protection from adverse weather conditions, predators and risks to their health. **Council Directive 98/58/EC** (concerning the protection of animals kept for farming purposes), **Annex point 13**. All automated or mechanical equipment essential for the health and well-being of the animals must be inspected at least once daily. Where defects are discovered, these must be rectified immediately, or if this is	**Recommendation concerning cattle** (adopted by the Council of Europe on 21 October 1988) **Article 11**: 2. The facilities for storing and handling manure in or outside the accommodation shall be designed, maintained and managed to prevent the exposure of the animals to gases in concentrations detrimental to their health.

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4.3.2 Bonding facilities There should be holding facilities for the isolation of sick and injured livestock. Access for veterinary treatment, equipment for treatment, adequate light and washable walls above 2m of washable wall surface. **4.3.3 Plain and open cattle pens (not applicable without plain or open pens)** 4.3.3.1 Plain and open pens should ensure that the behaviour of cows such as lying down, regurgitating and standing up is not affected. 4.3.3.2 Cows should be provided with a dry and comfortable resting place with clean and dry bedding or cow. The cow shall be provided with a dry and comfortable resting place with clean and dry bedding or bedding. 4.3.3.3 Daily hygiene cleaning and bedding removal should ensure that cattle beds are clean and dry.	impossible, appropriate steps must be taken to safeguard the health and well-being of the animals. **Council Directive 98/58/EC, Annex point 4.** Any animal which appears to be ill or injured must be cared for appropriately without delay and, where an animal does not respond to such care, veterinary advice must be obtained as soon as possible. Where necessary sick or injured animals shall be isolated in suitable accommodation with, where appropriate, dry comfortable bedding. 7. The freedom of movement of an animal, having regard to its species and in accordance with established experience and scientific knowledge, must not be restricted in such a way as to cause it unnecessary suffering or injury. 1. Animals shall be cared for by a sufficient number of staff who possess the appropriate ability, knowledge and professional competence. 2. All animals kept in husbandry systems in which their welfare depends on frequent human attention shall be inspected at least once a day. Animals in other systems shall be inspected at intervals sufficient to avoid any suffering.	**Recommendation concerning cattle** (adopted by the Council of Europe on 21 October 1988), Appendix B: special provisions for cows and heifers 1. In loose housing, the number of animals housed should not exceed the number of cubicles available nor, if roughage is not provided ad lib., the number of eating places. It is advisable that spare cubicles should be available. The design and dimensions of the passageways and of the

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4.3.3.4 Adequate bedding should be provided to prevent injury to cattle. 4.3.3.5 Adequate number of free lying pens are provided and there should be at least one pen for each cow. 4.3.3.6 For a given herd, the number of pens available should exceed the needs of the cows, preferably by more than 5% of the maximum number of cows to be housed. 4.3.3.7 Provide suitable free-range areas, the calculation of which should be based on the average of the areas required for 10% of the largest individuals in the group. 4.3.3.8 The design of the cattle bed or pen should provide a comfortable space for the cow. **4.3.4 Exercise yards** 4.3.4.1 Free-range housing should provide space large enough to allow all cows to lie, regurgitate and stand freely at the same time, as required by cow housing density. 4.3.4.2 The dairy cow exercise yard should be large enough to meet the needs of this herd. 4.3.4.3 The calculation of the area of exercise yard required per cow should be based on the average of the area required for the largest 10% of individuals in the group.		exercising area shall be such as to avoid unnecessary social pressure. **Recommendation concerning cattle** (adopted by the Council of Europe on 21 October 1988) **Article 8**: The space allowance for cattle housed in groups should be calculated in relation to the whole environment, the age, sex, live weight and behavioural needs of the stock, taking account of the presence or absence of horns and the size of the group. Lack of space or overstocking leading to trampling, behavioural or other disorders shall be avoided. **Recommendation concerning cattle** (adopted by the Council of Europe on 21 October 1988), **Article 16** 1. Where cattle are kept outdoors in areas without natural shelter or shade some form of protection from the weather should be provided.

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4.3.4.4 Dairy cattle exercise areas should be kept clean and dry. 4.3.4.5 Daily hygiene cleaning such as manure removal and bedding removal should be carried out to maintain a clean and hygienic environment and to avoid contamination by excessive dust, manure etc.		2. Pastures should be selected and managed in such a way so as to ensure grazing animals are not subjected to physical, chemical or other health hazards which can be reasonably avoided by the stockkeeper. **Recommendation concerning cattle** (adopted by the Council of Europe on 21 October 1988), **Article 9** 1. Animals should be maintained in a clean condition. 2. Those parts of the accommodation with which the animals come into contact should be thoroughly cleansed, and where appropriate, disinfected, every time the accommodation has been emptied and before new animals are brought in. While the accommodation is occupied by the animals, the interior surfaces and all equipment therein shall be kept satisfactorily clean.
4.4 Veterinary Health Programme 4.4.1 All cows should receive regular annual veterinary checks. To safeguard the health of the herd, accurate records of veterinary examinations should be kept. If a veterinarian finds a problem, corrective action should be taken	**Council Directive 98/58/EC, Annex point 4.** Any animal which appears to be ill or injured must be cared for appropriately without delay and, where an animal does not respond to such care, veterinary advice must be obtained as soon as possible.	

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4.4.2 The veterinary health programme should contain routine preventive measures: e.g. hoof care (prevention of hoof and hoof rot), tuberculosis and brucellosis monitoring and decontamination, mastitis prevention, vaccination and deworming procedures.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum- primary production** Food business operators producing or, as appropriate, collecting raw milk and colostrum must ensure compliance with the requirements laid down in this Chapter. **I. Health requirements for raw milk and colostrum production** 1. Raw milk and colostrum must come from animals: (a) that do not show any symptoms of infectious diseases communicable to humans through milk and colostrum; (b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and colostrum and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder; c) that do not have any udder wound likely to affect the milk and colostrum; 2. (a) In particular, as regards brucellosis, raw milk and colostrum must come from: (i) cows or buffaloes belonging to a herd which, within the	

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4.4.3 Records of herd health monitoring should be kept. 4.4.4 The quality of the cow and the animal health of the cow should be determined from the results of analytical testing of raw milk.	meaning of Directive 64/432/EEC (1), is free or officially free of brucellosis; b) As regards tuberculosis, raw milk and colostrum must come from: (i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis; **Regulation (EC) No 852/2004, Annex I, III.** Record keeping 7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Food business operators are to make relevant information contained in these records available to the competent authority and receiving food business operators on request. 8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on: (b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods; (c) the occurrence of diseases that may affect the safety of products of animal origin;	

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4.4.5 Dairy farms should establish a cleaning and disinfection system and regularly disinfect the environment around the farm, employees and their clothing, the barn, production utensils and cattle bodies. The dairy farm's Hygiene complies with the requirements of GB 16568.	(d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health; **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum- primary production II Hygiene on milk and colostrum production holdings, A Requirements:** 3. Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and must be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.	
4.4.6 Establish contingency measures for sudden onset infectious diseases. The emergence of a statutory category 1 infectious disease should be reported to the relevant authorities in a timely manner and appropriate measures should be taken.	**Regulation (EU) 2016/429, Part 3, Title 1, Chapter 1, Article 43 ("Animal Health Law")** 1. The Member States shall, after appropriate consultation of experts and relevant stakeholders, draw up, and keep up to date, contingency plans and, where necessary, detailed instruction manuals laying down the measures to be taken in the Member State concerned in the event of the occurrence of a listed disease referred to in point (a) of Article 9(1) or, as the	→ preparedness and the ability to launch a rapid response. **Regulation (EU) 2016/429, Part 3, Title 1, Chapter 1, Article 43** continued: 2. Those contingency plans and, where applicable, detailed instruction manuals shall cover at least the following matters: etc, etc.

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
	case may be, of an emerging disease, in order to ensure a high level of disease awareness and →	
4.5 Milking 4.5.1 Regular milking practices shall be established. 4.5.2 All milking facilities, including floors, shall be structurally designed to minimise injury to cows. 4.5.3 The parlour should be equipped to ensure that the cow is comfortable and does not cause discomfort during milking. 4.5.4 In addition to having records of drug use, a drug tracking and monitoring system should be in place and effectively implemented to ensure that milk produced by cows that have used drugs during the off period is treated harmlessly and does not reach the market. 4.5.5 Milking procedures should be developed to ensure that the cow's udder is clean and dry prior to milking. 4.5.6 Clean water for washing dirty cows and their rump and tail, the floor and potable water for cleaning milking equipment during milking shall be readily available. 4.5.7 Each cow is checked for abnormalities and infectious diseases before being admitted to the parlour	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum- primary production II Hygiene on milk and colostrum production holdings, B Hygiene during milking:** 1. Milking must be carried out hygienically, ensuring in particular: (a) that, before milking starts, the teats, udder and adjacent parts are clean; (b) that milk and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption; (c) that milk and colostrum from animals showing clinical signs of udder disease are not used for human consumption otherwise than in accordance with the instructions of a veterinarian; (d) the identification of animals undergoing medical treatment likely to transfer residues to the milk and colostrum, and that milk and colostrum obtained from such animals before the end of the prescribed withdrawal period are not used for human consumption; and	

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4.5.8 Sick cows with mastitis should be promptly reported to the veterinarian and promptly treated by hand milking. Mechanical milking shall not be used on cows with mastitis.	(e) that teat dips or sprays are used only after authorisation or registration in accordance with the procedures laid down in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (f) that colostrum is milked separately and not mixed together with raw milk.	
4.6 Milking facilities **4.6.1 Milking equipment** 4.6.1.1 Equipment and appliances in contact with raw milk should be inspected and identified at least once a year. The equipment should be used in accordance with the requirements of the dairy farm and the manufacturer. The results of the appraisal and test records are well maintained. 4.6.1.2 Records should be kept of replacement of milking cup liners and worn parts as required by the manufacturer. 4.6.1.3 Records shall be kept to ensure that the water used for recirculating scrubbing and cleaning meets the requirements of GB 5749 and that the water temperature is appropriate. Chemicals used for washing and cleaning equipment are used according to instructions.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum- primary production II Hygiene on milk and colostrum production holdings, A Requirements for premises and equipment:** 1. Milking equipment and premises where milk and colostrum are stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk and colostrum. **Regulation (EC) No 852/2004, Annex I, III, Record keeping** 7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Food business operators are to make relevant information contained in these records available	

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
	to the competent authority and receiving food business operators on request. 8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records…	
4.6.2 Milking parlour 4.6.2.1 The milking parlour shall maintain. -free from pests, birds and pets.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum- primary production II Hygiene on milk and colostrum production holdings, A Requirements for premises and equipment:**	**Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP** **3.3 Pest control:** f) A pest control program should be available
- free from potential contamination hazards such as fragile glass, impurities, etc.	2. Premises for the storage of milk and colostrum must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment.	**3.6 physical and chemical contaminations** 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?).
-walls, gates and floors easily cleaned and washed.	3. Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and must be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.	b) A procedure should be available explaining what to do in case of breakage of glass, hard plastic, knives, etc. **3.1 Infrastructure:**
-sufficient brightness.	4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period	c) Non-slippery floors should be constructed with waterproof, non-absorbent material, and should be washable and without fissures. Walls should be likewise at least up to appropriate height. It is also recommended that walls and floors are in light colors that facilitate visual hygiene assessment.

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
-Walls and windows designed with devices or facilities to protect against the effects of weather -free from hiding places for pest animals and birds. -cleanliness of equipment maintained in accordance with relevant operating instructions. -free from unwanted residues. -free of litter and waste.	of time between unloading and the following loading is very short, but in all cases at least once a day, containers and tanks used for the transport of milk and colostrum must be cleaned and disinfected in an appropriate manner before re-use. **Regulation (EC) No 852/2004, Annex II, Chapter VI Food waste** 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. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect. 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.	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. **3.3 Pest control:** a) External walls should be free of cracks or chinks, surroundings should be neat and free from debris which could provide harborage from pests, and areas for cleaning should be accessible. Access by pets or wild animals must be prohibited/ prevented. b) Insect screen should be placed at windows. When electronic devices are used for insect control, the device has to be used according to its specification.
-Good drainage. 4.6.2.2 The milking parlour shall have a clear drainage system. The sewer has an easy-to-clean anti-odour device to ensure that the parlour is free of foul air and odours. Wastewater discharge	**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	

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
is treated in accordance with GB18596 to avoid contamination of surface and ground water. 4.6.2.3 Documented standard operating procedures for milking hygiene are established. **4.6.3 Milk storage hall** 4.6.3.1 The milk storage parlour shall be maintained. -a dedicated door leading to the milk storage hall. -security measures and requirements to prevent casual entry by uninvolved persons. -with personal hygiene facilities. -free from birds, vermin, cats, dogs, etc. -have measures in place to control pests. -free of hiding places for vermin and pest birds -free from other debris and waste. -lighting should have an explosion-proof cover or explosion-proof device. -The floor is sufficiently spacious. -free from dirt or litter.	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. **Regulation (EC) No 852/2004, Annex I, III Record keeping** 7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. **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;	**Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP,** **3.1 Infrastructure** 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 and strategically placed

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
-walls and doors are easy to clean and wash. -free from wind, rain, cold air, etc. entering the hall. -Smoking is strictly prohibited 4.6.3.2 The milk storage room should be kept clean and hygienic at all times. **4.6.4 Milk collection equipment (storage tanks, mixing systems, etc.)** 4.6.4.1 All equipment used to collect raw milk should be clean and in a closed position when empty.	(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control; 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. 9. Where necessary, adequate changing facilities for personnel are to be provided. 10. Cleaning agents and disinfectants are not to be stored in areas where food is handled 1. Food premises are to be kept clean and maintained in good repair and condition. **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 **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum- primary production II Hygiene on milk and colostrum production holdings, A Requirements for premises and equipment:** 3. Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils, containers, tanks, etc. intended for	signs informing about the obligation, when applicable, to remove protective clothing before using the toilets. j) Barriers should be in place to avoid access of stray animals. **3.3 Pest control** a) External walls should be free of cracks or chinks, surroundings neat and free from debris which could provide harborage from pests, and areas for cleaning should be accessible. Access by pets or wild animals must be prohibited/ prevented. f) A pest control program should be available. **3.11 Personnel** e) Eating, drinking and/or smoking rooms should be separated and clean.

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
	milking, collection or transport) must be easy to clean and, where necessary, disinfect and must be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials. **II, B Hygiene during milking** 2. Immediately after milking, milk and colostrum must be held in a clean place designed and equipped to avoid contamination. (a) Milk must be cooled immediately to not more than 8° C in the case of daily collection, or not more than 6° C if collection is not daily;	
4.6.4.2 Raw milk should be cooled to below 4°C within 2h.		*There is a difference in cooling temperature of raw milk after milking*.
4.6.4.3 All surfaces of materials in contact with raw milk should be kept clean to avoid contamination.	**II, A Requirements for premises and equipment:** 1. Milking equipment and premises where milk and colostrum are stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk and colostrum.	
4.6.5 Milk tanker parking sites 4.6.5.1 There shall be a well-drained hard surface connected to the milk storage hall to facilitate the movement of milk tankers. 4.6.5.2 The milk tanker docking site should be kept clean and protected from contamination. 4.6.5.3 The milk tanker docking site should be free of other obstructions.	**Regulation (EC) No 852/2004, Annex II, Chapter IV Transport** 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	

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
	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. 4. Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked 'for foodstuffs only'.	
4.7 Health 4.7.1 Dairy employees shall have a valid medical examination at least once a year and the relevant department shall establish a health file for the employees 4.7.2 Employees involved in milking should wear clean and appropriate work clothes, work caps and work shoes (boots). Milkers shall not wear accessories and cosmetics when on duty and shall trim their nails regularly.	**Regulation (EC) No 852/2004, Annex II, 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. 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	**Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP, 3.11:** 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.

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4.7.3 Milkers with traumatic injuries should be temporarily removed from work. 4.7.4 Employees with infectious diseases should be registered and prohibited from participating in any work on the dairy farm. 4.7.5 The arms of milkers or employees who have direct contact with milk should be clean and hygienic. 4.7.6 Smoking shall be prohibited in the dairy. 4.7.7 Documented hygiene management practices related to the dairy farm are established.	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. **Regulation (EC) No 852/2004, Annex I, III** 7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business.	b) Hands should be washed regularly (and disinfected if necessary), as a minimum, before starting work, after using the lavatory, after breaks, after rubbish disposal, after coughing or sneezing (in a disposable paper or, if no alternative, into your elbow), after handling of raw materials, between tasks, etc. Disposable gloves used hygienically can be effective in preventing cross contamination when handling ready-to-eat foods. Hands must be washed thoroughly before and after use. Gloves must be used only once and should be changed between tasks to prevent cross contamination. e) Eating, drinking and/or smoking rooms should be separated and clean. g) The number of visitors should be minimized and visits should follow the conditions set by the FBO so as not to compromise the food safety. Visitors should at least wash hands and wear appropriate protective clothing, provided by the FBO..
4.8 Cleaning and disinfecting agents and other chemicals 4.8.1 The use of chemicals, insecticides or other cleaning and disinfecting agents should be carried out in strict accordance with the instructions for use.	**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. **Chapter V** 3. Where chemical additives have to be used to prevent corrosion of equipment and containers,	**Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP** **3.2 Cleaning and disinfection** a) What, when, how and by who to clean and disinfect should be considered.

GB/T 20014.8-2013 - Good agricultural practice	EU legislation	Implementing rules and comparative evaluation
4.8.2 Prohibited chemicals shall be prohibited in the dairy station. 4.8.3 Pest control methods or treatment options should be confirmed before use. 4.8.4 Chemicals temporarily not in use should be stored in controlled locations away from equipment associated with the milking facility. 4.8.5 There shall be documented cleaning and disinfection procedures and records. Documentation of cleaning and disinfectant use and supplier instructions is available.	they are to be used in accordance with good practice. **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. **Regulation (EC) No 852/2004, Annex I, III** 7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business.	b) Typical steps should be the removal of visible dirt, followed by cleaning, followed by rinsing, followed by disinfection and rinsing again. c) Cleaning should start in high risk areas and should end in low risk areas. Materials and equipment for cleaning equipment should be different between low and high risk areas and in any case never move from a high contaminated area to a low one. Special attention must be paid to the contamination of disinfected surfaces due to splash when rinsing other surfaces. d) Potable water and/or cleaning agent or disinfectant should be used as much as needed to gain the desired effect in cleaning and/or disinfection. The water should be at an appropriate temperature and the chemicals should be used as per the manufacturer's instructions. e) Technical information should be available in your native language regarding detergents, disinfection agents (e.g. instructions for use, active component, contact time, concentration, use of potable water if appropriate). f) Visual checks on cleaning and sampling for analysis should be used to control disinfection activities.

3 GB 14881 General Hygiene Practice for food production

As outlined in deail in the tabulated comparison below, Chinese general food safety requirements with regard to process hygiene are fully addressed by applicable EU legislation. Legally authorized establishments that produce or process dairy products in the EU fulfil applicable Chinese hygiene standards.

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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;	

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
	(f) it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment; (g) it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard. This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.	
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	**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.**	**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

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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 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 business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies *(see Article 4.1.)* shall comply with the general hygiene requirements laid down in Annex II. Chapter I of Annex II states: Food premises are to be kept clean and maintained in good repair and condition. **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.	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 (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	**Regulation (EC) No 852/2004,** Annex II, Chapter I, 2. states: The layout, design, construction, siting and size of food premises are to:	

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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. 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.	(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.	
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	**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	*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** (see below under the National Standards dealing with slaughter).*

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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.	condensation, the growth of undesirable mold and the shedding of particles;	
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 avoid the accumulation of dirt, for example, the arrangement of smooth and accessible surfaces.	(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;	
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.	(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	

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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.	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 requirements shall be met. The quality	**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 is 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 LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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. **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.	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. **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 LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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	

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
	legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.	
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. Switches shall be non-manual for the disinfection facilities. 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	**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: … 3. 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 LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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. 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.	4. 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.

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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.
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	**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	

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
and shall be kept apart from materials, semi-finished products, finished products and packaging materials.	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; **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	**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;	

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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 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.	
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:	*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;

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
	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;	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 2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives.	*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.
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

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
		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 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.	**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; (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**	*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 broilers, for retail, for bovine slaughterhouses, for wholesale markets, etc.)* *In these guides requirements are explained in detail to enable application in that sector using simplified language, practical examples and, if necessary, providing flexibility.*

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
	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). 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	

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
	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. 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	*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:*** a) Personnel should be aware of hazards from gastro-intestinal infections, hepatitis and wounds with appropriate exclusion from food handling or

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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	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.	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.

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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.		
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	**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. *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:* Guides may also usefully include procedures that must ensure a proper implementation of the Regulation, such as: • Procedures to prevent the introduction of hazards at the level primary production, • A procedure for the cleaning and disinfection of food businesses, • A procedure for pest control.

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
equipment or tools shall be cleaned thoroughly in time to eradicate contamination.		
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	**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.

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
replaced timely. During the process of food production, work clothes shall be kept clean and in perfect condition. 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.	**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	

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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. 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.	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 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	**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 1333/2008 on food additives** provides general principles of safety and application for all food additives and sets out*

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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 out"; where necessary, it shall be determined according to the characteristics of food additives.	**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.	*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 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. 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 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. **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,	*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 LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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".	where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection. **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.	
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 inertness for 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	**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), There is inconsistency between the National Standard GB 14881-2013 that specifies "shall be used" and the National Standard GB 12694-2016 (point 11.1.2) where it is mentioned "it is encouraged to be adopted" (i.e. not mandatory).*

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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.		*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 (see page 54 and following).*
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 (see page 56 and following).*
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. 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 food inspection agencies or companies 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**	**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:	Point 9 in Annex II of Guidance document: '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.' *Guidance document **Commission Notice 2016/C 278/01** provides that adequate infrastructure and*

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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.**	(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); (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;	*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 LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
	(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.	
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**	**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	

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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.**	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**	**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 3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.	

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
knowledge level shall be improved through the process of training. **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.**		
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.**	**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

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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.		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. 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		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 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 (+/- oPRPs) identification;

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
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 be adopted to implement record and document management.**		— 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 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

CHINESE LEGISLATION: NATIONAL STANDARD GB 14881	EU LEGISLATION: REGULATION (EC) NO 852/2004	IMPLEMENTING RULES AND COMPARATIVE EVALUATION
		checklists to record, for example, product temperatures.
Appendix A Microbial Monitoring Procedure Guide of Food Processing		Regulation 2073/2005 provides microbiological criteria for foodstuffs. A detailed discussion and comparison to Chinese standards is provided below in table 2 (GB 29921).

4 National standard GB 12693-2010 - Good manufacturing practice for milk products

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard applies to the production enterprises that process various types of dairy products with cow's milk (or sheep's milk) and its processed products as the main raw material.	**Regulation (EU) No 853/2004** laying down specific hygiene rules for food of animal origin**, Chapter I, Article 1** This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.	
2 Normative references The documents cited in this standard are essential for the application of this standard. Where the reference documents are dated, only the dated version is applicable to this standard. Where the reference documents are not dated, the latest version (including all revision sheets) is applicable to this standard.	*Not present in EU legislation*	
3 Terms and definitions **3.1 cleaning work area** An area where cleanliness is required, e.g. in the storage of semi-finished products to be packaged, filling and inner packaging plants, etc. **3.2 quasi-cleaning work area**	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I: raw milk and colostrum- primary production II Hygiene on milk and colostrum production holdings, A Requirements for premises and equipment:** 1. Milking equipment and premises where milk and colostrum are stored, handled or cooled	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
Work area with lower cleanliness requirements than the clean work area, such as raw material pre-processing workshop, etc. **3.3 Commonly work area** Cleanliness requirements are lower than the quasi-cleaning work area, such as milk collection room, raw material warehouse, packaging materials warehouse, packaging workshop and finished goods warehouse.	must be located and constructed so as to limit the risk of contamination of milk and colostrum. 2. Premises for the storage of milk and colostrum must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment. 3. Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and must be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.	
4 Site selection and plant environment In accordance with the relevant provisions of GB 14881.	**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:	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
	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;	
5 Plant and workshop **5.1 Design and layout** 5.1.1 All new construction, expansion and alteration projects should be designed and constructed in accordance with the relevant national regulations. 5.1.2 The layout of the plant and workshop should prevent cross-contamination during the processing of dairy products and avoid contact with toxic and unclean substances. 5.1.3 Appropriate measures shall be taken between the clean working area, the quasi-clean working area and the general working area in the workshop to prevent cross-contamination. **5.2 Internal building structure** 5.2.1 Roof 5.2.1.1 Interior roofs and roof corners of processing, packaging and storage areas shall be easily cleaned to prevent dust accumulation and	**Regulation (EC) No 852/2004, Annex II, Chapter I, 2.** states: 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; (c) permit good food hygiene practices, including protection against contamination and, in particular, pest control; **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	**Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP** **3.1 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, etc. should be taken into account. This should also be considered for primary production (fields). b) Lay-out should strictly separate contaminated (high risk) from clean areas (low risk) (or there should be a separation in time and suitable cleaning in between); suitable arrangements of rooms should be made for one-direction production flow and cooled rooms or heating facilities should be insulated.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
to avoid condensation, mould growth or peeling. Clean work areas, quasi-clean work areas and other food exposed areas (except milk collection rooms) with smooth, easily cleanable ceilings are recommended if the roof is of a structure that can easily trap dirt or, in the case of reinforced concrete structures, the interior roof should be flat and free from gaps. 5.2.1.2 Flat roofs or ceilings in workshops should be constructed of non-toxic, odourless white or light-coloured waterproofing materials, and if painted, should be mould-resistant, non-flaking and easy to clean. 5.2.1.3 Steam, water, electricity and other pipework should not be located directly above exposed foodstuffs, or else facilities should be installed to prevent dust and condensation from falling. 5.2.2 Walls 5.2.2.1 They should be constructed of non-toxic, odourless, smooth, impermeable and easily cleaned light coloured corrosion resistant materials.	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; **Regulation (EC) No 852/2004, Annex II, Chapter IX, 3** 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. (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	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
5.2.2.2 The corners of walls and columns in cleaning and quasi-cleaning work areas should be well constructed and easy to clean and disinfect. 5.2.3 Doors and windows 5.2.3.1 They should be made of smooth, non-absorbent materials and be easily cleaned and disinfected. 5.2.3.2 Doors and windows of production workshops and storage premises shall be fitted tightly, shall be equipped with facilities to protect against dust, animals and other pests and shall be easy to clean. 5.2.3.3 External entrances and exits to clean working areas and quasi-clean working areas shall be fitted with doors and/or air curtains capable of being closed automatically (e.g. by installing automatic sensors or door closers, etc.). 5.2.4 Floors 5.2.4.1 Floors shall be constructed of non-toxic, odourless, impermeable materials and shall be flat, non-slip, free from cracks and easily cleaned and disinfected.	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; e) doors are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate; 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	**Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP** **2.1 Infrastructure:** d) Doors should have smooth and non-absorbent surfaces. Automatic opening and closing should be considered to avoid contamination by touching. 3.1. Infrastructure j) Barriers should be in place to avoid access of stray animals. 3.3. Pest control: focus on prevention c) Doors should be kept closed except when loading and or unloading. Gaps between doors and floors should be pest-proofed. 3.1. c) Non-slippery floors should be constructed with waterproof, non-absorbent material, and should be washable and without fissures. Walls should be likewise at least up to appropriate height. It is also recommended that walls and floors are in light colors that facilitate visual hygiene assessment.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
5.2.4.2 Floors in areas where drainage or wastewater flows through the workplace, and in areas where the workplace is often wet or where cleaning is carried out by water washing, should be acid and alkali resistant and have a certain drainage slope and drainage system.	appropriate, floors are to allow adequate surface drainage; **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.	
5.3 Facilities 5.3.1 Water supply facilities 5.3.1.1 The water quality, pressure and quantity of water used for production should be in accordance with production needs. 5.3.1.2 The water supply equipment and appliances shall obtain a health permit from a health administrative department at or above the provincial level for products involving the health and safety of drinking water. 5.3.1.3 The entrances and exits of water supply facilities should be equipped with additional safety and hygiene facilities to prevent the entry of animals and other substances leading to food contamination.	**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; When clean water is used, adequate facilities and procedures are to be available for its supply to ensure that such use is not a source of contamination for the foodstuff. **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	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
5.3.1.4 Where secondary water supplies are used, they should comply with the provisions of GB 17051. 5.3.1.5 The water supply process using self-provided water sources should comply with the relevant hygiene requirements of the national health administrative authorities for centralised water supply units for domestic drinking water. 5.3.1.6 The piping system for non-potable water that does not come into contact with food (e.g. cooling water, sewage or waste water, etc.) should be clearly distinguishable from that for production water and should be conveyed in completely separate lines without backflow or interconnection. 5.3.1.7 The quality of the water used for production should be in accordance with the provisions of GB5749.	having access to places where food is prepared, handled or stored. **Regulation (EC) No 852/2004, Annex II, Chapter VII** 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.	**Guidance document Commission Notice 2022/C 355/01**, **Annex I, Examples of GHP, 3.10 water:** b) As a general rule, only potable water may be used on food of animal origin. At least clean water or where applicable clean sea water should be used in other cases. Potable water is strongly recommended in washing of fruit and vegetables for direct consumption. **Council Directive 98/83/EC** on the quality of water intended for human consumption, **Article 2:** 1. 'water intended for human consumption' shall mean: (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; **Article 4:** 1. Without prejudice to their obligations under other Community provisions, Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
		and clean. For the purposes of the minimum requirements of 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;
5.3.2 Drainage systems 5.3.2.1 Adequate drainage systems should be provided and should be designed and constructed to avoid contamination of the product or production water. 5.3.2.2 The drainage system shall be sloped, kept clear and easily cleaned, and the sides and bottom of the drains shall be curved at the joints. 5.3.2.3 Drainage system inlets should be fitted with water-sealed floor drains to prevent solid waste from entering and cloudy air from escaping. 5.3.2.4 There should be no water supply lines for production water in or under the drainage system. 5.3.2.5 The outlet of the drainage system should be protected from animal intrusion.	**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.	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
5.3.2.6 The flow of indoor drainage water should be directed from areas requiring high cleanliness to areas requiring low cleanliness, and designed to prevent backflow of waste water. 5.3.2.7 Wastewater shall be discharged to a wastewater treatment system or treated by other appropriate means. 5.3.3 Cleaning facilities Appropriate facilities shall be provided specifically for the cleaning and disposal of foodstuffs, utensils and equipment, and for the storage of waste, etc.	**Regulation (EC) No 852/2004, Annex II, Chapter VI** 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. **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. **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. These	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
5.3.4 Personal hygiene facilities 5.3.4.1 Personal hygiene facilities should comply with the provisions of GB 14881. 5.3.4.2 Disinfection facilities should be set up before entering the cleaning work area, and secondary changing rooms should be set up if necessary. 5.3.5 Ventilation facilities 5.3.5.1 There should be natural or artificial ventilation measures to reduce pollution from air sources and control odours to ensure food safety and product characteristics. Ambient temperature and, where necessary, air humidity should also be controlled in clean working areas during the production of dairy powders. 5.3.5.2 Air conditioning facilities should be installed in clean working areas to prevent steam condensation and to maintain fresh indoor air; ventilation facilities should be installed in general working areas to remove moist and dirty air in a timely manner. When air conditioning, air intake and exhaust or fans are used in the plant, the air should flow from areas with high cleanliness requirements to areas with low cleanliness	containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect. **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, 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. **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. **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	*More detailed requirements on this subject (changing room) are mentioned in the* **Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP, 3.1 Infrastructure:** g) The specific clothes changing room(s) should be clean and ordered and, where possible, not used as a refectory or a smoking room. A separation between normal clothing, clean work clothing and used work clothing should be facilitated.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
requirements to prevent contamination of foodstuffs, production equipment and inner packaging materials. 5.3.5.3 In areas where odours and gases (vapours and toxic gases) or dusts are generated which may contaminate food, there should be appropriate exclusion, collection or control devices. 5.3.5.4 Air inlets should be located at least 2m from the ground or roof, away from sources of contamination and exhaust vents, and be equipped with air filtration equipment. Exhaust vents should be fitted with easily cleanable, corrosion-resistant mesh covers to prevent animal intrusion; ventilation and exhaust devices should be easily dismantled for cleaning, maintenance or replacement. 5.3.5.5 Compressed air or other gases used for food, cleaning food contact surfaces or equipment should be filtered and purified to prevent indirect contamination. 5.3.6 Lighting facilities 5.3.6.1 There shall be sufficient natural or artificial lighting in the plant, and the lighting factor of the workshop shall not be lower than standard class IV. The mixed illuminance should not be less than 5401x on the working surface of	designed to allow those temperatures to be monitored and, where necessary, recorded. **Regulation (EC) No 852/2004, Annex II, Chapter I, 7:** 7. Food premises are to have adequate natural and/or artificial lighting.	**Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP, 3.10:** e) Ventilation systems should be robust and reliable. Ventilation systems should be 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. **Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP, 3.1:**

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
the quality control premises, 2201x on the working surface of the processing premises and 1101x in other premises, except for light sensitive testing areas. The light source should not change the colour of the food. 5.3.6.2 Lighting should not be installed directly above the exposure of food, otherwise safety type lighting should be used to prevent breakage contaminating the food. 5.3.7 Storage facilities 5.3.7.1 The enterprise shall have storage facilities appropriate to the variety and quantity of dairy products produced and operated. 5.3.7.2 Storage facilities shall be divided according to the nature of raw materials, semi-finished products, finished products, packaging materials, etc., and shall have a refrigerated (frozen) warehouse if necessary. The same warehouse storage nature of different items, should be appropriate isolation (such as classification, sub-shelves, partition storage), and have obvious signs. 5.3.7.3 The warehouse should be built of non-toxic, solid materials, with a level floor, easy to ventilate, and should have devices to prevent the intrusion of animals (e.g. the entrance to the	**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. 5. Raw materials, ingredients, intermediate products and finished products likely to support	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.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
warehouse should be equipped with anti-rodent plates or anti-rodent ditches). 5.3.7.4 The warehouse should have a sufficient number of pallets (storage racks for goods) and the goods should be kept at a suitable distance from the walls and the ground to facilitate air circulation and the handling of goods. 5.3.7.5 Refrigerated (frozen) warehouses should be equipped with thermometers, thermometers or automatic temperature recorders that can correctly indicate the temperature in the warehouse, and the temperature should be monitored and recorded in due course.	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. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health. Food businesses manufacturing, handling and wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials from processed material and sufficient separate refrigerated storage. 6. Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.	**Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP, 3.4 Raw materials:** d) Storage conditions at the establishment itself should take into account any instructions provided by the supplier, 'first in, first out' or 'first expired, first out' principles, accessibility for inspection from all sides (e.g. not placed directly on the ground, against walls, etc.). **3.12** Temperature control and storage a) Temperature and humidity should be (automatically) recorded where relevant. b) Alarm devices should preferably be automatic. c) Temperature fluctuations should be minimized e.g. by using a separate room/freezer to freeze products from that used for storage of frozen products. d) Chilling/heating capacity should be adapted to the amounts handled. e) Temperatures in the product during storage and transport should also be monitored. f) Verification should occur regularly.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
6 Equipment **6.1 Production equipment** 6.1.1 General requirements 6.1.1.1 There shall be production equipment appropriate to the variety and quantity of dairy products produced and operated, and the capacity of each piece of equipment shall match each other. 6.1.1.2 All production equipment shall be arranged in an orderly manner in accordance with the process flow to avoid causing cross contamination. 6.1.1.3 Operating procedures for special equipment used in the production process (e.g. pressure vessels, pressure pipes, etc.) shall be established. 6.1.2 Materials 6.1.2.1 All equipment and utensils in direct or indirect contact with raw materials, semi-finished products and finished products shall be made of materials that are safe, non-toxic, odourless or tasteless, resistant to absorption, corrosion-	**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; (c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected; and (d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area. 2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives. *Same requirements apply as for equipment (see above)*	**Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP, 3.1:** k) Equipment and monitoring/recording devices (e.g. thermometers) should be clean and the equipment suitable for contact with food products. l) 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 uses) for raw products and cooked products (chopping boards, knives, dishes, clothing of staff, thermometers, etc.). m) There should be an appropriate number of monitoring devices to measure critical parameters e.g. temperature.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
resistant and can withstand repeated cleaning and disinfection. 6.1.2.2 The materials used for product contact surfaces shall comply with the relevant standards for food-related products and shall be made of materials that have a smooth surface, are easy to clean and disinfect, are non-absorbent and do not peel off easily. 6.1.3 Design 6.1.3.1 All production equipment shall be designed and constructed in such a way that it can be easily cleaned and disinfected, and easily inspected. It should be constructed in such a way as to avoid the mixing of lubricating oils, metal fragments, sewage or other substances that may cause contamination into the food and should comply with the appropriate requirements. 6.1.3.2 Food contact surfaces shall be smooth and free from depressions or cracks to reduce the accumulation of food debris, dirt and organic matter. 6.1.3.3 Storage, transport and processing systems (including gravity, pneumatic, containment and automatic systems) shall be designed and	**Regulation (EC) No 852/2004, Annex II, Chapter II:** (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 corrosionresistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate. **Regulation (EC) No 852/2004, Annex II, Chapter IV:** 1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
constructed so as to be easily maintained in good hygienic condition. Storage equipment for materials shall be capable of being sealed. 6.1.3.4 A dedicated area shall be provided for the storage of equipment spares so that the necessary spares are available in time for maintenance of the equipment; the spares storage area shall be maintained clean and dry. **6.2 Monitoring equipment** 6.2.1 Monitoring equipment used for measurement, control and recording, such as pressure gauges and thermometers, should be regularly calibrated and maintained to ensure accuracy and validity. 6.2.2 When a computer system and its network technology are used for the collection of monitoring data at key control points and the management of various records, the relevant functions of the computer system and its network technology may refer to the provisions of Appendix A of this Standard. **6.3 Maintenance and repair of equipment**	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. **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 852/2004, Annex II, Chapter V:** 2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives.	**Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP, 3.1:** f) Clearly defined storage facilities should be available for raw material, receptacles for food and packaging materials. Only products that may be added to food (e.g. additives) should be stored in the area with the food, excluding common storage with toxic products (e.g. pesticides). **Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP, 3.5:** c) Calibration of monitoring devices (e.g. weighing scales, thermometers, flow meters) is important in controlling food safety and hygiene. Records of calibration should be kept.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
6.3.1 Procedures for the maintenance and repair of equipment shall be established and strictly enforced. 6.3.2 A routine maintenance and servicing plan for the equipment shall be established, regularly serviced and well documented. 6.3.3 The equipment shall be checked before each production run to ensure that it is in normal condition and to prevent situations affecting the hygienic quality of the products; faults shall be rectified promptly and the time and cause of the fault and the batch of products that may be affected shall be recorded.		**Guidance document Commission Notice 2022/C 355/01, Annex I, Examples of GHP, 3.5:** 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, etc. 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, …
7 Hygiene management **7.1 Hygiene management system** 7.1.1 A hygiene management system and assessment criteria shall be developed and a job responsibility system shall be implemented. 7.1.2 A hygiene inspection plan shall be established and the implementation of the plan shall be recorded and archived.	**Regulation (EC) No 852/2004, Annex II, Chapter XI a Food Safety Culture:** 1. Food business operators shall establish, maintain and provide evidence of an appropriate food safety culture by fulfilling the following requirements: (a) commitment of the management, in accordance with point 2, and all employees to the safe production and distribution of food; (b) leadership towards the production of safe food and to engage all employees in food safety practices;	**Guidance document Commission Notice 2022/C 355/01, Annex I, 5. Documentation and record keeping of GHP:** GHP should be documented in the GHP plan and may need to be continuously supplemented by records when GHP requiring greater attention have been identified. Such GHP plan should be part of (integrated in) the HACCP plan (see Annex II, Section 11).

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
7.2 Hygienic management of plant and facilities 7.2.1 All facilities in the plant should be kept clean and repaired or renewed in a timely manner; if there is damage to the roof, ceiling and walls of the plant, they should be repaired immediately and the ground should not be damaged or waterlogged.	(c) awareness of food safety hazards and of the importance of food safety and hygiene by all employees in the business; (d) open and clear communication between all employees in the business, within an activity and between consecutive activities, including communication of deviations and expectations; (e) availability of sufficient resources to ensure the safe and hygienic handling of food. 2. Management commitment shall include: (a) ensuring that roles and responsibilities are clearly communicated within each activity of the food business; (b) maintaining the integrity of the food hygiene system when changes are planned and implemented; (c) verifying that controls are being performed timely and efficiently and documentation is up to date; (d) ensuring that the appropriate training and supervision are in place for personnel; (e) ensuring compliance with relevant regulatory requirements; (f) encouraging continual improvement of the food safety management system of the business, where appropriate, taking into account	**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.5 Technical maintenance** a) The maintenance plan should be considered with a technical specialist.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
	developments in science, technology and best practices.	
7.2.2 Equipment and utensils used for processing, packaging, storage and transport, production piping and food contact surfaces shall be cleaned and disinfected regularly. Care should be taken to prevent contamination of food, food contact surfaces and internal packaging materials during cleaning and disinfection operations.	**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: (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;	
7.2.3 Movable equipment and utensils that have been cleaned and disinfected shall be kept in a suitable place where they can be protected from recontamination of their food contact surfaces and maintained in a suitable condition.	**Regulation (EC) No 852/2004, Annex II, Chapter IV Transport** 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.	
7.3 Cleaning and disinfection 7.3.1 Effective cleaning and disinfection programmes and procedures shall be in place to ensure the cleanliness and hygiene of food processing premises, equipment and facilities etc. and to prevent contamination of food.		**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.2. Cleaning and disinfection** a) What, when, how and by who to clean and disinfect should be considered.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
7.3.2 Methods of cleaning and disinfection may be selected according to product and process characteristics.		b) Typical steps should be the removal of visible dirt, followed by cleaning, followed by rinsing, followed by disinfection and rinsing again. c) Cleaning should start in high-risk areas and should end in low risk areas. Materials and equipment for cleaning equipment should be different between low and high-risk areas and in any case never move from a high contaminated area to a low one. Special attention must be paid to the contamination of disinfected surfaces due to splash when rinsing other surfaces.
7.3.3 Equipment and utensils used for cleaning and disinfection shall be placed in a dedicated place for proper storage. 7.3.4 Records shall be kept of cleaning and disinfection procedures, such as the type of detergent and disinfectant, time of action, concentration, object, temperature, etc.	**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 I, III Record keeping:** 7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business.	
7.4 Personnel health and hygiene requirements 7.4.1 Health of personnel 7.4.1.1 The enterprise shall establish and implement a health management system for the personnel employed. 7.4.1.2 Dairy processing personnel shall undergo annual health checks and obtain health certificates before they are allowed to work.	**Regulation (EC) No 852/2004, Annex II, 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. 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	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
7.4.1.3 Persons suffering from infectious diseases of the digestive tract such as dysentery, typhoid fever, viral hepatitis A or viral hepatitis E, as well as persons suffering from diseases that hinder food safety such as active tuberculosis, purulent or exudative skin diseases, and persons with unhealed skin wounds, shall be reassigned to other jobs that do not affect food safety. 7.4.2 Personal hygiene 7.4.2.1 Dairy product processors shall maintain good personal hygiene. 7.4.2.2 Before entering the production plant, they should wear neat and tidy work clothes, a work cap and work shoes (boots). Work clothes should cover outer clothing, hair should not be exposed outside the cap and a mask is required if necessary; work clothes and work shoes (boots) should not be worn in clean work areas or quasi-clean work areas to enter toilets, leave production and processing premises or work across areas. 7.4.2.3 Hands should be washed and disinfected before starting work, after using the toilet, after coming into contact with objects that may	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. **Regulation (EC) No 852/2004, Annex II, 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. **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, II, C Staff hygiene:** 1. Persons performing milking and/or handling raw milk and colostrum must wear suitable clean clothes. 2. Persons performing milking must maintain a high degree of personal cleanliness. Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk and colostrum to wash their hands and arms.	*No annual health checks or health certificates are required according to EU legislation. The responsibility to produce safe food is upon the food business operator.* **Guidance document Commission Notice 2022/C 355/01, Annex I, 3.11 Personnel** 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. **Guidance document Commission Notice 2022/C 355/01, Annex I, 3.11 Personnel** b) Hands should be washed regularly (and disinfected if necessary), as a minimum, before starting work, after using the lavatory, after breaks, after rubbish disposal, after coughing or sneezing (in a disposable paper or, if no alternative, into your elbow), after handling of raw materials, between tasks, etc. Disposable gloves used hygienically can be effective in preventing cross contamination when handling ready-to-eat foods. Hands must be washed thoroughly before and after use. Gloves must be

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
contaminate food or after engaging in other activities not related to production. Hands shall be kept clean during production processing and operation. 7.4.2.4 Dairy processors should not wear nail polish, perfume, watches and ornaments. 7.4.2.5 Smoking, eating food or other activities that hinder food hygiene are strictly prohibited in the workplace. 7.4.2.6 Personal clothing should be stored in a locker for personal use in the changing room. Other items for personal use should not be brought into the production hall. 7.4.3 Visitors Visitors to food production, processing and operating premises should comply with the hygiene requirements for on-site operators.	**Regulation (EC) No 852/2004, Annex II, Chapter I** 9. Where necessary, adequate changing facilities for personnel are to be provided.	used only once and should be changed between tasks to prevent cross contamination. c) Hair covers (and beard snoods) should be considered and appropriate clothing with high degree of cleanliness, minimum of pockets, absence of jewelry and watches. The use by workers of clothing or items of clothing with different colors is recommended in different microbiological risk areas. d) Protective clothing should preferably not be worn when using the toilets or when wheeling the rubbish bins onto the street. e) Eating, drinking and/or smoking rooms should be separated and clean. f) First aid kits should be easily accessible and available for immediate use. g) The number of visitors should be minimized and visits should follow the conditions set by the FBO so as not to compromise the food safety. Visitors should at least wash hands and wear appropriate protective clothing, provided by the FBO.
7.5 Pest control 7.5.1 Pest control measures should be developed to keep the building intact and the environment tidy to prevent pest intrusion and breeding.	**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,	**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.3. Pest control** a) External walls should be free of cracks or chinks, surroundings should be neat and free from debris which could provide harborage from

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
7.5.2 Insect traps (traps) should be provided at the entrances to production workshops and storage areas, and screens should be installed or other measures taken at windows and other areas directly connected to the outside world to prevent or eliminate pests. 7.5.3 The plant environment and production premises should be regularly monitored and inspected for signs of pest infestation and if found to exist, the source of the infestation should be traced and its recurrence should be prevented.	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 II,** (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;	pests, and areas for cleaning should be accessible. Access by pets or wild animals must be prohibited/ prevented. b) Insect screen should be placed at windows. When electronic devices are used for insect control, the device has to be used according to its specification. c) Doors should be kept closed except when loading and/or unloading. Gaps between doors and floors should be pestproofed. d) Unused equipment and rooms should be kept clean. e) The presence of an indoor pool of water should be addressed as soon as possible. Ponding or pooling of water must be prevented or avoided. f) A pest control programme should be available: i. Baits and traps (inside/outside) should be considered in appropriate numbers and also their strategic placement; ii. The programme should cover rodents, crawling, walking and flying pests; iii. Dead pests and insects should be frequently removed ensuring no possible contact with food; iv. The cause should be determined in case of a recurrent problem;

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
7.5.4 Physical, chemical or biological agents may be used for treatment and the method of extermination should not affect the safety and product characteristics of the food and should not contaminate food contact surfaces and packaging materials (e.g. avoid the use of pesticides etc. as far as possible).		v. Chemicals used to control harmful organisms have to be authorized by the Biocidal Products Regulation. Pesticides should be stored safely and used so that there is no possible contact with, inter alia, food, packaging material and equipment. Fly traps (including electric fly killers) should not be placed directly above areas where food is processed or stored. vi. Chemical substances (e.g. biocidal products used for the control rodents) should not be used to monitor the occurrence of pests but restricted to pest control activities only.
7.6 Waste disposal 7.6.1 A waste storage and removal system should be in place. 7.6.2 Containers for waste, processing by-products and inedible or hazardous substances should be specially marked and constructed to be impermeable and, where necessary, closed to prevent contamination of food. 7.6.3 Temporary storage facilities for waste shall be provided at appropriate locations and shall be classified according to the characteristics of the waste and perishable waste shall be removed regularly. 7.6.4 Waste should be placed in such a way that no undesirable odours or harmful or toxic gases	**Regulation (EC) No 852/2004, Annex II, Chapter VI Food waste** 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.	**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.9. Waste management** Compliance with the requirements in Chapter VI of Annex II to Regulation (EC) No 852/2004 can be best achieved and illustrated by the FBO by implementing procedures for each type of waste (animal by-products, spoiled food, chemical waste, redundant/used packing material). When applicable, it should be recorded who is responsible for the removal, how it is collected, where it is stored and how it is removed from the establishment.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
are emitted and that pests are prevented from breeding and contaminating food, food contact surfaces, water sources and ground surfaces.	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.	
7.7 Management of toxic and hazardous substances In accordance with the relevant provisions of GB 14881. **7.8 Management of sewage and dirt** 7.8.1 Sewage discharge should comply with the requirements of GB 8978, and purification measures should be taken if the standards are not met, and discharge should only be allowed after the standards are met. 7.8.2 Dirt management shall be carried out in accordance with the relevant provisions of GB 14881.	**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. **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	A detailed comparative assessment of the Chinese Food Safety Standard GB 14881 is available elsewhere – see Pont 3 above. No relevant discrepancies were identified between EU rules and Chinese Food Safety Standards.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
7.9 Workwear management Implemented in accordance with the relevant provisions of GB 14881.	food is present as quickly as possible, so as to avoid their accumulation. 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.	*A detailed comparative assessment of GB 14881 can be found in the document comparing the meat hygiene requirements in Chinese national standards with the EU legislation. No relevant discrepancies were identified.*
8 Requirements for raw materials and packaging materials **8.1 General requirements** 8.1.1 Enterprises should establish a management system related to the purchase, acceptance, transport and storage of raw materials and packaging materials to ensure that the raw materials and packaging materials used meet the requirements of laws and regulations. No substances hazardous to human health and life safety shall be used. 8.1.2 Raw milk purchasing stations built by the enterprises themselves shall comply with relevant national and local regulations.	**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. 2. Raw materials and all ingredients stored in a food business are to be kept in appropriate	**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.4. Raw materials** 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.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
	conditions designed to prevent harmful deterioration and protect them from contamination.	
8.2 Requirements for the purchase and acceptance of raw materials and packaging materials 8.2.1 The enterprise shall establish a supplier management system, stipulating the selection, audit and evaluation procedures of suppliers. 8.2.2 The enterprise shall establish a system for the inspection of incoming raw materials and packaging materials. 8.2.2.1 Enterprises using raw milk shall inspect the raw milk purchased in accordance with the relevant food safety standards on a batch-by-batch basis, record the quality testing, the name and contact details of the supplier, the date of purchase, and check the raw milk handover sheet of the transport vehicle. Enterprises should not purchase raw milk from units or individuals who have not obtained a raw milk purchase permit.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, III:** 1. (a) The following criteria for raw milk apply pending the establishment of standards in the context of more specific legislation on the quality of milk and dairy products. 2. A representative number of samples of raw milk and colostrum collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4 in case of raw milk and with the existing national criteria referred to in point 1(b) in case of colostrum. The checks may be carried out by, or on behalf of:	b) A strict supply policy, containing an agreement on specifications (e.g. microbiological) and hygiene assurance and/or the request for a certified quality management system can be taken into account in respect of the extent of details on the GHP and HACCP plan of the establishment itself. It is recommended that raw materials are labelled when allergens are present (See Section 3.7).

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
	(a) the food business operator producing the milk; (b) the food business operator collecting or processing the milk; (c) a group of food business operators; or (d) in the context of a national or regional control scheme.	
8.2.2.2 When accepting other raw materials and packaging materials, the company should check the qualification documents of the raw materials and packaging materials (self-test report or inspection report issued by a third party); if no valid qualification documents can be provided, the raw materials and packaging materials purchased should be inspected in accordance with the corresponding food safety standards or the acceptance standards of the company and should be accepted and used only after passing. The relevant information on raw materials and packaging materials should 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. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured. 4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.	**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.4. Raw materials** c) Apart from agreements with and the 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 the agreed delivery period, accuracy of the 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 delivery checks. 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, also by allergens.
8.2.3 Rejected raw materials and packaging materials shall be marked and stored separately, and the supplier shall be notified for further processing.	**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	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
8.2.4 If food safety problems are found with raw materials and packaging materials, they should be reported to the food safety supervisory authorities of the jurisdiction in which the enterprise is located. 8.3 Transport and storage requirements for raw materials and packaging materials 8.3.1 Enterprises should transport and store raw materials and packaging materials in accordance with the requirements for quality and safety. 8.3.2 Transport and storage of raw milk 8.3.2.1 Containers used for the transport and storage of raw milk shall comply with relevant national safety standards. 8.3.2.2 Raw milk should be cooled to 0°C to 4°C within 2 hours of milking. Use insulated milk tankers for transport. The transport vehicle shall have sound certification and records. 8.3.2.3 Raw milk should be processed in a timely manner upon arrival at the plant. If it cannot be processed in a timely manner, there should be refrigerated storage facilities with temperature	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 IV Transport** 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. **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter II, I Temperature requirements:** 1. Food business operators must ensure that, upon acceptance at a processing establishment, (a) milk is quickly cooled to not more than 6° C; (b) colostrum is quickly cooled to not more than 6° C or maintained frozen, and kept at that temperature until processed. 2. However, food business operators may keep milk and colostrum at a higher temperature if:	*A difference in cooling temperature of raw milk has been detected: 0-4° C in the Chinese national standard, while 6° C is required in EU legislation.*

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
and related indicators monitored and records kept.	(a) processing begins immediately after milking, or within four hours of acceptance at the processing establishment; or (b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy or colostrum-based products. **Regulation (EC) No 852/2004, Annex II, Chapter IX**	
8.3.3 Transport and storage of other raw materials and packaging materials 8.3.3.1 Raw materials and packaging materials should be protected from direct sunlight, rain, strong temperature and humidity changes and impacts during transport and storage; they should not be mixed with toxic and hazardous substances. 8.3.3.2 In the process of transport and storage, raw materials and packaging materials should be protected from contamination and damage, and to minimize the deterioration of quality; temperature, humidity and other special requirements of raw materials and packaging materials should be transported and stored in accordance with the specified conditions.	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 852/2004, Annex II, Chapter IV** 6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination. 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. 5. Where conveyances and/or containers have been used for transporting anything other than	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
8.3.3.3 During storage, different raw materials and packaging materials should be stored in accordance with the characteristics of the partition, and the establishment of signs, indicating the relevant information and quality status. 8.3.3.4 The stock of raw materials and packaging materials should be regularly checked, for longer storage time, the quality of raw materials and packaging materials may change, should be regularly sampled to confirm the quality; timely cleaning of deterioration or exceed the shelf life of raw materials and packaging materials. 8.3.4 Qualified raw materials and packaging materials should be used in accordance with the "first in first out" or "expiry date first out" principle, reasonable arrangements for use. 8.4 Keep records of the purchase, acceptance, storage and transport of raw materials and packaging materials.	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 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.	**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.4. Raw materials** d) Legal requirements during transport (e.g. temperature conditions) should be verified and maintained during unloading. e) Storage conditions at the establishment itself should take into account any instructions provided by the supplier, 'first in, first out' or 'first expired, first out' principles, accessibility for inspection from all sides (e.g. not placed directly on the ground, against walls, etc.)
9 Food safety control of the production process **9.1 Control of microbiological contamination** 9.1.1 Temperature and time 9.1.1.1 Methods used to kill microorganisms or inhibit their growth and reproduction, such as	**Regulation (EC) No 852/2004, Annex II, Chapter XI Heat treatment** The following requirements apply only to food placed on the market in hermetically sealed containers:	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
heat treatment, freezing or refrigerated storage, shall be specified and effectively monitored according to the characteristics of the product. 9.1.1.2 Temperature and time control measures and corrective measures shall be established and periodically verified. 9.1.1.3 For processing where temperature and time are strictly controlled, real-time monitoring measures shall be established and monitoring records maintained. 9.1.2 Humidity 9.1.2.1 Air humidity in areas requiring humidity control should be controlled according to product and process characteristics to reduce the propagation of harmful microorganisms; critical air humidity limits should be established and effectively implemented. 9.1.2.2 Real-time air humidity control and monitoring measures are established, regularly verified and recorded. 9.1.3 Air cleanliness in production areas 9.1.3.1 The production workshop shall be kept clean of air to prevent contamination of food.	1. any heat treatment process used to process an unprocessed product or to process further a processed product is: (a) to raise every party of the product treated to a given temperature for a given period of time; and (b) to prevent the product from becoming contaminated during the process; 2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices; 3. the process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation) **Regulation (EC) No 852/2004, Annex II, Chapter I** 5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical	**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.1. Infrastructure** m) There should be an appropriate number of monitoring devices to measure critical parameters e.g. temperature. **Guidance document Commission Notice 2022/C 355/01, Annex I, 3.12. Temperature control** a) Temperature and humidity should be (automatically) recorded where relevant. b) Alarm devices should preferably be automatic. c) Temperature fluctuations should be minimized e.g. by using a separate room/freezer to freeze products from that used for storage of frozen products. d) Chilling/heating capacity should be adapted to the amounts handled. e) Temperatures in the product during storage and transport should also be monitored. f) Verification should occur regularly. **Guidance document Commission Notice 2022/C 355/01, Annex I, 3.10 Water and air control**

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
	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.	e) Ventilation systems should be robust and reliable. Ventilation systems should be 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. f) Condensation is mostly the result of poor ventilation. Condensation should be avoided in areas where food is being produced, handled or stored, especially if exposed or not packed.
9.1.3.2 The total number of bacteria colonies in the air of the clean working area shall be controlled below 30 CFU/dish, as determined by the natural sedimentation method in GB/T 18204.1. 9.1.4 Prevention of microbial contamination 9.1.4.1 Necessary measures shall be taken to prevent microbial contamination throughout the entire process from when raw materials and packaging materials enter the factory to when finished products leave the factory.	**Regulation (EC) No 852/2004, Article 4** 3. Food business operators shall, as appropriate, adopt the following specific hygiene measures: (a) compliance with microbiological criteria for foodstuffs; **Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, Article 3** 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	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
9.1.4.2 Equipment, containers and utensils used for conveying, loading or storing raw materials, semi-finished products and finished products shall be operated, used and maintained in such a way as to avoid contamination of the food being processed or stored. 9.1.4.3 Ice and steam in direct contact with food during processing, the water used should comply with the provisions of GB5749. 9.1.4.4 Recycled water from evaporation or drying processes in food processing, and recycled water may be reused, but should ensure that it does not pose a hazard to the safety and product characteristics of the food, should be treated with water if necessary, and should be effectively monitored.	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. **Article 5** 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 **Regulation (EC) No 852/2004, Annex II, Chapter VII** 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,	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
	handled and stored under conditions that protect it from contamination. **Regulation (EC) No 852/2004, Annex II, Chapter V**	
9.2 Control of chemical contamination 9.2.1 A management system for the prevention of chemical contamination shall be established, possible sources and routes of contamination shall be analysed and control measures shall be proposed. 9.2.2 Detergents, disinfectants, insecticides and lubricants that meet the requirements should be selected and used in accordance with the product instructions; their use should be registered and records of their use kept to avoid the occurrence of hazards of contaminated food. 9.2.3 Chemical substances should be stored separately from foodstuffs, clearly labelled, and have a person to keep them.	3. Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice. **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.	**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.6. Chemical contaminations** 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) Lubricants must be food grade when used in environments in which foods are processed and where there is the possibility of accidental contact with food. e) Possible chemical hazards should only be dealt with by specialized, trained staff. Weighing scales for additives should be preferably automatic
9.3 Control of physical contamination 9.3.1 Measures should be taken to ensure that products are protected from contamination by foreign substances (e.g. glass or metal fragments, dust, etc.) through equipment maintenance, hygiene management, site management, management of external personnel and supervision of the processing.	**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.	**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.6. Physical contaminations** a) The frequency of the control of physical hazards (such as glass, plastic and metal) should be determined using a risk-based analysis (how big is the likelihood of occurrence in an establishment in question?).

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
9.3.2 Effective measures (e.g. screens, traps, magnets, electronic metal detectors, etc.) should be taken to prevent the mixing of metal or other foreign debris into the product. 9.3.3 Welding, cutting and grinding should not be carried out during the production process to avoid the production of odours and debris. **9.4 Food additives and food nutrient fortification** 9.4.1 Food additives and food nutrient fortification should be used reasonably in accordance with the variety, scope and dosage specified in the food safety standards. 9.4.2 Food additives and food fortification agents should be weighed accurately and recorded when in use. **9.5 Packaging materials** 9.5.1 Packaging materials shall be clean, non-toxic and in accordance with relevant national regulations. 9.5.2 Packaging materials or gases used for packaging shall be non-toxic and shall not affect	**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.	b) A procedure should be available explaining what to do in case of the breakage of glass, hard plastic, knives, etc. **Guidance document Commission Notice 2022/C 355/01, Annex I, 3.5. Technical maintenance** 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, etc. b) Attention should be paid to hygiene during maintenance operations **Guidance document Commission Notice 2022/C 355/01, Annex I, 3.6. Chemical contaminations** e) Possible chemical hazards should only be dealt with by specialized, trained staff. Weighing scales for additives should be preferably automatic. **Guidance document Commission Notice 2022/C 355/01, Annex I, 3.1. Infrastructure** f) Clearly defined storage facilities should be available for raw material, and receptacles for food and packaging materials. Only products that

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
the safety and product characteristics of the food under the specified conditions of storage and use. 9.5.3 The inner packaging material shall be capable of adequately protecting the food from contamination and preventing damage during normal storage, transport and sale. 9.5.4 Reusable packaging materials such as glass bottles and stainless steel containers should be thoroughly cleaned and disinfected as necessary before use. 9.5.5 Prior to the packaging operation, the identification of the packaging materials to be put into use should be checked to avoid misuse of the packaging materials and recorded, including the name of the product corresponding to the packaging materials, the quantity, the operator and the date. **9.6 Product information and labelling** Product labelling should comply with GB 7718, the corresponding national product standards and other relevant national regulations.	3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured. 4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect. **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter III, Wrapping and packaging** Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products and colostrum-based products, takes place by means of sealing devices that prevent contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check. **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter IV, Labelling** 1. In addition to the requirements of Directive 2000/13/EC, except in the cases envisaged in Article 13(4) and (5) of that Directive, labelling must clearly show:	may be added to food (e.g. additives) should be stored in the area with the food, excluding common storage with toxic products (e.g. pesticides). **Guidance document Commission Notice 2022/C 355/01, Annex I, 34. Raw materials** 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.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
	(a) in the case of raw milk intended for direct human consumption, the words 'raw milk'; (b) in the case of products made with raw milk, the manufacturing process for which does not include any heat treatment or any physical or chemical treatment, the words 'made with raw milk'; (c) in case of colostrum, the word 'colostrum'; (d) in case of products made with colostrum, the words 'made with colostrum'. 2. The requirements of paragraph 1 apply to products destined for retail trade. The term 'labelling' includes any packaging, document, notice, label, ring or collar accompanying or referring to such products.	
10 Inspection 10.1 Enterprises can test their own raw materials and products, but can also be entrusted to obtain the qualification of the food inspection agency to test. Self-testing enterprises should have the appropriate testing capabilities. 10.2 Each batch of products should be tested in accordance with the relevant standards, and retain samples.	**Regulation (EC) No 2073/2005, Article 4** 1. Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice. **Regulation (EC) No 2073/2005, Article 5** 4. If the aim of the testing is to specifically assess the acceptability of a certain batch of foodstuffs or a process, the sampling plans set out in Annex I shall be respected as a minimum.	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
10.3 Laboratory quality management should be strengthened to ensure the accuracy and authenticity of test results. 10.4 The test records and test reports should be kept intact.	**Regulation (EU) 2017/625 on official controls, Article 34** 1. Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods. 4. Wherever possible, methods used for laboratory analyses shall be characterised by the relevant criteria set out in Annex III. **Regulation (EC) No 852/2004, Article 5** 4. Food business operators shall: (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.	*Directive 2004/9/EC lays down rules for the inspection and verification of good laboratory practice (GLP).* **Regulation (EC) No 852/2004, Annex I, Part A, III** 7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Food business operators are to make relevant information contained in these records available to the competent authority and receiving food business operators on request.
11 Storage and transport of products 11.1 Storage and transport shall be selected according to the type and nature of the product and in accordance with the storage conditions identified on the product label. 11.2 During storage and transport, direct sunlight, rain, violent temperature and humidity	**Regulation (EC) No 852/2004, Annex II, Chapter IV Transport** 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,	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
changes and impacts should be avoided to prevent the composition and quality of dairy products from being adversely affected; products should not be stored and transported with odorous, toxic or harmful substances. 11.3 Containers, tools and equipment used for storage, transport and handling should be clean, safe and in good condition to prevent contamination of the product. 11.4 Products in the warehouse should be checked regularly, with temperature records and/or humidity records if necessary, and any abnormalities should be dealt with promptly. 11.5 Products after inspection shall be marked with their quality status. 11.6 There should be corresponding records for storage and transport of products and shipping records for products leaving the factory so that	where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection. 6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination. 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. **Regulation (EC) No 178/2002 (General food law), Article 19**	**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.5 Raw materials** e) Storage conditions at the establishment itself should take into account any instructions provided by the supplier, 'first in, first out' or 'first expired, first out' principles, accessibility for inspection from all sides (e.g. not placed directly on the ground, against walls, etc.). **Guidance document Commission Notice 2022/C 355/01, Annex I, 3.12 Temperature** a) Temperature and humidity should be (automatically) recorded where relevant. *Quality status is not considered in the EU food safety legislation.* **Guidance document Commission Notice 2022/C 355/01, Annex I, 3.13 Working methodology**

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
they can be recalled quickly if problems are found.	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.	Work instructions or standard operation procedures should be clear, accurate and simple, visible or easily accessible.
12 Product traceability and recall 12.1 A product traceability system shall be established to ensure that all aspects of the product from the purchase of raw materials to the sale of the product can be effectively traced.	**Regulation (EC) No 178/2002 (General food law), Article 18** 1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution. 2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
12.2 A product recall system shall be established. When a batch or category of products is found to contain or may contain factors that pose a health hazard to consumers, the product recall procedure shall be initiated in accordance with relevant national regulations, and the relevant authorities shall be notified in a timely manner and relevant records shall be kept. 12.3 Measures such as harmless disposal and destruction of recalled food products shall be taken, and the recall and disposal of food products shall be reported to the relevant authorities. 12.4 A customer complaint handling mechanism shall be established. The relevant management department of the enterprise shall keep records of written or verbal comments and complaints made by customers and find out the causes and deal with them properly.	be, or expected to be, incorporated into a food or feed. 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. **Regulation (EC) No 178/2002 (General food law), 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.	A customer complaint handling mechanism is not formally required by EU legislation. However, the obligation of immediate product recall obliges operators to establish procedures to handle feedback information from commercial customers and/or consumers.

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
	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.	
13 Training 13.1 A training system shall be established to provide training in food safety for all personnel working in the enterprise. 13.2 An annual training plan shall be drawn up according to the different needs of the position and training shall be provided accordingly. Special types of work shall be performed with a certificate. 13.3 Training plans should be regularly reviewed and revised, the effectiveness of the training evaluated and routine checks carried out to ensure effective implementation of the plan. 13.4 Training records should be maintained.	**Regulation (EC) No 852/2004, Annex II, Chapter XIa Food safety culture** 1. Food business operators shall establish, maintain and provide evidence of an appropriate food safety culture by fulfilling the following requirements: (a) commitment of the management, in accordance with point 2, and all employees to the safe production and distribution of food; 2. Management commitment shall include: (d) ensuring that the appropriate training and supervision are in place for personnel; **Regulation (EC) No 852/2004, Annex II, Chapter XII 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	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
14 Management structure and personnel 14.1 A sound food safety management system shall be established and appropriate management measures shall be taken to implement safety and quality control of the whole process of dairy production, from raw material intake to finished product delivery, to ensure that products meet the requirements of laws, regulations and relevant standards. 14.2 A food safety management body shall be established and be responsible for the food safety management of the enterprise. 14.3 The person in charge of the food safety management body shall be the representative of the legal person of the enterprise or the person authorised by the legal person of the enterprise. 14.4 Each department in the organisation should have clear management responsibilities and ensure that management responsibilities related to quality and safety are in place. There should be an effective division of labour between departments to avoid crossover, duplication or absence of responsibilities. A corresponding management system should be established for	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. **Regulation (EC) No 852/2004, Annex II, Chapter XIa Food safety culture** 1. Food business operators shall establish, maintain and provide evidence of an appropriate food safety culture by fulfilling the following requirements: (a) commitment of the management, in accordance with point 2, and all employees to the safe production and distribution of food; (b) leadership towards the production of safe food and to engage all employees in food safety practices; (c) awareness of food safety hazards and of the importance of food safety and hygiene by all employees in the business; (d) open and clear communication between all employees in the business, within an activity and between consecutive activities, including communication of deviations and expectations; (e) availability of sufficient resources to ensure the safe and hygienic handling of food. 2. Management commitment shall include:	

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
the internal and external environment of the plant, maintenance and management of plant facilities and equipment, quality and safety management of the production process, hygiene management, quality tracking, etc., with clear management responsibilities and duties. 14.5 Each department in the food safety management organisation should have a professionally trained, full-time or part-time **food** safety manager to publicise and implement food safety regulations and relevant rules and regulations, and to be responsible for supervising their implementation and keeping records thereof.	(a) ensuring that roles and responsibilities are clearly communicated within each activity of the food business; (b) maintaining the integrity of the food hygiene system when changes are planned and implemented; (c) verifying that controls are being performed timely and efficiently and documentation is up to date; (d) ensuring that the appropriate training and supervision are in place for personnel; (e) ensuring compliance with relevant regulatory requirements; (f) encouraging continual improvement of the food safety management system of the business, where appropriate, taking into account developments in science, technology and best practices.	
15 Management of records and documentation **15.1 Record management** 15.1.1 A records management system shall be established to record in detail the purchase, production, storage, inspection and sale of raw materials and packaging materials etc. in the processing of dairy products in order to increase the credibility and effectiveness of the food safety management system.	**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: (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective	**Guidance on the implementation of several articles of Regulation (EC) No 178/2002 (version of 26 January 2010)** III.3.2. Implementation of traceability requirements i) Identification of suppliers and customers by food business operators iv) Information to be kept

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
15.1.1.1 The name, specification, quantity, name and contact details of the supplier and date of purchase of food ingredients, food additives and food-related products should be recorded faithfully. 15.1.1.2 The processing of the product (including process parameters, environmental monitoring, etc.), product storage and product inspection batch number, inspection date, inspector, test methods, test results, etc. should be recorded faithfully. 15.1.1.3 The name, specification, quantity, date of production, production batch number, place of shipment, name and contact details of the consignee, date of shipment, etc. of the product shall be recorded faithfully. 15.1.1.4 The name, batch, specification, quantity, reason for recall and subsequent rectification plan of the recalled food shall be recorded faithfully. 15.1.2 All records shall be reviewed and signed by the executive and the supervisor concerned. If the contents of the records are amended, the original text shall not be obliterated so as to be illegible, and the amendment shall be signed or sealed by the person making the amendment near the amended text.	application of the measures outlined in subparagraphs (a) to (f). 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. **Implementing Regulation (EU) No 931/2011, Article 3 Traceability requirements** 1. Food business operators shall ensure that the following information concerning consignments of food of animal origin is made available to the food business operator to whom the food is supplied and, upon request, to the competent authority: (a) an accurate description of the food; (b) the volume or quantity of the food; (c) the name and address of the food business operator from which the food has been dispatched;	Article 18 does not specify what type of information should be kept by the food and feed business operators. However, to fulfil the objective of Article 18, the following information should be kept at least. - Name, address of supplier, and identification of products supplied; - Name, address of customer, and identification of products delivered; - Date and, where necessary, time of transaction / delivery; - Volume, where appropriate, or quantity; vi) Time for keeping Records Article 18 does not specify a minimum period of time for keeping records, and therefore it is for the businesses to decide, bearing in mind that failure to produce adequate records would constitute an offence. On a broad basis, it is considered that commercial documents are usually registered for a period of 5 years for taxation controls. It is suggested that this 5 year period, where applied from date of manufacturing or delivery to traceability records, would be likely to meet the objective of Article 18. However, this common rule would need to be adapted in some cases:

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
15.1.3 All production and quality control records shall be reviewed by the relevant department to ensure that all processing is in accordance with the regulations and that any anomalies found are dealt with immediately. 15.1.4 The relevant records specified in this specification shall be kept for a period of not less than two years.	(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	- For highly perishable products, which have a "use by" date less than 3 months or without a specified date, destined directly to final consumer, records could be kept for the period of 6 months after date of manufacturing or delivery. - For other products with a "best before" date, records could be kept for the period of the shelf-life plus 6 months; - For products without a specified durability date, the general rule of 5 years could apply. Finally, it should be taken into account that, apart from the traceability provisions of Article 18 of the Regulation, many food businesses are subject to more specific requirements in terms of record keeping (type of information to be kept and time). Competent authorities should ensure that they comply with these rules.
15.2 Document management 15.2.1 A document management system shall be established and a complete quality management file shall be built up, and documents shall be classified and kept. The documents distributed and used shall be the approved current version. Documents that have been abrogated or expired should not be present at the work site except to be kept on file for inspection.	**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: (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective	**Guidance document Commission Notice 2022/C 355/01, Annex I, 5 Documentation** Regulation (EC) No 852/2004 does not explicitly require the documentation of GHP. However, it seems difficult to carry out a hazard analysis and demonstrate compliance with GHP, if these are not documented and some records kept. GHP should be documented in the GHP plan and may

GB 12693-2010 - Good manufacturing practice	EU legislation	Implementing rules and comparative evaluation
15.2.2 Enterprises are encouraged to adopt advanced technical means (e.g. electronic computer information systems) for the management of documents and records.	application of the measures outlined in subparagraphs (a) to (f).	need to be continuously supplemented by records when GHP requiring greater attention have been identified. Such GHP plan should be part of (integrated in) the HACCP plan (see Annex II, Section 11). Procedures on documentation and record keeping recommended in the HACCP plan apply: adapted to the nature and size of the business, use of generic guidance, nominated responsible person, period kept, etc.

5 GB 27341 - Hazard Analysis and Critical Control Point (HACCP) System - General Requirements for Food Processing Plant

A detailed comparative assessment of the Chinese Food Safety Standard GB 27341 is available in the document *'A comparison of PRC legislation and food standards related to hygiene and food safety in the production of pork, beef and poultry meat and offal versus pertinent EU legislation'* of 17 November 2020 that was conducted under the same contract. TO BE ADDED LATER

The analysis found that Chinese general requirements related th Hazard Analysis and Critical Control Points in food production are fully addressed by applicable EU legislation and guidance. Legally authorized establishments that produce or process dairy products in the EU fulfil Chinese HACCP standards.

6 National standard GBT 527342 – 2009 - Hazard analysis and critical control point (HACCP) system - Requirements for dairy processing plant

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	EU legislation: Regulation (EC) No	Implementing rules and comparative evaluation
1 Scope This standard specifies the requirements for a Hazard Analysis and Critical Control Point (HACCP) system for dairy producers to be able to provide safe dairy products that meet the requirements of laws, regulations and customers. This standard applies to the establishment, implementation and evaluation of the HACCP system for dairy product manufacturers, including the procurement of raw and auxiliary materials and packaging materials, processing, packaging, storage and transport.	**Regulation (EC) No 852/2004, Article 1** 1. 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; (d) general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility.	

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	EU legislation: Regulation (EC) No	Implementing rules and comparative evaluation
3 Terms and definitions The terms established in GB/T 27341-2009 and the following terms and definitions apply to this standard. 3.1 dairy product Products made from raw cow (sheep) milk and its products as the main raw material and processed. These include: liquid milk (pasteurised milk, sterilised milk, sour cow's milk, formula milk); milk powder (whole milk powder, skim milk powder, whole milk powder with sugar and flavouring, infant formula milk powder, other formula milk powder); condensed milk (whole milk without sugar, whole milk with sugar, flavoured/modified condensed milk, formula condensed milk); milk fat (thin cream, cream, anhydrous cream); cheese (raw cheese, reconstituted cheese) other dairy products (casein, lactose, whey powder, etc.). 3.2 Cleaning-in-place The circular flushing of closed circuit food equipment and its piping with water, cleaning agents, disinfectants and associated equipment (CIP).	**Regulation (EC) No 853/2004 Annex I Definitions** 4.1. 'Raw milk' means milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40 °C or undergone any treatment that has an equivalent effect. 4.2. 'Milk production holding' means an establishment where one or more farmed animals are kept to produce milk with a view to placing it on the market as food. 7.2. 'Dairy products' means processed products resulting from the processing of raw milk or from the further processing of such processed products.	

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
4 HACCP systems for dairy producers Dairy production enterprises should plan, establish, document, implement, maintain, update and continuously improve the HACCP system and ensure its effectiveness in accordance with the requirements of 4.1 and 4.2 in GB/T 27341-2009.	**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. 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.	GB Standard 27341 is evaluated elsewhere - see Pont 5 above.
5 Management responsibilities Dairy producers should meet the requirements of Chapter 5 of GB/T 27341-2009.		GB Standard 27341 is evaluated elsewhere - see Pont 5 above.

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
6 Prerequisite plans **6.1 General principles** Dairy production enterprises shall establish and implement appropriate prerequisite plans in accordance with the requirements of Chapter 6 in GB/T 27341-2009, taking into account the specific conditions of the enterprise. **6.2 Human resource protection plan** Personnel involved in the production, inspection and management of dairy products should meet the requirements of GB 12693. **6.3 Good Manufacturing Practices (GMP)** Dairy product manufacturers should establish and implement GMPs suitable for their enterprises in accordance with relevant laws and regulations and the requirements of GB 12693.	**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 and any specific requirements provided for in Regulation (EC) No 853/2004.	*For GB 12693 see above (under National food safety standard - good manufacturing practice for milk products).* *For GB 12693 see above.* **Guidance document Commission Notice 2022/C 355/01, Annex I, 3.13** Work instructions or standard operation procedures should be clear, accurate and simple, visible or easily accessible. They may include instructions to clean and report, 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, etc.

6.4 Sanitary Standard Operating Procedures (SSOP) Dairy producers shall establish and implement SSOPs that meet the requirements of 6.4 of GB/T 27341-2009 and are appropriate for their enterprise. where appropriate, these shall include, but not be limited to, the following a) For recycled packaging of dairy products, appropriate hygienic operating procedures shall be established and implemented, monitoring requirements shall be clearly defined, and the packaging shall be inspected before it is put into use. Disposable pre-packaged containers are prohibited from recycling. b) Enterprises should specify CIP system procedures and verify their effectiveness, specify the temperature, time, flow rate, acid and alkali concentration requirements for each step, and implement them as specified. the effect of CIP cleaning and chemical residues should be effectively monitored and tested (e.g. conductivity meter, pH test paper or other monitoring and testing measures) c) When equipment and facilities are cleaned and disinfected, it should be ensured that there are	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter III, Wrapping and packaging** Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products and colostrum-based products, takes place by means of sealing devices that prevent contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check. **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, II, A** 3. Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and must be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials. 4. After use, such surfaces must be cleaned and, where necessary, disinfected. **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, II, A** 1. Milking equipment and premises where milk and colostrum are stored, handled or cooled	

no blind areas or dead ends for cleaning and disinfection. d) In the production of dairy products, clean work areas such as semi-finished product storage, fermentation inoculation, filling and inner packaging workshops should be clearly defined to control the flow of people, goods, water and air. (e) should be equipped with refrigeration and freezing equipment or take refrigeration and freezing measures to ensure the temperature requirements of refrigerated and frozen dairy products. f) Suitable testing and control protocols should be developed, and hygienic testing should be carried out on dairy product packaging materials, air or staff arms, production equipment, work appliances, etc. g) The water used for cleaning equipment and utensils in contact with dairy products should comply with the provisions of GB5749.	must be located and constructed so as to limit the risk of contamination of milk and colostrum. 2. Premises for the storage of milk and colostrum must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment. **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, III, Criteria for raw milk** 2. A representative number of samples of raw milk and colostrum collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4 in case of raw milk and with the existing national criteria referred to in point 1(b) in case of colostrum. **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter III, Wrapping and packaging** Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products and colostrum-based products, takes place by means of sealing devices that prevent contamination.	*For GB 5749 see the comparison of Chinese national standards concerning meat with EU legislation requirements.*

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
h) When packaging dairy powder, the hygiene of the environment, personnel, packaging machines and work utensils should be controlled.		GB Standard 27341 is evaluated elsewhere - see Pont 5 above.
6.5 Raw and auxiliary materials, packaging materials safety and health protection system Dairy producers should fully meet the requirements of 6.5 in GB/T 27341-2009 and establish a safety and hygiene protection system for raw milk, other raw and auxiliary materials and packaging materials. This shall include, but not be limited to, the following aspects. a) Raw milk shall originate from dairy farms, farming communities and/or raw milk purchasing stations with raw milk purchasing permits. Vehicles transporting raw milk shall have a certificate of permission to transport. A raw milk handover slip shall be available. b) In order to prevent raw milk containing potentially or unknown unsafe ingredients from entering the processing plant, the dairy producer shall establish a conformity assessment of the milk source supplier and conduct quality monitoring of raw milk in due course.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, Raw milk and colostrum – primary production, I Health requirements** Food business operators producing or, as appropriate, collecting raw milk and colostrum must ensure compliance with the requirements laid down in this Chapter. 1. Raw milk and colostrum must come from animals: (a) that do not show any symptoms of infectious diseases communicable to humans through milk and colostrum; (b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and colostrum and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with	GB Standard 27341 is evaluated elsewhere - see Pont 5 above.

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	EU legislation: Regulation (EC) No	Implementing rules and comparative evaluation
c) A safety and health assurance system shall be established for other raw and auxiliary materials, additives and packaging materials, etc. Purchased products shall come from enterprises that meet the requirements of laws and regulations and comply with relevant quality and safety standards.	diarrhoea and fever, or a recognisable inflammation of the udder; (c) that do not have any udder wound likely to affect the milk and colostrum; (d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC; (e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed. **Regulation (EC) No 852/2004, Annex II, Chapter IX, Provisions applicable to foodstuffs** 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.	

6.6 Maintenance plans Dairy product manufacturers should fully meet the requirements of 6.6 in GB/T 27341-2009. The development of a maintenance plan should include, but not Limited to the following. a) Measures to prevent disruption and contamination of other lines in production when emergency repairs are carried out. b) It shall ensure that equipment is in good condition, including sterilisation, sterilisation and monitoring equipment, automatic program control systems, CIP systems, dosing systems, water supply facility systems, single or combined anti-mixing valves, sealing of important units or components, important metering and testing facilities, aseptic filling and packaging systems, steam and compressed air safeguard systems, air purification systems, refrigeration systems, etc. c) The equipment and facilities should meet the process requirements such as temperature and pressure required for production. d) Production equipment and facilities should be inspected and maintained in a timely manner to prevent metal and other foreign objects from being mixed into the dairy products. e) Equipment, pipes or lines should be reasonably marked.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, Raw milk and colostrum – primary production, II Hygiene on milk and colostrum production holdings** A. Requirements for premises and equipment 1. Milking equipment and premises where milk and colostrum are stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk and colostrum. 2. Premises for the storage of milk and colostrum must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment. 3. Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and must be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials. 4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once	*For GB/T 27341-2009 see the comparison of Chinese national standards concerning meat with EU legislation requirements.*

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	EU legislation: Regulation (EC) No	Implementing rules and comparative evaluation
	a day, containers and tanks used for the transport of milk and colostrum must be cleaned and disinfected in an appropriate manner before re-use.	
6.7 Marking and traceability schemes, dairy product recalls Dairy product manufacturers shall meet the requirements of 6.7 in GB/T 27341-2009. This shall include, but not be limited to, the following (a) Raw materials such as raw milk, auxiliary materials, semi-finished products to finished products should be clearly marked and traceable. The finished products shall be marked in accordance with the requirements of relevant standards and regulations such as GB 7718 and GB 13432. (b) Raw milk should be traced back to the dairy farm, farming community and/or raw milk purchase station. (c) Dairy product manufacturers should establish raw milk purchase records, recording truthfully the name of the supplier as well as contact details, date of purchase and quantity. c) Dairy product manufacturers should take measures such as harmless disposal and	**Regulation (EC) No 178/2002 (General food law), Article 18** 1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution. 2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. 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. **Regulation (EC) No 178/2002 (General food law), Article 19**	

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	EU legislation: Regulation (EC) No	Implementing rules and comparative evaluation
destruction of recalled unsafe dairy products to prevent them from re-entering the market. d) Enterprises should record the variety, specification, batch number, quantity and destination of all products shipped. e) Enterprises should establish product recall procedures. If a dairy product manufacturer finds that the dairy products it produces do not meet the national standards for quality and safety of dairy products, are hazardous to human health and life safety, or are likely to endanger the health or growth and development of infants and young children, it shall immediately stop production, report to the relevant competent authorities, and shall inform sellers and consumers, recall the problematic dairy products that have been shipped and marketed for sale, and record the recall.	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.	
6.8 Emergency Preparedness Dairy producers should meet the requirements of 6.8 in GB/T 27341-2009 and identify potential dairy product safety incidents or emergencies, develop emergency plans and respond when necessary to reduce the impact of possible safety hazards.		**Guidance document Commission Notice 2022/C 355/01, Annex I, 3.5 Technical maintenance** 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, etc.

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	EU legislation: Regulation (EC) No	Implementing rules and comparative evaluation
7 Establishment and implementation of the HACCP plan **7.1 General rules** 7.2.1 General principles Dairy producers should complete the preparatory steps in accordance with the requirements in 7.2 of GB/T 27341-2009. 7.2.2 Composition of the HACCP team The composition of the HACCP team should meet the requirements of the dairy production enterprise's professional coverage and consist of multi-disciplinary personnel, including health and quality control personnel, product development personnel, dairy production process technicians, equipment management personnel, raw milk and auxiliary materials procurement, sales, storage and transport management personnel. If necessary, the HACCP team may include personnel with expertise in dairy farming and veterinary animal husbandry.		**Commission Notice 2022/C 355/01** **Annex II, 4 Preliminary activities** The preliminary activities below are not explicitly laid down in EU legislation, nevertheless they are considered as essential when developing and implementing HACCP-based procedures. These preliminary activities traditionally consist of 5 steps and when combined with the 7 HACCP principles, result a 12-steps approach. 4.1. 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 the overall FSMS. Where necessary, the team should be assisted by specialists who will help it to solve difficulties in the development and implementation of the HACCP-based procedures.

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
7.2.3 Product description Dairy producers should describe their products in accordance with the requirements of 7.2.2 in GB/T 27341-2009. 7.2.4 Determination of intended use		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. food microbiology, legislative requirements, machinery used for food manufacturing, its maintenance and cleaning. 4.2. Description of the product(s) at the end of the process A full description of the end product should be drawn up, including relevant safety information such as: (*examples are given*). 4.3. Identification of intended use The HACCP team should also define the reasonably foreseeable 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,

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
Manufacturers of dairy products should determine the intended use of the product in accordance with the requirements of 7.2.3 in GB/T 27341 - 2009. The intended use of dairy products by different population groups should be determined. 7.2.5 Development and validation of flow charts Dairy producers should develop and validate flow charts in accordance with the requirements of 7.2.4 and 7.2.5 in GB/T 27341-2009. 7.3 Hazard analysis and development of control measures 7.3.1 General provisions Dairy producers should carry out hazard analysis and develop control measures in accordance with the requirements of 7.3 in GB/T 27341-2009. For significant hazards caused by human damage or deliberate contamination, dairy producers should also establish a protection plan for dairy products as a control measure. 7.3.2 The following information should also be considered when carrying out a hazard analysis. a) Adulteration and forgery of raw milk, etc.		travelers, etc. and for vulnerable groups of the population may have to be considered. 4.4. Construction of a flow diagram (description of manufacturing process) 4.5. On-site confirmation of flow diagram **Commission Notice 2022/C 355/01 Annex II,** **5. Hazard analysis (principle 1)** 5.1. Identification of relevant hazards A hazard is a biological, chemical (including allergens) or physical agent in food or feed with the potential to cause an adverse health effect. While allergens are considered a chemical hazard, some FBOs find it easier to treat allergens as a fourth hazard during hazard analysis. All major potential biological, chemical or physical hazards that may be reasonably expected to occur in a product 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 then identify where these potential hazards are reasonably likely to occur at each process step (including production, acquisition, storage, transport and handling of raw materials and ingredients and

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	EU legislation: Regulation (EC) No	Implementing rules and comparative evaluation
b) Environmental contaminants (e.g. heavy metals, nitrates and nitrites, etc.). c) Biotoxins (e.g. aflatoxins, etc.). d) Suitable conditions for microbial reproduction. e) antibiotics. f) allergens. g) foreign bodies. 7.3.3 Dairy product safety risk assessment Based on information published by government departments on the safety of dairy products, dairy producers should conduct dairy product safety risk evaluations when appropriate. 7.4 Determination of Critical Control Points (CCPs) and Critical Limit Values (CLs) 7.4.1 General rules Dairy producers shall determine Critical Control Points (CCPs) and Critical Limit Values (CLs) in		delays during manufacture). The HACCP team should next evaluate the hazards to identify at which hazards are of such a nature that their prevention, elimination or reduction to acceptable levels is essential to the production of a safe food (end product). In conducting the hazard analysis to determine whether there are significant hazards, wherever possible the following should be considered: *(examples are given).* 5.2. Control measures The FBO should consider and describe what control measures, if any, can be applied for each hazard at each process step *(examples are given).* **Commission Notice 2022/C 355/01) Annex II,** **6. Identification of critical control points (CCP) (principle 2) and** **7. Critical limits at CCP (principle 3)** 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. CCP are intended to address only significant hazards in an establishment. In addition, for each

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
accordance with the requirements of 7.4 and 7.5 of GB/T 27341-2009. 7.4.2 Factors to be considered in determining Critical Control Points (CCPs) and Critical Limit Values (CLs) 7.4.2.1 It is appropriate to consider, but not limited to, the following important production control processes and factors for the receipt and storage of raw milk and other raw materials.		control measure, the systematic approach shall include an assessment of the feasibility of: — establishing measurable/observable critical limits and/or measurable/observable action criteria; — monitoring to detect any failure to remain within critical limit and/or measurable/observable action criteria; — applying timely corrections in case of failure. *See below for the evaluation of national standard GB 19301 dealing with raw milk.*
a) Raw milk should meet the requirements of GB/T 6914 and GB 19301 quality and hygiene indicators, etc., and avoid contamination by toxic and hazardous substances. It shall be accepted only after passing the test. b) Accepted raw milk should be processed for dairy products as soon as possible. When temporary storage is required, it should be quickly cooled to 0°C ~ 4°C and included in the milk storage tank (milk silo) for temporary storage, with a storage temperature of no more than 7°C and a storage time of no more than 24h.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, Raw milk and colostrum – primary production, II. Hygiene on milk and colostrum production holdings, B** 2. Immediately after milking, milk and colostrum must be held in a clean place designed and equipped to avoid contamination. (a) Milk must be cooled immediately to not more than 8° C in the case of daily collection, or not more than 6° C if collection is not daily; **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter II, Requirements concerning dairy products, I. Temperature requirements**	*The minimal difference in prescribed storage temperature will not affect the microbiological safety of the product. More relevant is the strict compliance with the respective requirements in practice.*

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
(c) the receipt of raw milk powder should be in line with GB/T 5410 and GB 19644 index requirements, the receipt of raw whey powder should be in line with the index requirements of GB 11674. (d) The storage temperature and humidity of milk powder and whey powder should comply with the regulations. d) Safety and health indicators that are not covered by the inspection department of the enterprise, such as aflatoxin, pesticide and veterinary drug residues, heavy metals, etc., should be sent for regular inspection by the enterprise and an inspection report should be issued by an institution with relevant qualifications. (e) Enterprises should conduct regular verification of the nutritional fortification agents used, such as vitamins and trace elements. 7.4.2.2 It is appropriate to consider, but not limited to, the following important production control processes and factors for additives and ingredients.	1. Food business operators must ensure that, upon acceptance at a processing establishment, (a) milk is quickly cooled to not more than 6° C; **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, III. Criteria for raw milk** 2. A representative number of samples of raw milk and colostrum collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4 in case of raw milk and with the existing national criteria referred to in point 1(b) in case of colostrum. The checks may be carried out by, or on behalf of: (a) the food business operator producing the milk; (b) the food business operator collecting or processing the milk; (c) a group of food business operators; or	*See below for the evaluation of national standard GB 19644 dealing with milk powder.* *See below for the evaluation of national standard GB 11674 dealing with whey powder.*

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
a) The variety and addition of food additives used in dairy products should be in accordance with GB2760 and GB14880. b) Depending on the variety of dairy product, its batching process should have a review procedure to ensure the correct type, order and quantity of ingredients are fed. c) When producing powdered formula, the homogeneity of the ingredient mix should be regularly confirmed. When the formula, raw materials, equipment, process, etc. are changed, they should be reconfirmed in time. 7.4.2.3 Sterilisation and sterilisation should consider, but not be limited to, the following important production control processes and factors. a) When heat sterilisation and sterilisation processes are used, well-founded heating parameters should be developed and correctly implemented according to the requirements of the different types of product to ensure the safety characteristics of the product. The sterilisation temperature and holding time for pasteurised milk is generally 63°C to 65°C for 30	(d) in the context of a national or regional control scheme. 4. Without prejudice to Directive 96/23/EC, food business operators must initiate procedures to ensure that raw milk is not placed on the market if either: (a) it contains antibiotic residues in a quantity that, in respect of any one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90, exceeds the levels authorised under that Regulation; or (b) the combined total of residues of antibiotic substances exceeds any maximum permitted value. **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter II, Requirements concerning dairy products, II. Requirements for heat treatment** 1. When raw milk, colostrum, dairy or colostrum-based products undergo heat treatment, food business operators must ensure that this satisfies the requirements laid down in Chapter XI of Annex II to Regulation (EC) No 852/2004. In particular, they shall ensure, when using the following processes, that they comply with the specifications mentioned:	

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	EU legislation: Regulation (EC) No	Implementing rules and comparative evaluation
min or 72°C to 85°C for 15s to 20s; the sterilisation temperature and holding time for ultra-high temperature instantaneous sterilised milk should be above 135°C for a few seconds; The sterilisation temperature and holding time for holding sterilisation (secondary sterilisation) is generally not less than 110°C and more than 10min. There should be relevant sterilization, sterilization records and, if necessary, automatic temperature records.	(a) Pasteurisation is achieved by a treatment involving: (i) a high temperature for a short time (at least 72° C for 15 seconds); (ii) a low temperature for a long time (at least 63° C for 30 minutes); or (iii) any other combination of time-temperature conditions to obtain an equivalent effect, such that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment. (b) Ultra high temperature (UHT) treatment is achieved by a treatment: (i) involving a continuous flow of heat at a high temperature for a short time (not less than 135° C in combination with a suitable holding time) such that there are no viable microorganisms or spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature, and (ii) sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at 30° C in closed containers or for seven days at 55° C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.	

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	EU legislation: Regulation (EC) No	Implementing rules and comparative evaluation
(b) The sterilisation and sterilisation effect of the product shall be confirmed before the sterilisation and sterilisation unit is used, or after the unit has been modified and the process has been adjusted.	2. When considering whether to subject raw milk and colostrum to heat treatment, food business operators must: (a) have regard to the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) No 852/2004; and (b) comply with any requirements that the competent authority may impose in this regard when approving establishments or carrying out checks in accordance with Regulation (EC) No 854/2004. **Regulation (EC) No 852/2004, Annex II, Chapter XI Heat treatment** The following requirements apply only to food placed on the market in hermetically sealed containers: 1. any heat treatment process used to process an unprocessed product or to process further a processed product is: (a) to raise every party of the product treated to a given temperature for a given period of time; and (b) to prevent the product from becoming contaminated during the process; 2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant	

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
	parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices; 3. the process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation).	
7.4.2.4 It is appropriate to consider, but not limited to, the following important production control processes and factors for fermented dairy products. a) Purity and viability of the fermenting agent. b) Preparation of the culture medium.		No specific requirements for fermented dairy products are laid down in EU legislation. However, general and specific hygiene rules apply to raw materials, processes and products.
7.4.2.5 It is appropriate to consider, but not limited to, the following important production control processes and factors for packaging (filling). a) Aseptic filling machine concentration of hydrogen peroxide or spray volume, UV lamp life. b) When applicable, the stacking rate of dairy products in audible form should be tested. c) Product packaging for dairy products should be tight and free from breakage.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter III, Wrapping and packaging** Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products and colostrum-based products, takes place by means of sealing devices that prevent contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check.	
7.4.2.6 It is appropriate to consider, but not limited to, the following important production control processes and factors for the		No specific requirements for dried dairy dairy products are laid down in EU legislation. However, general and specific hygiene rules apply to raw materials, processes and products.

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
concentration and spray drying processes in the wet production of dairy powders. a) Concentrated milk concentration, concentrated milk temperature. b) Spray pressure or centrifugal disc speed. c) drying chamber inlet air temperature and inlet air volume, drying chamber exhaust air temperature and exhaust air volume. 7.4.2.7 Storage and transport of chilled and frozen dairy products should include, but not be limited to, the following important control processes and factors. a) Refrigeration at a typical temperature of 2°C to 6°C. b) The freezing temperature for cream and anhydrous cream products is generally -15°C or less. c) During transport, the temperature inside the transport vehicle compartment should be maintained within the temperature range required for product storage. 7.4.2.8 The enterprise shall also consider other control processes and factors affecting the safety of dairy products in relation to its own process conditions, product characteristics, equipment and facilities, personnel and other circumstances.	**Regulation (EC) No 852/2004, Annex II, Chapter IX, Provisions applicable to foodstuffs** 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. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health. Food businesses manufacturing, handling and wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials	See also below for the assessment of GB 19644-2010 dealing with milk powder.

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
7.4.3 Where 7.4.2 processes and factors are controlled by standard operating procedures (SOPs) that can be equated to CCP controls, the basis, parameters and documentation identified in the SOPs are to be maintained. 7.5 CCPs monitoring Dairy producers should implement CCPs monitoring in accordance with the requirements of 7.6 in GB/T 27341-2009. 7.6 Corrective measures Dairy producers should establish corrective measures for deviations from key limits in accordance with the requirements of 7.7 in GB/T 27341-2009. 7.7 Confirmation and validation of HACCP plans Dairy producers shall confirm and validate the HACCP plan in accordance with the requirements	from processed material and sufficient separate refrigerated storage. 6. Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.	**Commission Notice 2022/C 355/01) Annex I, 3.13 Working methodology** Work instructions or standard operation procedures should be clear, accurate and simple, visible or easily accessible. **Commission Notice 2022/C 355/01) Annex II, 8. Monitoring procedures at CCP (principle 4)** *For GB/T 27341-2009 see the comparison of Chinese national standards concerning meat with EU legislation requirements.* **Commission Notice 2022/C 355/01) Annex II, 9. Corrective actions (principle 5)** *For GB/T 27341-2009 see the comparison of Chinese national standards concerning meat with EU legislation requirements.* **Commission Notice 2022/C 355/01) Annex II, 10. Validation and verification procedures (principle 6)**

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
of 7.8 in GB/T 27341-2009. This should include, but is not limited to, the following areas. a) Holding inspection and preservation testing of dairy products. b) Packaging effectiveness of aseptic filling or packaging systems. c) Evidence of testing for compliance of additives and food fortification additions.	**Regulation (EC) No 852/2004, Annex II, Chapter XI Heat treatment** The following requirements apply only to food placed on the market in hermetically sealed containers: 1. any heat treatment process used to process an unprocessed product or to process further a processed product is: (a) to raise every party of the product treated to a given temperature for a given period of time; and (b) to prevent the product from becoming contaminated during the process; 2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices; **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, I Health requirements** 1. Raw milk and colostrum must come from animals:	*For GB/T 27341-2009 see the comparison of Chinese national standards concerning meat with EU legislation requirements.*

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
d) Dairy product manufacturers shall inspect dairy products leaving the factory in accordance with the requirements of relevant regulations or standards.	(d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC;	**Commission Notice 2022/C 355/01) Annex II, 10. Validation and verification procedures** After the procedures based on the HACCP principles have been implemented, the HACCP team should establish verification procedures to confirm that the HACCP-based procedures are working correctly. Methods for verification may include: — random sampling and analysis, reinforced analysis or tests at selected critical points: — intensified analysis of intermediate or end products e.g. on compliance with microbiological criteria
e) Dairy products for special consumption purposes (e.g. powdered milk formula for infants and young children) shall be regularly verified for their nutritional and other special ingredients.	**Regulation (EU) No 2016/127 as** regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding	**Commission Notice 2022/C 355/01) Annex II, 11. Documentation and record keeping (principle 7)**
7.8 Record keeping	**Regulation (EC) No 852/2004, Annex I, III Record keeping**	

GBT 527342 – 2009 - HACCP system - Requirements for dairy processing plant	**EU legislation: Regulation (EC) No**	**Implementing rules and comparative evaluation**
Dairy product manufacturers should maintain records related to HACCP plans and other relevant records in accordance with the requirements of 7.9 in GB/T 27341 - 2009. Relevant inspection reports should be kept for at least 2 years.	7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business.	*For GB/T 27341-2009 see the comparison of Chinese national standards concerning meat with EU legislation requirements.* **Commission Notice 2022/C 355/01) Annex II, 11. Documentation and record keeping** The documentation should be kept permanently available in any format for the HACCP team and at the request of the competent authorities e.g. for auditing purposes. Records should be kept for an appropriate period of time in any format. That period should be long enough to ensure information to be available in case of an alert that can be traced back to the food in question. For certain foods the date of consumption is certain. For instance, in food catering, consumption takes place shortly after the time of production. For food for which the date of consumption is uncertain, records should be kept for a reasonably short period after the expiry date of the food.

7 National standard GB 19301-2010 – Raw milk

GB 19301-2010 – Raw milk	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard applies to raw milk and does not apply to ready-to-eat raw milk.	**Regulation (EC) No 853/2004, Article 1 Scope** 1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.	
3 Terms and definitions **3.1 Raw milk** Standing milk that has not been altered in any way from the udders of healthy dairy animals that meet the relevant national requirements. Colostrum from seven days after calving, milk during the application of antibiotics and during the break in medication, and spoiled milk should not be used as raw milk.	**Regulation (EC) No 853/2004, Annex I** 4.1. 'Raw milk' means milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40 °C or undergone any treatment that has an equivalent effect. **Regulation (EC) No 853/2004, Annex III, Section IX Raw milk, colostrum, dairy products and colostrum-based products** 1. 'Colostrum' means the fluid secreted by the mammary glands of milkproducing animals up to three to five days post parturition that is rich in antibodies and minerals, and precedes the production of raw milk.	
4 Technical requirements **4.1 Sensory requirements:** the requirements in Table 1 should be met.	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, II Hygiene on milk and colostrum production holdings, B Hygiene during milking**	

GB 19301-2010 – Raw milk	EU legislation	Implementing rules and comparative evaluation
Sensory requirements: Colour: Milky white or slightly yellow Taste and smell: Aromas inherent to milk, without odour Tissue: It is a homogeneous and consistent liquid, without clots, precipitation or Foreign matter visible to normal vision **4.2 Physico-chemical indicators:** shall conform to the provisions of Table 2. **Physical and chemical indicators:** Freezing point (tested after 3h of extrusion; only applicable to Holstein cows) (℃) -0.500~-0.560 Relative density (20℃/4℃) ≥ 1.027 Protein (g/100g) ≥ 2.8 Fat (g/100g) ≥ 3.1 Impurity (mg/kg) ≤ 4.0 Non-fat milk solids (g/100g) ≥ 8.1 Acidity (°T) buttermilk (only applicable to Holstein cows) 12~18 goat's milk 6~13 **4.3 Contaminant limits:** should comply with the provisions of GB 2762.	1. Milking must be carried out hygienically, ensuring in particular: (a) that, before milking starts, the teats, udder and adjacent parts are clean; (b) that milk and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption; **Regulation (EC) No 1881/2006** lays down the maximum levels for certain contaminants in foodstuffs. 3.1.1 Raw milk (6), heat-treated milk and milk for the manufacture of milk-based products	Details on Standard 2762-2017 in Annex 3 provides further details for dairy products.

GB 19301-2010 – Raw milk	EU legislation	Implementing rules and comparative evaluation
4.4 Mycotoxin limits: should comply with the provisions of GB 2761. **4.5 Microbiological limits**: should be in accordance with the provisions of Table 3. **Microbiological limits** Total number of colonies ≤ 2 x 10^6 Limit CFU/g (mL)	maximum levels of lead: 0,020 (mg/kg wet weight) 3.1.19 milk fat maximum levels of lead: 0,10 (mg/kg wet weight) 5.8 raw milk and dairy products, including butterfat maximum levels of sum of dioxins: 2,5 pg/g fat of sum of dioxins and dioxin-like PCBs: 5,5 pg/g fat of other specified PCB's: 40 ng/g fat 2.1.13 Raw milk, heat-treated milk and milk for the manufacture of milk-based products maximum level of aflatoxin: 0,050 (µg/kg) **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, III Criteria for raw milk** 1. (a) The following criteria for raw milk apply pending the establishment of standards in the context of more specific legislation on the quality of milk and dairy products. 2. A representative number of samples of raw milk and colostrum collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4 in case of raw milk and with the existing national criteria referred to in point 1(b) in case of colostrum.	A difference in requirements for raw milk applies: in the Chinese national standard the microbiological limit is ≤ 2 x 10^6 CFU/g (ml) of total number of colonies, while the EU legislative requirement is for raw cows' milk a plate count at 30° C (per ml) of ≤ 100 000 and a somatic cell count (per ml) of ≤ 400 000.

GB 19301-2010 – Raw milk	EU legislation	Implementing rules and comparative evaluation
4.6 Pesticide residue limits and veterinary drug residue limits 4.6.1 Pesticide residues shall comply with GB2763 and relevant national regulations and announcements. 4.6.2 Residues of veterinary drugs should be in accordance with the relevant national regulations and announcements.	3. (a) Food business operators must initiate procedures to ensure that raw milk meets the following criteria: (i) for raw cows' milk: Plate count at 30° C (per ml) ≤ 100 000 (*) Somatic cell count (per ml) ≤ 400 000 (**) (*) rolling geometric average over a two-month period, with at least two samples per month (**) rolling geometric average over a three-month period, with at least one sample per month, … **Regulation (EC) No 396/2005 lays down maximum residue levels of pesticides in food such as raw milk, cream or butter. The levels vary between 0.01 and 0.03 mg/kg depending on the pesticide involved. Only a few levels are set on 0.05, 0.07 or 0.1 mg/kg.** **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, II Hygiene on milk and colostrum production holdings, B Hygiene during milking** 1. Milking must be carried out hygienically, ensuring in particular: (d) the identification of animals undergoing medical treatment likely to transfer residues to the milk and colostrum, and that milk and colostrum obtained from such animals before the	GB 2763 sets over 10.000 residue limits for pesticides that are applicable in China – like EU Regulation (EC) No 396/2005 does for the EU. A brief comparison was undertaken in the document *Comparative Analysis of Chinese Rules for Fishery Products - Overview of EU law versus Chinese law concerning the export of fish and fishery products to the People's Republic of China,* dated 22 November 2022 that was produced under the same contract. Few, minor differences were found, which are not considered to be of any relevance for consumer safety. Dairy products produced in accordance with EU provisions related to pesticide residues and environmental contaminants fulfil Chinese food safety standards. See annex 4 for details

GB 19301-2010 – Raw milk	EU legislation	Implementing rules and comparative evaluation
	end of the prescribed withdrawal period are not used for human consumption;	

8 National standard GB 19644 – 2010: Milk powder

GB 19644 – 2010 – Milk powder	EU legislation	Implementing rules and comparative evaluation
3 Terms and definitions **3.1 milk powder** A powdered product made from raw cow's (sheep's) milk and processed. **3.2 formulated milk powder** Powdered products made from raw cow's (sheep's) milk or its processed products, with or without the addition of other raw materials, food additives and nutritional fortification, and processed to a milk solids content of not less than 70 %.	**Regulation (EC) No 853/2004, Annex I** 7.2. 'Dairy products' means processed products resulting from the processing of raw milk or from the further processing of such processed products. **Commission Decision 97/80/EC, Annex I, Explanatory notes** Powdered dairy products: product obtained by eliminating water from cream, whole milk, semi-skimmed milk, skimmed milk, buttermilk and acidified milk. — Also includes additives to the raw material before the product is made into powder, — Also includes milk powder manufactured in dairies and contained in powders for infants and in animal feeds. Whole milk powder: milk powder with a milk fat content of not less than 26 % and less than 42 % by weight of the product.	
4 Technical requirements **4.1 Raw material requirements** 4.1.1 Raw milk: should comply with the provisions of GB 19301.		An assessment of GB 19301-2010 is provided under Point 7 above.

GB 19644 – 2010 – Milk powder	EU legislation	Implementing rules and comparative evaluation
4.1.2 Other raw materials: should comply with the corresponding safety standards and/or relevant regulations. **4.2 Sensory requirements**: Colour: Milk powder: a uniform, creamy yellow colour. Prepared milk powder: has the desired colour. Taste, Odour: milk powder: a pure, creamy flavour Prepared milk powder: Taste and smell as it should be. Tissue state: Dry and homogeneous powder. **4.3 Physico-chemical indicators:** should be in accordance with Table 2. **Physical and chemical indicators** Protein (g/100g) Milk powder ≥ 34% of non-fat milk solids ("Non-fat milk solids (%) = 100 % - fat (%) - moisture (%) Prepared milk powder ≥ 16.5 Fat (%) milk powder ≥ 26.0 (only applicable to full fat milk powder) Recovered milk acidity (T) cow's milk milk powder ≤ 18 goat's milk milk powder 7 ~ 14 Impurity (mg/kg) milk powder ≤ 16 Moisture (%) milk powder ≤ 5.0	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, II Hygiene on milk and colostrum production holdings, B Hygiene during milking** 1. Milking must be carried out hygienically, ensuring in particular: (a) that, before milking starts, the teats, udder and adjacent parts are clean; (b) that milk and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption; **Physico-chemical parameters for milk powder are laid down in the Agricultural Market Order of the European Union. This is not relevant for food safety or product hygiene.** Commission Regulation (EC) No 273/2008 of 5 March 2008 laying down detailed rules for the application of Council Regulation (EC) No 1255/1999 as regards methods for the analysis and quality evaluation of milk and milk products (OJL 88, 29.3.2008, p.1)	Milk powder exported to China must comply with specifications provided by Chinese law. This is not a question of food safety or product hygiene.

GB 19644 – 2010 – Milk powder	EU legislation	Implementing rules and comparative evaluation
4.4 Contaminant limits: should comply with the provisions of GB 2762.		*For GB 2762 see above under raw milk. More details in Annex 3*
4.5 Mycotoxin limits: should comply with the provisions of GB 2761.		*For GB 2761 see above under raw milk. More details in Annex 2.*
4.6 Microbiological limits: should be in accordance with the provisions of Table 3. Microbiological limits Sampling programme# and limits (if not specified, are expressed in CFU/g) Total number of colonies* n 5 c 2 m 50000 M 200000 Coliform bacteria n 5 c 1 m 10 M 100 Staphylococcus aureus n 5 c 2	**Regulation (EC) No 2073/2005, Annex I, Chapter 2. Process hygiene criteria 2.2, milk and dairy products** 2.2.7 Milk powder and whey powder* Enterobacteriaceae n 5 c 0 m 10 cfu/g M 10 cfu/g applies to end of the manufacturing process Coagulase-positive staphylococci n 5 c 2	*The criterion of Enterobacteriaceae as required in the EU legislation will cover both total number of colonies and Coliform bacteria as mentioned in the Chinese national food safety standard.* *The criterion for Enterobacteriaceae in EU legislation is slightly stricter than in the Chinese national food safety standard.*

GB 19644 – 2010 – Milk powder	EU legislation	Implementing rules and comparative evaluation
m 10 M 100 Salmonella n 5 c 0 m 0/25g M - **#** Samples are analysed and processed according to GB 4789.1 and GB 4789.18. ***** Not applicable to products with added active bacterial strains (aerobic and partly anaerobic probiotics). **4.7 Food additives and nutritional fortification** 4.7.1 The quality of food additives and nutritional fortification should comply with the corresponding safety standards and relevant regulations. 4.7.2 The use of food additives and nutrient fortification agents shall comply with the provisions of GB 2760 and GB 14880.	m 10 cfu/g M 100 cfu/g applies to end of the manufacturing process **Chapter I. Food safety criteria** 1.12 Milk powder and whey powder Salmonella n 5 c 0 m absence in 25 g M absence in 25 g 1.21. Staphylococcal enterotoxins n 5 c 0 m absence in 25 g M absence in 25 g Applies to products placed on the market during their shelf-life Regulation (EC) No 1333/2008 on food additives lays down general rules.	*Certain food additives are allowed only in flavoured milk according to Regulation (EU) No 1130/2011, which lists food additives approved for use in food.*

9 National standard GB 11674-2010 - Whey powder and whey protein powder

GB 11674-2010 Whey powder and whey protein powder	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard applies to desalted whey powder, non-desalted whey powder, whey protein powder concentrate and isolated whey protein powder.	**Regulation (EC) No 853/2004, Article 1 Scope** 1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.	
3 Terms and definitions **3.1 whey** The liquid obtained by separating the curd masses in the production of cheese, casein and other similar products from raw milk by means of rennet, acidification or membrane filtration. **3.2 whey powder** A powder product made from whey and dried. 3.2.1 Demineralised whey powder A powder made from whey, desalted and dried. 3.2.2 Non-desalted whey powder non-demineralized whey powder made from whey, not desalted, and dried. **3.3 whey protein powder** Whey protein powder made from whey with a protein content of not less than 25% by separation, concentration and drying processes.	**Regulation (EC) No 853/2004, Annex I** 7.2. 'Dairy products' means processed products resulting from the processing of raw milk or from the further processing of such processed products. **Commission Decision 97/80/EC, Annex I, Explanatory notes** Whey: by-product obtained during the manufacture of cheese or casein. In the liquid state, whey contains natural constituents (on average 4,8 % lactose, 0,8 % protein and 0,2 % fats by weight of the product) which remain when the casein and the majority of the fat have been removed from the milk.	Bovine milk basic whey protein isolate has been authorized as a novel food according to **Regulation (EU) 2018/1632 amending Regulation (EU) 2017/2470**. Description Bovine milk basic whey protein isolate is a yellowish grey powder obtained from bovine skimmed milk via a series of isolation and purification steps. Characteristics/Composition Total protein (w/weight of product): ≥ 90 % Lactoferrin (w/weight of product): 25-75 % Lactoperoxidase (w/weight of product): 10-40 % Other proteins (w/weight of product): ≤ 30 % TGF-β2: 12-18 mg/100 g Moisture: ≤ 6,0 % pH (5 % solution w/v): 5,5 – 7,6 Lactose: ≤ 3,0 % Fat: ≤ 4,5 %

GB 11674-2010 Whey powder and whey protein powder	EU legislation	Implementing rules and comparative evaluation
		Ash: ≤ 3,5 % Iron: ≤ 25 mg/100 g Heavy Metals Lead: < 0,1 mg/kg Cadmium: < 0,2 mg/kg Mercury: < 0,6 mg/kg Arsenic: < 0,1 mg/kg Microbiological criteria: Aerobic mesophilic count: ≤ 10 000 CFU/g Enterobacteriaceae: ≤ 10 CFU/g Escherichia coli: Negative/g Coagulase positive Staphylococci: Negative/g Salmonella: Negative/25 g Listeria: Negative/25 g Cronobacter spp.: Negative/25 g Moulds: ≤ 50 CFU/g Yeasts: ≤ 50 CFU/g CFU: Colony Forming Units
4 Technical requirements **4.1 Raw material requirements** 4.1.1 Whey: whey obtained from raw milk that meets the requirements of GB 19301 for the production of dairy products. 4.1.2 Other raw materials: should comply with the corresponding safety standards and/or relevant regulations.		*For national standard GB 19301-2010 see above*

GB 11674-2010 Whey powder and whey protein powder	EU legislation	Implementing rules and comparative evaluation
4.2 Sensory requirements: should be consistent with the provisions of Table 1. **Sensory requirements** Colour: a uniform colour. Taste and odour: the product has a characteristic taste and smell, without any odour. Tissue state: dry and homogeneous powdered product, no lumps, no miscellaneous visible to normal vision. Quality. **4.3 Physico-chemical indicators: shall conform to the provisions of Table 2.** **Physicochemical indicators** Protein (g/100g) Desalted whey powder ≥ 10.0 Non-desalted whey powder ≥ 7.0 Whey protein powder ≥ 25.0 Ash content (g/100g) Desalted whey powder ≤ 3.0 Non-desalted whey powder ≤ 15.0 Whey protein powder ≤ 9.0 Lactose (g/100g） Whey powder ≥ 61.0 Whey protein powder -- Water content (g/100g） whey powder ≤ 5.0 Whey protein powder ≤ 6.0	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, II Hygiene on milk and colostrum production holdings, B Hygiene during milking** 1. Milking must be carried out hygienically, ensuring in particular: (a) that, before milking starts, the teats, udder and adjacent parts are clean; (b) that milk and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption;	*For GB 2762 see see above under raw milk. See Annex 3 for more details.*

GB 11674-2010 Whey powder and whey protein powder	EU legislation	Implementing rules and comparative evaluation
4.4 Contaminant limits: should comply with the provisions of GB 2762. **4.5 Mycotoxin limit**: should comply with the provisions of GB 2761. **4.6 Microbial limits**: Staphylococcus aureus n 5 c 2 m 10 M 100 Salmonella n 5 c 0 m 0/25g	**Regulation (EC) No 2073/2005, Annex I, Chapter 2. Process hygiene criteria** **2.2, milk and dairy products** 2.2.7 Milk powder and whey powder* Enterobacteriaceae n 5 c 0 m 10 cfu/g M 10 cfu/g applies to end of the manufacturing process Coagulase-positive staphylococci n 5 c 2 m 10 cfu/g M 100 cfu/g applies to end of the manufacturing process **Chapter I. Food safety criteria** 1.12 Milk powder and whey powder Salmonella n 5 c 0 m absence in 25 g	*For GB 2761 see the comparison of Chinese national standards concerning fish with EU legislative requirements. See Annex 2 for more details..*

GB 11674-2010 Whey powder and whey protein powder	EU legislation	Implementing rules and comparative evaluation
M - Sampling scheme and limits (if not specified, are expressed in CFU/g) Sample analysis and processing according to GB 4789.1 and GB 4789.18. **4.7 Food additives and nutritional fortification** 4.7.1 The quality of food additives and nutritional fortification should comply with the corresponding safety standards and relevant regulations. 4.7.2 The use of food additives and nutrient fortification agents should be in accordance with the provisions of GB2760 and GB 14880.	M absence in 25 g 1.21. Staphylococcal enterotoxins n 5 c 0 m absence in 25 g M absence in 25 g Applies to products placed on the market during their shelf-life	*For GB 2760 see above under milk powder. See annex 1 for more details.*

10 National standard GBT 5413.2-1997 - Milk powder and formula foods for infant and young children - determination of whey protein

This standard specifies a method for the determination of the ratio of casein to whey protein content in infant formulae and milk powders. The ratio is determined by SDS-PAGE (Laemmli method) using an optical densitometer on the spectral bands of casein and whey protein separated in order of molecular weight.

Milk powders exported from the EU, which must comply with Chinese legal requirements and market order, but the standard has no relevance for process hygiene and food safety. It is, therefore, not evaluated in detail.

11 National standard GB 25190-2010 - Sterilized milk

GB 25190-2010 - Sterilized milk	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard applies to whole, skim and partially skimmed sterilized milk.	**Regulation (EC) No 853/2004, Article 1 Scope** 1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.	
3 Terms and definitions **3.1 ultra-high-temperature milk** A liquid product made from raw cow's (sheep's) milk, with or without the addition of recovered milk, which is sterilised by heating to at least 132°C in a continuous flow state and maintained for a short period of time, and then filled aseptically. **3.2 retort sterilized milk** Liquid products made from raw cow's (sheep's) milk, with or without the addition of retort milk, with or without preheating, which are filled and sealed and then sterilised, etc.	**Commission Decision 97/80/EC, Annex I, Explanatory notes** Sterilized: sterilized milk must: — have been heated and sterilized in hermetically sealed wrappings or containers, the seal of which must remain intact, — in the event of random sampling, be of preservability such that no deterioration can be observed after it has spent 15 days in a closed container at a temperature of + 30° C. Uperized: uperized milk (or UHT milk) must be produced by applying a continuous flow of heat using a high temperature for a short time (not less than 135° C for not less than 1 second.	Definitions are not identical but considered equivalent.
4 Technical requirements **4.1 Raw material requirements**		

GB 25190-2010 - Sterilized milk	EU legislation	Implementing rules and comparative evaluation
4.1.1 Raw milk: shall comply with the provisions of GB 19301. 4.1.2 Milk powder: should comply with the provisions of GB 19644. **4.2 Sensory requirements:** should be in accordance with the provisions of Table 1. **Sensory requirements** Colour: Milky white or slightly yellow Taste and smell: With the inherent flavour of milk, without odour. Tissue: A homogeneous liquid with no clots, no precipitation and no foreign matter visible to normal vision. **4.3 Physico-chemical indicators**: Fat* (g/100g) ≥ 3.1 Protein (g/100g) Cow's milk ≥ 2.9 Goat milk ≥ 2.8 Non-fat milk solids (g/100g) ≥ 8.1 Acidity (°T) Buttermilk 12~18 Goat's milk 6~13 * Only applicable to full fat sterilized milk	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, II Hygiene on milk and colostrum production holdings, B Hygiene during milking** 1. Milking must be carried out hygienically, ensuring in particular: (a) that, before milking starts, the teats, udder and adjacent parts are clean; (b) that milk and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption;	*See above.* *See above.* Physico-chemical parameters for milk and dairy products are defined in the market order of the European Union and have no relevance for food hygiene. Products exported to China must comply with Chinese quality criteria and market order.

GB 25190-2010 - Sterilized milk	EU legislation	Implementing rules and comparative evaluation
4.4 Contaminant limits: should comply with the provisions of GB 2762. **4.5 Limits of mycotoxins**: should comply with the provisions of GB 2761. **4.6 Microbiological requirements**: should comply with the requirements of commercial sterility and be tested according to the method specified in GB/T 4789.26.		*A comparative assessment of contaminant limits and microbial criteria is provided above.*
5 Other 5.1 Ultra-high temperature sterilized milk made from raw cow (goat) milk only shall be marked "Pure Cow (Goat) Milk" or "Pure Cow (Goat) Milk" in Chinese characters no smaller than the font size of the product name and no less than one-fifth of the height of the main display surface on the main display surface of the product packaging. ". 5.2 Sterilized milk produced entirely from dairy powder shall be labelled "recovered milk" or "recovered milk" in the immediate vicinity of the product name; sterilized milk produced from raw cow (sheep) milk with some dairy powder shall be labelled in the immediate vicinity of the	**Regulation (EU) No 1169/2011 on the provision of food information to consumers, Article 4** 1. Where mandatory food information is required by food information law, it shall concern information that falls, in particular, into one of the following categories: (a) information on the identity and composition, properties or other characteristics of the food; (b) information on the protection of consumers' health and the safe use of a food. In particular, it shall concern information on: (i) compositional attributes that may be harmful to the health of certain groups of consumers; (ii) durability, storage and safe use;	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter IV: Labelling** 1. In addition to the requirements of Directive 2000/13/EC, except in the cases envisaged in Article 13(4) and (5) of that Directive, labelling must clearly show: (a) in the case of raw milk intended for direct human consumption, the words 'raw milk'; (b) in the case of products made with raw milk, the manufacturing process for which does not include any heat treatment or any physical or chemical treatment, the words 'made with raw milk'; 2. The requirements of paragraph 1 apply to products destined for retail trade. The term 'labelling' includes any packaging, document,

GB 25190-2010 - Sterilized milk	EU legislation	Implementing rules and comparative evaluation
product name "Containing xX% recovered milk" or "Containing xx% recovered milk". Note: "xxx%'%" refers to the mass fraction of whole milk solids in the sterilized milk to which dairy powder has been added. 5.3 "Recovered Milk" or "Recovered Milk" and the product name shall be identified on the same main display page of the packaging container; the words "Recovered Milk" or "Recovered Milk" shall be identified The words "Recovered Milk" or "Restored Milk" shall be conspicuous, with a font size no smaller than that of the product name and a height no less than one-fifth of the height of the main display page.	(iii) the health impact, including the risks and consequences related to harmful and hazardous consumption of a food; (c) information on nutritional characteristics so as to enable consumers, including those with special dietary requirements, to make informed choices. **Article 9** lays down a list of mandatory particulars **Article 13** lays down the presentation of mandatory particulars: 2. Without prejudice to specific Union provisions applicable to particular foods, when appearing on the package or on the label attached thereto, the mandatory particulars listed in Article 9(1) shall be printed on the package or on the label in such a way as to ensure clear legibility, in characters using a font size where the x-height, as defined in Annex IV, is equal to or greater than 1,2 mm. 3. In case of packaging or containers the largest surface of which has an area of less than 80 cm^2, the x-height of the font size referred to in paragraph 2 shall be equal to or greater than 0,9 mm.	notice, label, ring or collar accompanying or referring to such products. Products exported to China must comply with Chinese labelling provisions.

12 National standard GB 19645-2010 – Pasteurized milk

GB 19645-2010 – Pasteurized milk	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard applies to whole, skim and partially skim pasteurized milk.	**Regulation (EC) No 853/2004, Article 1 Scope** 1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.	
3 Terms and definitions **3.1 Pasteurised milk pasteurised milk** A liquid product made from raw cow's (sheep's) milk only, which has been pasteurised and other processes.	**Commission Decision 97/80/EC, Annex I, Explanatory notes** Pasteurized milk must have been obtained by means of a treatment involving a high temperature for a short time (at least 71,7°C for 15 seconds or any equivalent combination) or pasteurization process using different time and temperature combinations to obtain an equivalent effect.	
4 Technical requirements **4.1 Raw material requirements**: Raw milk should meet the requirements of GB 19301. **4.2 Sensory requirements**: Colour: Milky white or slightly yellow Taste and smell: It has the inherent flavour of milk and is free of odour	**Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, II Hygiene on milk and colostrum production holdings, B Hygiene during milking** 1. Milking must be carried out hygienically, ensuring in particular:	*See above for the requirements listed in the National food safety standard GB 19301.*

GB 19645-2010 – Pasteurized milk	EU legislation	Implementing rules and comparative evaluation
Tissue: It is a homogeneous and consistent liquid, without clots, precipitation or normal Visually visible foreign matter. **4.3 Physico-chemical indicators:** shall conform to the provisions of Table 2. **Physico-chemical indicators** Fat* (g/100g) ≥ 3.1 Protein (g/100g) Cow's milk ≥ 2.9 Goat milk ≥ 2.8 Non-fat milk solids (g/100g) ≥ 8.1 Acidity (°T) Buttermilk 12~18 Goat's milk 6~13 * Only applicable to full fat pasteurized milk **4.4 Contaminant limits:** should comply with the provisions of GB 2762. **4.5 Mycotoxin limits:** should comply with the provisions of GB 2761. **4.6 Microbiological limits:** should be in accordance with the provisions of Table 3. **Microbiological limits** Sampling scheme* and limits (if not specified, are expressed in CFU/g or CFU/mL) Total number of colonies n 5 c 2	(a) that, before milking starts, the teats, udder and adjacent parts are clean; (b) that milk and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption; **Regulation (EC) No 2073/2005, Annex I, Chapter 2. Process hygiene criteria 2.2, milk and dairy products** 2.2.7 Milk powder and whey powder*	Physico-chemical parameters for milk and dairy products are defined in the market order of the European Union and have no relevance for food hygiene. Products exported to China must comply with Chinese quality criteria and market order. *A comparative assessment of contaminant limits and mycotoxin limits is provided above.* *The criterion of Enterobacteriaceae as required in the EU legislation will cover Coliform bacteria as mentioned in the Chinese national food safety*

GB 19645-2010 – Pasteurized milk	EU legislation	Implementing rules and comparative evaluation
m 50000 M 100000 Coliform bacteria n 5 c 2 m 1 M 5 Staphylococcus aureus n 5 c 0 m 0/25g(mL) M - Salmonella n 5 c 0 m 0/25g(mL) M -	Enterobacteriaceae n 5 c 0 m 10 cfu/g M 10 cfu/g applies to end of the manufacturing process Coagulase-positive staphylococci n 5 c 2 m 10 cfu/g M 100 cfu/g applies to end of the manufacturing process **Chapter I. Food safety criteria** 1.12 Milk powder and whey powder Salmonella n 5 c 0 m absence in 25 g M absence in 25 g 1.21. Staphylococcal enterotoxins n 5 c 0 m absence in 25 g M absence in 25 g	*standard. Both criteria can be considered equivalent.*

GB 19645-2010 – Pasteurized milk	EU legislation	Implementing rules and comparative evaluation
	Applies to products placed on the market during their shelf-life.	
5 Other 5.1 The product name should be displayed on the main surface of the product packaging immediately adjacent to the location, using a font size no smaller than the product name and a height of not less than one-fifth of the height of the main display surface of Chinese characters marked "fresh cow (goat) milk" or "fresh cow (goat) milk".	**Regulation (EU) No 1169/2011 on the provision of food information to consumers, Article 4** 1. Where mandatory food information is required by food information law, it shall concern information that falls, in particular, into one of the following categories: (a) information on the identity and composition, properties or other characteristics of the food; (b) information on the protection of consumers' health and the safe use of a food. In particular, it shall concern information on: (i) compositional attributes that may be harmful to the health of certain groups of consumers; (ii) durability, storage and safe use; (iii) the health impact, including the risks and consequences related to harmful and hazardous consumption of a food; (c) information on nutritional characteristics so as to enable consumers, including those with special dietary requirements, to make informed choices.	Products exported to China must comply with Chinese labelling provisions.

13 National standard GB 19302-2010 – Fermented milk

GB 19302-2010 – Fermented milk	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard applies to whole, skim and partially skimmed fermented milks.	**Regulation (EC) No 853/2004, Annex I defines 'dairy products' as** processed products resulting from the processing of raw milk or from the further processing of such processed products. Accordingly, all requirements related to process hygiene and food safety are fully applicable to fermented products	
3 Terms and definitions **3.1 Fermented milk** A product made from raw cow's (sheep's) milk or milk powder, which has been sterilised and fermented to a reduced pH. 3.1.1 yoghurt Product made from raw cow's (sheep's) milk or milk powder, sterilised and fermented with Streptococcus thermophilus and Lactobacillus bulgaricus (Lactobacillus bulgaricus subspecies). **3.2 flavored fermented milk** Products made from more than 80% raw cow's (sheep's) milk or milk powder, with other raw materials added, after sterilisation, fermentation	**Commission Decision 97/80/EC, Annex I, Explanatory notes** Acidified milk: milk products with a pH of between 3,8 and 5,5. — Relates to yoghurts, drinkable yoghurts, prepared yoghurts, heat-treated fermented milk and others, — Also includes products based on or containing bifidus.	

GB 19302-2010 – Fermented milk	EU legislation	Implementing rules and comparative evaluation
and pH reduction, with or without the addition of food additives, nutritional fortification, fruits and vegetables, cereals, etc. before or after fermentation. 3.2.1 Flavored yoghurt Products made from more than 80% raw cow's (sheep's) milk or milk powder with other raw materials, sterilised, inoculated with Streptococcus thermophilus and Lactobacillus bulgaricus (Lactobacillus bulgaricus subspecies) before or after fermentation with or without the addition of food additives, nutritional fortification, fruits, vegetables, cereals, etc.		
4 Indicator requirements **4.1 Raw material requirements** 4.1.1 Raw milk: shall comply with GB19301. 4.1.2 Other raw materials: shall comply with the corresponding safety standards and/or relevant regulations. 4.1.3 Fermentation strains: Lactobacillus bulgaricus (Lactobacillus bulgaricus subspecies), Streptococcus thermophilus or other strains approved for use by the health administrative department of the State Council. **4.2 Sensory requirements:** Colour Fermented milk: The colour should be		Sensory requirements and physico-chemical parameters for fermented products may be defined in the market order of the European Union or industry guides to good practice. These criteria have no relevance for food hygiene. Products exported to China must comply with Chinese quality criteria and market order.

GB 19302-2010 – Fermented milk	EU legislation	Implementing rules and comparative evaluation
uniform, creamy white or slightly yellow. Flavored fermented milk: A colour consistent with the added ingredients. Taste and odour Fermented milk: The taste and smell are characteristic of fermented milk. Flavored fermented milk: Taste and odour consistent with the added ingredients. Tissue condition: Fine and homogeneous organisation, with a small amount of whey precipitation allowed; flavoured fermented milk with added ingredients The fermented milk shall have a unique organisational state. **4.3 Physico-chemical indicators**: should comply with the provisions of Table 2. **Physico-chemical indicators** Fat* (g/100g) Fermented milk: ≥ 3.1 Flavored fermented milk: ≥ 2.5 Non-fat milk solids (g/100g) Fermented milk: ≥ 8.1 Flavored fermented milk: -- Protein (g/100g) Fermented milk: ≥ 2.9 Flavored fermented milk ≥ 2.3 Acidity (°T) ≥ 70.0 * Only applicable to full fat products		

GB 19302-2010 – Fermented milk	EU legislation	Implementing rules and comparative evaluation
4.4 Contaminant limits: should comply with the provisions of GB 2762. **4.5 Mycotoxin limits**: should comply with the provisions of GB 2761. **4.6 Microbiological limits**: should be in accordance with the provisions of Table 3. **Microbiological limits** Sampling scheme* and limits (if not specified, are expressed in CFU/g or CFU/mL) Coliform bacteria n 5 c 2 m 1 M 5 Staphylococcus aureus n 5 c 0 m 0/25g(mL) M - Salmonella n 5 c 0 m 0/25g(mL) M Yeast ≤ 100		*A comparative assessment of contaminant limits and microbial criteria is provided above.* *Criteria can be considered equivalent.*

GB 19302-2010 – Fermented milk	EU legislation	Implementing rules and comparative evaluation
Mould ≤ 30 **4.7 Lactic acid bacteria count**: should comply with the provisions of Table 4. **Number of lactic acid bacteria** Number of lactic acid bacteria* ≥ $1x10^6$ CFU/g (mL) * No requirement for lactic acid bacteria count for products heat-treated after fermentation. **4.8 Food additives and nutritional fortification** 4.8.1 The quality of food additives and nutritional fortificants shall comply with the corresponding safety standards and relevant regulations. 4.8.2 The use of food additives and nutrient fortification agents should comply with the provisions of GB 2760 and GB 14880.		*For GB 2760 see above under milk powder. See annex 1 for more details*
5 Others 5.1 Heat-treated products after fermentation should be labelled "xx heat-treated fermented milk", "xx heat-treated flavoured fermented milk", "xx heat-treated yoghurt/milk" or "xx Heat Treated Flavoured Yoghurt/Milk". 5.2 Products produced entirely from dairy powder shall be labelled with "recovered milk" or "recovered milk" in the immediate vicinity of the product name; products produced from raw cow		Products exported to China must comply with Chinese labelling provisions.

GB 19302-2010 – Fermented milk	EU legislation	Implementing rules and comparative evaluation
(sheep) milk with some dairy powder shall be labelled with "containing xx% recovered milk" or "xx% recovered milk" in the immediate vicinity of the product name. The product should be labelled as "containing xx% recovered milk" or "containing xx% recovered milk". Note: "xx%" refers to the mass fraction of whole milk solids in the product to which dairy powder has been added. 5.3 "Recovered milk" or "recovered milk" and the product name should be marked on the same main display page of the packaging container; the words "recovered milk" or "recovered milk" marked The words "Recovered Milk" or "Restored Milk" shall be conspicuous, with a font size no smaller than that of the product name and a height of not less than one-fifth of the height of the main display page.		

14 National standard GB 19646-2010 – Cream, butter and anhydrous milkfat

GB 19646-2010 – Cream, butter and milkfat	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard applies to diluted cream, cream and anhydrous cream.	According to Regulation 853/2004 all products derived from milk are dairy products and, accordingly, all provisions related to food safety and process hygiene apply.	
3 Terms and definitions **3.1 Cream** A product with a fat content of 10.0% to 80.0%, made from milk, separated from the fatty part, with or without the addition of other raw materials, food additives and nutritional fortification. **3.2 Cream (butter) butter** Milk and (or) thin cream (fermented or unfermented) as raw material, with or without adding other raw materials, food additives and nutritional fortification, made by the processing of fat content of not less than 80.0% of the product. **3.3 anhydrous milkfat (anhydrous butter)** Milk and (or) cream or thin cream (fermented or unfermented) as raw material, with or without	**Council Regulation (EC) No 2991/94** of 5 December 1994 laying down standards for spreadable fats defines the terms 'butter' and 'cream'. **Commission Decision 97/80/EC provides:** Cream: a film of fat which forms naturally on the surface of the milk by slow agglomeration of emulsifying fat globules. If it is removed by skimming it from the surface of the milk or extracted from the milk by centrifuging in a cream separator, it has, in addition to the other components of the milk, a relatively high fat content (usually exceeding 10 % of the weight of the product).	

GB 19646-2010 – Cream, butter and milkfat	EU legislation	Implementing rules and comparative evaluation
food additives and nutrient fortification, processed to a fat content of not less than 99.8%.		
4 Technical requirements **4.1 Raw material requirements** 4.1.1 Raw milk: shall comply with the requirements of GB 19301. 4.1.2 Other raw materials: shall comply with the corresponding safety standards and/or relevant regulations. **4.2 Sensory requirements** **4.3 Physico-chemical indicators** **4.4 Contaminant limits**: should be in accordance with GB 2762. **4.5 Mycotoxin limits**: should be consistent with the provisions of GB 2761. **4.6 Microbiological limits** *The requirements in the Chinese national food safety standard apply to raw materials used for manufacturing cream, butter and anhydrous milkfat.* **4.7 Food additives and nutritional fortification** The use of food additives and nutritional fortification agents shall comply with the provisions of GB 2760 and GB 14880.		Sensory requirements and physico-chemical parameters for fermented products may be defined in the market order of the European Union or industry guides to good practice. These criteria have no relevance for food hygiene. Products exported to China must comply with Chinese quality criteria and market order. For GB 2762 see above under raw milk. For GB 2761 see above under raw milk. See annexes 2 and 3 for more details. A comparison of microbial limits applicable to milk and dairy products is provided under Point 12 above. There is no criterion in EU legislation concerning the presence of mould in cream, butter or anhydrous milkfat. *For GB 2760 see above under milk powder.* *See annex 1 for more details.*

15 National standard GB 25191 – 2010 – Modified milk

GB 25191 – 2010 – Modified milk	EU legislation	Implementing rules and comparative evaluation
1 Scope This Standard applies to whole, skim and partially skimmed prepared milk.	According to Regulation 853/2004 all products derived from milk are dairy products and, accordingly, all provisions related to food safety and process hygiene apply.	
3 Terms and definitions **3.1 Modified milk** A liquid product made from not less than 80% raw cow's (sheep's) milk or reconstituted milk, to which other raw materials or food additives or nutritional fortification have been added, and which has been sterilised or sanitised by an appropriate process.	The term 'modified milk' is not defined in EU legislation. **Regulation (EC) No 853/2004, Annex I defines 'dairy products' as** processed products resulting from the processing of raw milk or from the further processing of such processed products. Accordingly, all requirements related to process hygiene and food safety are fully applicable to modified milk.	
4 Technical requirements **4.1 Raw material requirements** **4.2 Sensory requirements** **4.3 Physico-chemical indicators** **4.4 Contaminant limits** **4.5 Mycotoxin limit** **4.6 Microbiological requirements**		Sensory requirements and physico-chemical parameters for modified milk products may be defined in the market order of the European Union or industry guides to good practice. These criteria have no relevance for food hygiene. Food business operators must ensure that products exported to China comply with Chinese quality criteria and market order. For GB 2762 see above under raw milk.

GB 25191 – 2010 – Modified milk	EU legislation	Implementing rules and comparative evaluation
4.6.1 Modified milk produced by the sterilization process should meet the requirements of commercial sterility and be tested according to the method specified in GB/T4789.26. 4.6.2 Other modulated milks should comply with the provisions of Table 3. **Microbiological limits** Sampling scheme and limits (if not specified, are expressed in CFU/g or CFU/mL)* Total number of colonies n 5 c 2 m 50000 M 100000 Coliform bacteria n 5 c 2 m 1 M 5 Staphylococcus aureus n 5 c 0 m 0/25 g(mL) M -- Salmonella n 5	*The requirements in the Chinese national food safety standard apply to raw materials used for manufacturing of modified milk.*	For GB 2761 see above under raw milk. See annexes 2 and 3 for more details A comparison of microbial limits applicable to milk and dairy products is provided under Point 12 above.

GB 25191 – 2010 – Modified milk	EU legislation	Implementing rules and comparative evaluation
c 0 m 0/25 g(mL) M -- **4.7 Food additives and nutritional fortification** The use of food additives and nutrient fortification agents should comply with the provisions of GB 2760 and GB 14880.		*For GB 2760 see above under milk powder.* See annex 1 for more details.
5 Others 5.1 Modified milk produced entirely from dairy powder should be labelled with "recovered milk" or "recovered milk" in the immediate vicinity of the product name; modified milk produced from raw cow (goat) milk with some dairy powder added should be labelled in the immediate vicinity of the product name with "Containing xx% recovered milk" or "Containing xx% recovered milk". Note: ""xx%'" refers to the mass fraction of whole milk solids in the blended milk that the added dairy powder represents.		Labelling rules have no relevance for food hygiene. Food business operators must ensure that products exported to China comply with Chinese labelling provisions.

16 National standard GB 13102 - 2010 – Evaporated milk, sweetened condensed milk and formulated condensed milk

GB 13102 - 2010 – Evaporated milk, sweetened condensed milk and formulated condensed milk	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard applies to light condensed milk, sweetened condensed milk and modified condensed milk.	According to Regulation 853/2004 all products derived from milk are dairy products. All EU provisions related to food safety and process hygiene apply.	
3 Terms and definitions **3.1 evaporated milk** A thick product made from raw milk and/or dairy products, processed with or without the addition of food additives and nutritional fortification. **3.2 sweetened condensed milk** A thick product made from raw milk and/or dairy products and sugar, with or without the addition of food additives and nutritional fortification. **3.3 formulated condensed milk** A thick product made from raw milk and/or dairy products, with or without the addition of sugar, food additives and nutritional fortification, and with the addition of supplementary ingredients.	The term 'evaporated milk' is not defined in EU legislation. **Regulation (EC) No 853/2004, Annex I defines 'dairy products' as** processed products resulting from the processing of raw milk or from the further processing of such processed products. Accordingly, all requirements related to process hygiene and food safety are fully applicable to evaporated or condensed milk. Commission Decision 97/80/EC of 18 December 1996 laying down provisions for the implementation of Council Directive 96/16/EC on statistical surveys of milk and milk products (OJ L 024, 25.1.1997, p.26) provides definitions.	

GB 13102 - 2010 – Evaporated milk, sweetened condensed milk and formulated condensed milk	EU legislation	Implementing rules and comparative evaluation
	Concentrated milk: a product obtained by partial elimination of water, from whole milk, semi-skimmed or skimmed milk only.	
4 Technical requirements **4.1 Raw material requirements** **4.2 Sensory requirements** **4.3 Physico-chemical indicators** **4.4 Contaminant limits** **4.5 Mycotoxin limit** **4.6 Microbiological requirements** 4.6.1 Light condensed milk, modulated light condensed milk should meet the requirements of commercial sterility, according to the methods specified in GB / T 4789.26 test. 4.6.2 Sweetened condensed milk, modulated sweetened condensed milk should comply with the following microbiological limits: Sampling scheme and limits (if not specified expressed as CFU/g or CFU/mL)* Total number of colonies n 5 c 2 m 30000 M 100000 Coliform bacteria n 5	The requirements in the Chinese national food safety standard apply to raw materials used for manufacturing of condensed milk.	Sensory requirements and physico-chemical parameters for modified milk products may be defined in the market order of the European Union or industry guides to good practice. These criteria have no relevance for food hygiene. Food business operators must ensure that products exported to China comply with Chinese quality criteria and market order. For GB 2762 see above under raw milk. For GB 2761 see above under raw milk. See annexes 2 and 3 for more details. A comparison of microbial limits applicable to milk and dairy products is provided under Point 12 above.

GB 13102 - 2010 – Evaporated milk, sweetened condensed milk and formulated condensed milk	EU legislation	Implementing rules and comparative evaluation
c 1 m 10 M 100 Staphylococcus aureus n 5 c 0 m 0/25 g(mL) M -- Salmonella n 5 c 0 m 0/25 g(mL) M -- **4.7 Food additives and nutritional fortification** The use of food additives and nutrient fortification agents should comply with the provisions of GB 2760 and GB 14880.		*For GB 2760 see above under milk powder.* *See annex 1 for more details.*
5 Other 5.1 The product should be labelled "This product is not intended to be used as a breast milk substitute for infants" or similar warnings.		Labelling rules have no relevance for food hygiene. Food business operators must ensure that products exported to China comply with Chinese labelling provisions.

17 National standard GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard applies to the microbiological examination of milk and dairy products.	**Regulation (EC) No 2073/2005** 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 Regulation (EC) No 852/2004. and Regulation (EC) No 853/2004.	
3 Equipment and materials **3.1 Sampling tools** Sampling tools should be made of stainless steel or other materials of suitable strength with smooth surfaces, free of gaps and with rounded edges. Sampling tools should be cleaned and sterilised and kept dry before use. Sampling tools include stirrers, sampling spoons, spoons, cutting wires, knives (pocket knives or spatulas), sampling augers, etc. **3.2 Sample containers** Sample containers should be of a material (e.g. glass, stainless steel, plastic, etc.) and construction that adequately ensures the original condition of the sample. Containers and lids should be clean, sterile and dry. The sample	**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. Regulation of the European Parliament and of the Council (EU) 2017/625 of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law (OJ No. L 95, 07.04.2017, p. 1):	EU rules related to sampling and analysis are less prescriptive than Chinese standards. Through the general reference to ISO and other international standards EU rules ensure state-of-the-art procedures. It is concluded that both standards are equivalent in terms of ensuring reliable analyses.

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
container should be of sufficient volume to allow the sample to be adequately mixed prior to testing. Sample containers include sampling bags, sampling tubes, sampling bottles, etc. **3.3 Other supplies** This includes thermometers, aluminium foil, sealing film, markers, sampling registration forms, etc. **3.4 Laboratory test supplies** 3.4.1 General test supplies according to GB 4789.1 implementation. 3.4.2 Microbiological indicator bacteria test according to GB 4789.2, GB 4789.3, GB 4789.15 respectively. 3.4.3 Pathogenic bacteria test according to GB 4789.4, GB 4789.10, GB 4789.30 and GB 4789.40, respectively. 3.4.4 Bifidobacterium and Lactobacillus tests are carried out according to GB/T 4789.34 and GB 4789.35 respectively.	Article 34 Methods used for sampling, analyses, tests and diagnoses: 1. Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods. 2. In the absence of the Union rules as referred to in paragraph 1, and in the context of official controls and other official activities, official laboratories shall use one of the following methods according to the suitability for their specific analytical, testing and diagnostic needs: (a) available methods complying with relevant internationally recognised rules or protocols including those that the European Committee for Standardisation (CEN) has accepted; or relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols; (b) in the absence of the suitable rules or protocols, as referred to in point (a), methods which comply with relevant rules established	

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
	at national level, or, if no such rules exist, relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols. 5. Samples shall be taken, handled and labelled in such a way as to ensure their legal, scientific and technical validity.	
4 Sampling programme Samples should be representative. The sampling process should be aseptic, and the sampling method and number of samples should be based on the characteristics of the specific product and the requirements of the product standard. During the storage and transport of samples, necessary measures should be taken to prevent changes in the number of microorganisms present in the samples and to maintain the samples in their original state. **4.1 Sampling of raw milk** 4.1.1 Samples shall be thoroughly mixed, and immediately after mixing, n samples shall be taken from the same batch (in this case a single	**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 853/2004, Annex III, Section IX Raw milk, colostrum, dairy products and colostrum-based products, Chapter I, III Criteria for raw milk and colostrum**	EU rules related to sampling and analysis are less prescriptive than Chinese standards. Through the general reference to ISO and other international standards EU rules ensure state-of-the-art procedures. It is concluded that both standards are equivalent in terms of ensuring reliable analyses.

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
milk storage tank or truck) using a sterile sampling tool in an amount that meets the requirements of the microbiological index test. 4.1.2 For milk storage units with separated areas, a proportional amount of mixed representative samples shall be collected from each separated area according to the amount of milk stored in the area, and the above milk samples shall be mixed and sampled.	1. (a) The following criteria for raw milk apply pending the establishment of standards in the context of more specific legislation on the quality of milk and dairy products. 2. A representative number of samples of raw milk and colostrum collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4 in case of raw milk and with the existing national criteria referred to in point 1(b) in case of colostrum. The checks may be carried out by, or on behalf of: (a) the food business operator producing the milk; (b) the food business operator collecting or processing the milk; (c) a group of food business operators; or (d) in the context of a national or regional control scheme. 3. (a) Food business operators must initiate procedures to ensure that raw milk meets the following criteria: (i) for raw cows' milk: Plate count at 30° C (per ml) ≤ 100 000 (*) Somatic cell count (per ml) ≤ 400 000 (**) (*) Rolling geometric average over a two-month period, with at least two samples per month.	

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
4.2 Sampling of liquid dairy products This applies to pasteurised milk, fermented milk, sterilised milk, prepared milk, etc. The smallest original retail package of the same batch should be taken, at least n pieces per batch. **4.3 Sampling of semi-solid dairy products** 4.3.1 Sampling of condensed milk Applicable to light condensed milk, sweetened condensed milk, condensed milk, etc. 4.3.1.1 Products in original packaging less than or equal to 500g (mL): take the smallest retail original packaging of the same batch and take at least n pieces per batch. Sampling volume is not less than 5 times or more the number of units tested. 4.3.1.2 Products in original packaging greater than 500 g (mL) (reprocessed products,	(**) Rolling geometric average over a three-month period, with at least one sample per month (ii) for raw milk from other species: Plate count at 30 o C (per ml) ≤ 1 500 000 (*) (b) However, if raw milk from species other than cows is intended for the manufacture of products made with raw milk by a process that does not involve any heat treatment, food business operators must take steps to ensure that the raw milk used meets the following criterion: Plate count at 30° C (per ml) ≤ 500 000 (*) (*) Rolling geometric average over a two-month period, with at least two samples per month. **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter II Requirements concerning dairy and colostrum-based products** **III. Criteria for raw cows' milk** 1. Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before being heat treated and if its period of acceptance specified in the HACCP-based procedures is exceeded: (a) raw cows' milk used to prepare dairy products has a plate count at 30 °C of less than 300 000 per ml; and	

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
import/export): Sampling should be done by shaking or mixing with a stirrer to achieve homogeneity before sampling. If the sample cannot be homogenously mixed, take a representative sample from each part of the sample container. Sample no less than 5 times or more the test unit. 4.3.2 Sampling of cream and its products Applicable to thin cream, cream, anhydrous cream, etc. 4.3.2.1 Products in original packaging less than or equal to 1000g (mL): Take a representative sample of the smallest retail original packaging of the same batch, sampling no less than 5 times or more the number of units tested. 4.3.2.2 Products in original packaging greater than 1000g (mL): shake or use a stirrer to mix before sampling to achieve homogeneity and then sample. For solid products, use a sterile spatula to remove the surface layer of product to a thickness of at least 5 mm. insert a clean, dry sampling auger at an even rate through the bottom of the packaging container in the direction of the cut. When the auger reaches the bottom of the container, rotate the auger 180°, withdraw the auger and transfer the collected	(b) heat treated cows' milk used to prepare dairy products has a plate count at 30 °C of less than 100 000 per ml. 2. When milk fails to meet the criteria laid down in paragraph 1, the food business operator must inform the competent authority and take measures to correct the situation.	

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
sample into the sample container. Sample no less than 5 times or more the number of units tested. **4.4 Sampling of solid dairy products** Applicable to cheese, reconstituted cheese, milk powder, whey powder, lactose and buttermilk powder. 4.4.1 Sampling of cheese and reconstituted cheese 4.4.1.1 For products with an original package of less than or equal to 500g: take the smallest original retail package of the same batch and sample not less than 5 times or more the number of units tested. 4.4.1.2 Products in original packaging greater than 500g: Depending on the shape and type of cheese, the following methods may be used respectively: (1) Insert the sampler diagonally towards the centre of the cheese onto a flat surface at a distance of not less than 10cm from the edge, once or several times. (2) Insert the sampler vertically into one face and through the centre of the cheese to the opposite side. (3) From between the two flat surfaces, insert the sampler horizontally into the vertical surface of the cheese, towards the centre of the cheese. (4) If the cheese is in a barrel, box or other large container, or if the cheese is made into large		

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
compacted pieces, sample by inserting the sampler diagonally through the top of the container to the bottom. The sample size should not be less than 5 times or more the test unit. 4.4.2 Sampling of milk powder, whey powder, lactose and buttermilk powder Applicable to milk powder, whey powder, lactose, buttermilk powder, etc. 4.4.2.1 For products in original packaging less than or equal to 500g: take the smallest retail original packaging of the same batch and sample not less than 5 times or more the number of units tested. 4.4.2.2 Products in original packaging greater than 500g: a clean, dry sampling auger is placed along the packaging container in the direction of the cut and penetrates the bottom at an even rate. When the auger reaches the bottom of the container, rotate the auger 180°, withdraw the auger and transfer the collected sample into the sample container. Sample no less than 5 times or more the test unit. **5 Handling of test samples** **5.1 Handling of milk and liquid dairy products** Shake the sample well and open the package in an aseptic manner. For plastic or paper boxes (bags), disinfect the lid or bag with a 75% alcohol		

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
cotton ball and cut with sterilised scissors; for glass bottles, remove the paper cover or cap of the bottle by aseptic operation and sterilise the mouth of the bottle by flame. Aspirate 25mL (for liquid milk with solid granules added, the sample should be taken after homogenisation) of the test sample with a sterilised pipette into a conical flask containing 225mL of sterilised saline and shake well. **5.2 Handling of semi-solid dairy products** 5.2.1 Condensed milk Clean the surface of the bottle or can, then disinfect around the mouth of the bottle or can with a lighted alcohol cotton ball, then open the bottle or can with a sterilised can opener, weigh 25g of the sample with aseptic procedures, place in a conical flask containing 225mL of sterilised saline (or other bacterial enhancing solution) preheated to 45°C and shake well. 5.2.2 Thin cream, cream, anhydrous cream, etc. Open the package aseptically, weigh 25 g of the sample and place it in a conical flask containing 225 mL of sterilised saline (or other bacteriological enrichment solution) preheated to 45°C and shake well. The time between melting and inoculation of the sample should not exceed 30 minutes.		

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
5.3 Handling of solid dairy products 5.3.1 Cheese and its products Open the packaging aseptically, remove some of the surface sealing wax from coated samples, and for uncoated samples cut the cheese directly with a sterilised knife through the aseptic procedure. Shake well. Mix well to disperse the sample evenly (1 min to 3 min) and do not exceed 40°C during dispersion. Avoid foam as far as possible. 5.3.2 Milk powder, whey powder, lactose, buttermilk powder Mix the samples well before sampling. For canned milk powder, open the cans and take the samples in the same way as for condensed milk. Milk powder in bags should be disinfected by wiping the mouth of the bag with a cotton ball of 75% alcohol and open the sample with aseptic procedures. Weigh 25g of the sample and add to a conical flask preheated to 45°C with 225mL of sterilised saline and other dilutions or bacteriological solutions (glass beads can be used to help dissolve), shake to dissolve and mix well. For whey powders produced by the acidification process, dilute with dipotassium hydrogen phosphate buffer pH 8.4±0.2. For specially formulated milk powders containing high levels		

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
of starch, alpha-amylase may be used to reduce the viscosity of the solution or the dilution may be doubled to reduce the viscosity of the solution. 5.3.3 Casein and caseinate In a sterile operation, weigh 25 g of the test sample and add 225 mL of a dilution solution such as sterilised saline or a bacteriological enrichment solution, depending on the product. When performing gradient dilutions of viscous sample solutions, the pipette should be repeatedly blown several times under aseptic conditions to transfer as much of the sample adhering to the inner wall of the pipette into the solution as possible. 5.3.3.1 For casein produced by the acid process: use a dipotassium hydrogen phosphate buffer with the addition of antifoaming agent to dissolve the sample at pH 8. pH 8.4 ± 0.2.2. 5.3.3.2 Casein from the rennet process: dissolve the sample in dipotassium phosphate buffer with defoamer at 7.5±0.2H7.5±0.2 and allow to stand for 15 min at room temperature. homogenise in a sterilised homogenising bag for 2 min if necessary and allow to stand for a further 5 min before testing.		

GB 4789.18 – 2010 - Food microbiological examination: Milk and milk products	EU legislation	Implementing rules and comparative evaluation
5.3.3.3 Caseinate: dissolve the sample using dipotassium hydrogen phosphate buffer at pH 7.5 ± 0.2.		
6 Test methods 6.1 Total number of colonies: tested according to GB4789.2. 6.2 Coliform: counted by direct count method in GB4789.3. 6.3 Salmonella: according to GB 4789.4 test. 6.4 Staphylococcus aureus: according to GB 4789.10 test. 6.5 Moulds and yeasts: According to GB 4789.15 count. 6.6 Listeria monocytogenes: According to GB4789.30 test. 6.7 Bifidobacterium: according to GB/T 4789.34 test. 6.8 Lactobacillus: according to GB4789.35 test. 6.9 Enterobacter sakazakii: According to GB 4789.40 test.	**Regulation (EC) No 2073/2005, Annex I** **Microbiological criteria for foodstuffs** *The analytical reference methods are indicated in Chapter 1. and Chapter 2.* EN/ISO 6579 for Salmonella European screening method of the Community Reference Laboratory for coagulase positive staphylococci ISO/TS 22964 for enterobacter Sakazakii ISO 21528 for enterobacteriaceae ISO 16649-1 or 2 for E; coli in cheeses EN/ISO 6888 for staphylococci in cheeses ISO 16649 for E. coli in butter EN/ISO 7932 for Bacillus cereus in infant formulae.	It is concluded that EU rules are at least equivalent to methods described in Chinese food safety standards. Both provisions are suitable to guarantee reliable analyses. EU legislation is adapted to technical progress more easily, as any update of ISO standards automatically becomes legally binding without formal legislative and administrative procedures.

18 National standard GB/T 21732-2008 Milk beverages

GB/T 21732-2008 Milk beverages	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard specifies the product classification, technical requirements, test methods, inspection rules, marking, packaging, transport and storage of dairy-containing beverages. This standard applies to dairy-containing beverages.	According to Regulation 853/2004 all products derived from milk are dairy products. All EU provisions related to food safety and process hygiene apply.	
3 Terms and definitions The following terms and definitions apply to this standard **3.1 Milk beverage** A beverage product made from milk or dairy products, prepared or fermented with the addition of water and an appropriate amount of excipients. Milk beverage may also be called milk (milk) drink or milk (milk) beverage.	The term 'milk beverage' is not defined in EU legislation. **Regulation (EC) No 853/2004, Annex I defines 'dairy products' as** processed products resulting from the processing of raw milk or from the further processing of such processed products. Accordingly, all requirements related to process hygiene and food safety are fully applicable to 'milk beverages'.	
4 Product classification **4.1 Prepared dairy beverages** A beverage made from milk or dairy products, with the addition of water, and one or more of sugar and/or sweeteners, acidulants, fruit juices, tea, coffee, plant extracts, etc. **4.2 Fermented dairy-based beverages**	The EU Food Law does not provide these classifications.	EU food business operators must ensure that products exported to China are classified and labelled in compliance with Chinese legal provisions. These parameters have no influence on process hygiene or food safety and are, therefore, not

GB/T 21732-2008 Milk beverages	EU legislation	Implementing rules and comparative evaluation
A beverage made from milk or dairy products, with water added to the emulsion made by fermenting beneficial bacteria such as lactic acid bacteria, and one or more types of sugar and/or sweeteners, acidulants, fruit juices, tea, coffee, plant extracts, etc., such as lactic acid bacteria milk drinks. They are differentiated into sterilised (non-live) and unpasteurised (live) according to whether they have been sterilised or not. Fermented lactic beverages can also be called yoghurt (milk) beverages and sour milk (milk) drinks. **4.3 Lactic acid bacteria beverages** A drink made from milk or dairy products, with water added to the emulsion made by fermentation of lactic acid bacteria, as well as one or more types of sugar and/or sweeteners, acidulants, fruit juices, tea, coffee, plant extracts, etc. They are differentiated according to whether they are sterilised or not (non-sterilised live) and unpasteurised (live) types.		relevant in the context of the registration of establishments under GACC Decree 248.
5 Technical requirements **5.1 Sensory indicators** Sensory indicators shall meet the requirements of Table 1. **Sensory indicators** Taste and odour:		EU food business operators must ensure that products exported to China are classified and labelled in compliance with Chinese legal provisions.

GB/T 21732-2008 Milk beverages	EU legislation	Implementing rules and comparative evaluation
Distinctive lactic taste and odour or a taste and odour consistent with the addition of excipients; fermented products with a characteristic fermented aromatic taste and odour; no off-flavours Colour: Uniformly creamy white, creamy yellow or with the corresponding colour of the added auxiliaries Tissue state: Uniform and fine emulsion, no stratification, a small amount of precipitation allowed, no foreign impurities visible to the normal eye. **5.2 Physical and chemical indicators** Physico-chemical indicators shall conform to the provisions of Table 2. **Physical and chemical indicators** Protein[a] (g/100g) Prepared milk-containing beverages ≥ 1.0 Fermented lactic beverages ≥ 1.0 Lactic acid bacteria drinks ≥ 0.7 Benzoic acid[b] (g/kg) Prepared milk-containing beverages ≤ -- Fermented lactic beverages ≤ 0.03 Lactic acid bacteria drinks ≤ 0.03 [a] The protein in dairy containing beverages should be dairy protein.		Sensory indicators or physico-chemical properties of a dairy product have no influence on process hygiene or food safety and are, therefore, not relevant in the context of the registration of establishments under GACC Decree 248.

GB/T 21732-2008 Milk beverages	EU legislation	Implementing rules and comparative evaluation
[b] Benzoic acid arising from the fermentation process; benzoic acid brought in from raw and auxiliary materials shall be in accordance with GB2760 **5.3 Lactic acid bacteria indicators** The indicators of the number of live lactic acid bacteria in unpasteurised (live) fermented lactic beverages and unpasteurised (live) lactic acid bacteria beverages shall comply with the provisions of Table 3. **Indicators of lactic acid bacteria viable count** Factory period: Unpasteurised (live) fermented lactic beverages ≥1x106 CFU/mL Unpasteurised (live) lactic acid bacteria beverage ≥1x106 CFU/mL Sales period: Unpasteurised (live) fermented lactic beverages According to the number of live lactic acid bacteria on the product label Unpasteurised (live) lactic acid bacteria beverage According to the number of live lactic acid bacteria on the product label **5.4 Hygiene indicators** The hygiene indicators of prepared lactic beverages should comply with the provisions of GB11673; the hygiene indicators of fermented		

GB/T 21732-2008 Milk beverages	EU legislation	Implementing rules and comparative evaluation
lactic beverages and lactic acid bacteria beverages should comply with the provisions of GB 16321. **5.5 Food additives and food nutrient fortification** Should comply with the provisions of GB 2760 and GB 14880. **5.6 Fermentation strains** Lactobacillus bulgaricus subspecies (Lactobacillus bulgaricus), Streptococcus thermophilus and other strains approved for use by national standards or regulations should be used.		*For GB 2760 see above under milk powder.* *See Annex 1 for more details*
6 Test methods **6.1 Sensory test** Take about 50mL of the sample to be tested in a colourless and transparent container, place it in a bright place, observe its colour and tissue state in the light, and smell and taste it at room temperature. **6.2 Physical and chemical tests** 6.2.1 Protein Determination according to the method specified in GB/T 5009.5. 6.2.2 Benzoic acid Determined by the method specified in GB/T 5009.29. **6.3 Health indicators**	EU legislation does not usually prescribe analytical methods in detail but rather refers to internationally agreed methodological standards. Both regulatory approaches are suitable to guarantee reliable analytical results and are, therefore, considered equivalent.	

GB/T 21732-2008 Milk beverages	EU legislation	Implementing rules and comparative evaluation
Determination according to the methods specified in GB 11673, GB 16321 and GB/T 5009.46. **6.4 Lactic acid bacteria indicators** According to GB/T 4789.35 method of determination.		
7 Test rules **7.1 Sampling method and sample size** Factory inspection, each batch of 12 randomly selected minimum independent packaging, 6 for sensory indicators, physical and chemical indicators test, 2 for microbiological testing, the other 4 spare. For type test, 12 smallest individual packages are randomly selected from each batch, 6 for organoleptic and physical and chemical indexes, 2 for microbiological test and 4 for standby. **7.2 Factory inspection** 7.2.1 The quality control department of the manufacturer determines the batch of the product in accordance with its corresponding rules. 7.2.2 Items to be tested at the factory include: protein, organoleptic, lactic acid bacteria count (for live products), colony count (for non-live products), coliforms.		

GB/T 21732-2008 Milk beverages	EU legislation	Implementing rules and comparative evaluation
7.2.3 Each batch of product shall be subject to factory inspection and shall be shipped only after passing the inspection. **7.3 Type inspection** 7.3.1 The type inspection items shall be 5.1 to 5.4 of the technical requirements. 7.3.2 The type test shall be carried out once a year or when one of the following conditions occurs. - Materials, processes, equipment when there are large changes. - When resuming production after a long hiatus. - When the factory inspection results are significantly different from normal production - When requested by the national quality supervision body. **7.4 unpasteurized (live) type sample inspection** The test should be carried out in a timely manner; if the test cannot be carried out in a timely manner, it should be stored under conditions of 2°C to 10°C. **7.5 Judgement rules** The total number of colonies, coliforms, moulds and yeasts, pathogenic bacteria indicators do not meet this standard, the batch is judged to be substandard products, and shall not be retested. In addition to the above microbiological		

GB/T 21732-2008 Milk beverages	EU legislation	Implementing rules and comparative evaluation
indicators, if the test items do not meet this standard, the failed items will be doubled from the batch for retesting. If the result of the retest is still unqualified, the batch will be judged as unqualified.		
8 Marking, packaging, transport and storage **8.1 Labelling** 8.1.1 The product label shall comply with GB 7718 and GB 13432 and the relevant regulations; the protein content shall be indicated. 8.1.2 Fermented dairy beverages and lactic acid bacteria beverages should be labelled as unpasteurised (live) or pasteurised (non-live). 8.1.3 Unpasteurised (live) fermented lactic beverages and unpasteurised (live) lactic acid bacteria products should be labelled with the number of live lactic acid bacteria; the temperature at which the product is transported and stored should be indicated. **8.2 Packaging** Packaging materials and containers shall comply with the requirements of relevant standards. **8.3 Transport** The product should be transported avoiding sun and rain and should not be mixed with toxic, odorous, volatile or corrosive substances.	**Regulation (EU) No 1169/2011 on the provision of food information to consumers, Article 4** 1. Where mandatory food information is required by food information law, it shall concern information that falls, in particular, into one of the following categories: (a) information on the identity and composition, properties or other characteristics of the food; (b) information on the protection of consumers' health and the safe use of a food. In particular, it shall concern information on: (i) compositional attributes that may be harmful to the health of certain groups of consumers; (ii) durability, storage and safe use; (iii) the health impact, including the risks and consequences related to harmful and hazardous consumption of a food; (c) information on nutritional characteristics so as to enable consumers, including those with special dietary requirements, to make informed choices.	Labelling rules have no relevance for food hygiene. Food business operators must ensure that products exported to China comply with Chinese labelling provisions.

GB/T 21732-2008 Milk beverages	EU legislation	Implementing rules and comparative evaluation
8.4 Storage The product should be stored in a clean, dry, ventilated and light-proof warehouse, free from insects and rodents. Unpasteurised (live) products should be transported and stored at a low temperature of 2°C to 10°C.	**Regulation (EC) No 852/2004, Annex II, Chapter X Provisions applicable to the wrapping and packaging of foodstuffs** **Regulation (EC) No 852/2004, Annex II, Chapter IV Transport** **Regulation (EC) No 852/2004, Annex II, 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. 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 853/2004, Annex III, Section IX, Chapter I, II, B Hygiene during milking, collection and transport**	

GB/T 21732-2008 Milk beverages	EU legislation	Implementing rules and comparative evaluation
	2. Immediately after milking, milk and colostrum must be held in a clean place designed and equipped to avoid contamination. (a) Milk must be cooled immediately to not more than 8° C in the case of daily collection, or not more than 6° C if collection is not daily; 3. During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk and the colostrum must not be more than 10° C **Regulation (EC) No 853/2004, Annex III, Section IX, Chapter II, I Temperature requirements** 1. Food business operators must ensure that, upon acceptance at a processing establishment, (a) milk is quickly cooled to not more than 6° C; and kept at that temperature until processed.	

19 National standard GB 31638-2016 - Casein

GB 31638-2016 - Casein	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard applies to acid casein, enzymatic casein and membrane separated casein.	**Directive (EU) 2015/2203 on the approximation of the laws of the Member States relating to caseins and caseinates intended for human consumption.** This Directive applies to caseins and caseinates which are intended for human consumption and mixtures thereof.	
2 Terms and definitions **2.1 Casein** A product made from milk and/or dairy products by an acid or enzymatic or membrane separation process, which is a mixture of a, β, k and γ and their isoforms. **2.2 Acid casein** A product made from milk and/or dairy products, which is defatted, acidified to precipitate casein, and then filtered, washed and dried. **2.3 Enzymatic casein** A product made from milk and/or dairy products by skimming, precipitation of casein by rennet, followed by filtration, washing and drying. **2.4 Membrane separation of casein** A product made from milk and/or dairy products by skimming, membrane separation of casein,	**Directive (EU) 2015/2203, Article 2** (a) 'edible acid casein' means a milk product obtained by separating, washing and drying the acid-precipitated coagulum of skimmed milk and/or of other products obtained from milk; (b) 'edible rennet casein' means a milk product obtained by separating, washing and drying the coagulum of skimmed milk and/or of other products obtained from milk; the coagulum is obtained through the reaction of rennet or other coagulating enzymes; (c) 'edible caseinate' means a milk product obtained by action of edible casein or edible casein curd coagulum with neutralizing agents, followed by drying.	**Commission Decision 97/80/EC, Annex I, Explanatory notes** Casein: is the main protein constituent of milk. It is obtained from skimmed milk by precipitation (curdling), generally with acids or rennet. The heading covers various types of casein which differ according to the method of curdling, e.g. acid casein and rennet casein (paracasein). Caseinates: (salts of casein) include the sodium and ammonium salts known as 'soluble caseins'; these salts are normally used to prepare concentrated foods and pharmaceutical products. Calcium caseinate is used in the preparation of foodstuffs or as a glue, depending on its character.

GB 31638-2016 - Casein	EU legislation	Implementing rules and comparative evaluation
followed by concentration, sterilisation and drying.		
3 Technical requirements 3.1 Raw material requirements The raw materials should comply with the corresponding food standards and relevant regulations. **3.2 Sensory requirements** The sensory requirements shall be in accordance with the provisions of Table 1. **Sensory requirements** Colour: Milky white to creamy yellow Taste and odour: Taste and odour characteristic of the product, no offensive smell Condition: Dry, homogeneous powder, with a few dark yellow particles and no foreign matter visible to the normal eye. **3.3 Physical and chemical indicators** Physico-chemical indicators shall comply with the provisions of Table 2. **Physico-chemical indicators** Protein (in dry basis) (g/100g) Acid method ≥ 90.0 Enzymatic method ≥ 84.0 Membrane separation ≥ 84.0 Casein (as a percentage of protein) (g/100g)	**Directive (EU) 2015/2203, Annex I** **I. Standards applicable to edible acid caseins** (a) Essential factors of composition 1. Maximum moisture content 12 % by weight 2. Minimum milk protein content calculated on the dried extract 90 % by weight of which minimum casein content 95 % by weight 3. Maximum milk fat content 2 % by weight 4. Maximum titratable acidity, expressed in ml of decinormal sodium hydroxide solution per g 0,27 5. Maximum ash content (P_2O_5 included) 2,5 % by weight 6. Maximum anhydrous lactose content 1 % by weight 7. Maximum sediment content (burnt particles) 22,5 mg in 25 g e) Organoleptic characteristics 1. Odour: No foreign odours. 2. Appearance: Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure. **II. Standards applicable to edible rennet caseins** (a) Essential factors of composition	

GB 31638-2016 - Casein	EU legislation	Implementing rules and comparative evaluation
Acid method ≥ 95.0 Enzymatic method ≥ 95.0 Membrane separation ≥ 82.0 Fat (g/100g) Acid method ≤ 2.0 Enzymatic method ≤ 2.0 Membrane separation ≤ 5.0 Moisture (g/100g) Acid method ≤ 12.0 Enzymatic method ≤ 12.0 Membrane separation ≤ 12.0 Free acid [0.1 mol/L NaOH/(mL/g) Acid method ≤ 0.27 Enzymatic method ≤ -- Membrane separation ≤ --	1. Maximum moisture content 12 % by weight 2. Minimum milk protein content calculated on the dried extract 84 % by weight of which minimum casein content 95 % by weight 3. Maximum milk fat content 2 % by weight 4. Minimum ash content (P_2O_5 included) 7,5 % by weight 5. Maximum anhydrous lactose content 1 % by weight 6. Maximum sediment content (burnt particles) 15 mg in 25 g e) Organoleptic characteristics 1. Odour: No foreign odours. 2. Appearance: Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure. **Directive (EU) 2015/2203, Annex II Edible caseinates** Standards applicable to edible caseinates a) Essential factors of composition 1. Maximum moisture content 8 % by weight 2. Minimum milk protein content calculated on the dried extract 88 % by weight of which minimum casein content 95 % by weight 3. Maximum milk fat content 2 % by weight	

GB 31638-2016 - Casein	EU legislation	Implementing rules and comparative evaluation
	4. Maximum anhydrous lactose content 1 % by weight 5. pH value 6,0 to 8,0 6. Maximum sediment content (burnt particles) 22,5 mg in 25 g (e) Characteristics 1. Odour: Very slight foreign flavours and odours. 2. Appearance: Colour ranging from white to creamy white; the product must not contain any lumps that would not break up under slight pressure. 3. Solubility: Almost entirely soluble in distilled water, except for calcium caseinate. **Annex I Edible caseins** **I. Standards applicable to edible acid caseins** (b) Contaminants Maximum lead content 0,75 mg/kg **II. Standards applicable to edible rennet caseins** (b) Contaminants Maximum lead content 0,75 mg/kg **Annex II Edible caseinates** (b) Contaminants Maximum lead content 0,75 mg/kg	

GB 31638-2016 - Casein	EU legislation	Implementing rules and comparative evaluation
3.4.1 Contaminant limits should be in accordance with GB2762. **3.4.2 Mycotoxin limits** should comply with the provisions of GB2761. **3.5 Microbiological limits** Total number of colonies n 5 c 2 m 5×10^4 M 5×10^5 Coliform bacteria n 5 c 1 m 10 M 10^2 Staphylococcus aureus n 5 c 2 m 10 M 10^2	**Casein is not mentioned in Regulation (EEC) No 315/93 nor in Regulation (EC) No 1881/2006.** **Regulation (EC) No 2073/2005, Annex I, Chapter 2. Process hygiene criteria** **2.2, milk and dairy products** 2.2.7 Milk powder and whey powder* Enterobacteriaceae n 5 c 0 m 10 cfu/g M 10 cfu/g applies to end of the manufacturing process Coagulase-positive staphylococci n 5	No specific microbiological criteria are defined for casein in EU legislation. Casein is a dairy product and, accordingly, pertinent microbial limits apply. These are consistent with Chinese food safety standards.

GB 31638-2016 - Casein	EU legislation	Implementing rules and comparative evaluation
Salmonella n 5 c 0 m 0/25g M - **3.6 Food additives** The use of food additives should comply with the provisions of GB2760.	c 2 m 10 cfu/g M 100 cfu/g applies to end of the manufacturing process **Chapter I. Food safety criteria** 1.12 Milk powder and whey powder Salmonella n 5 c 0 m absence in 25 g M absence in 25 g 1.21. Staphylococcal enterotoxins n 5 c 0 m absence in 25 g M absence in 25 g Applies to products placed on the market during their shelf-life Casein is not mentioned in Regulation (EU) No 1130/2011.	
Appendix A Determination of casein **A.1 Principle** After the sample is fully dissolved, the pH is adjusted to 4.6 with acetic acid and sodium	**Commission Directive 85/503/EEC of 25 October 1985 on methods of analysis for edible caseins and caseinates** (OJL 308, p.12).	

GB 31638-2016 - Casein	EU legislation	Implementing rules and comparative evaluation
acetate to precipitate the casein, and the casein is collected by filtration, as in the following GB 5009.5, the first or second method of determining the principle. **A.2 Reagents and materials** Unless otherwise specified, the reagents used in this method are analytically pure, water for GB / T 6682 provisions of the three levels of water. A.2.1 Sodium bicarbonate (NaHCO3). A.2.2 Sodium tripolyphosphate (NaNasP3(3O10). A.2.3 Glacial acetic acid (CH3COOH): Superiorly pure. A.2.4 Sodium acetate (CH3COONa-3H2O). A.2.5 Sodium acetate anhydrous (CH3COONa). A.2.6 % acetic acid solution: aspirate 10 mL of glacial acetic acid (A.2.3) in a 100 mL volumetric flask, add water to fix the volume. A.2.7 Sodium acetate solution (1 mol/L): weigh 41 g of anhydrous sodium acetate (A.2.5) or 68 g of sodium acetate (A.2.4), dissolve with water and dilute to 500 mL. A.2.8 Sodium acetate - acetic acid buffer solution: draw 1.0mL of sodium acetate solution (A.2.7) and 1.0mL of acetic acid solution (A.2.6) into a 100mL volumetric flask respectively and add water to fix the volume.	**Annex I Scope of the first community methods of analysis directive for edible caseins and caseinates** I. General Provisions II. Determination of moisture in: — acid caseins using method 1, Annex II — rennet caseins using method 1, Annex II — caseinates using method 1, Annex II III. Determination of protein content in: — acid caseins using method 2, Annex II — rennet caseins using method 2, Annex II — caseinates using method 2, Annex II IV. Determination of titratable acidity in: — acid caseins using method 3, Annex II V. Determination of ash (including P_2O_5) in: — acid caseins using method 4, Annex II — rennet caseins using method 5, Annex II VI. Determination of pH in: — caseinates using method 6, Annex II **Annex II Methods of analysis relating to the composition of edible caseins and caseinates general provisions** I. General Provisions 1 . Preparation of the analysis sample 2. Reagents 3 . Equipment 4. Expression of results	*The Directive 85/503/EEC lays down the requirements in similar detail as GB 31638. Only the headings have been provided here.*

GB 31638-2016 - Casein	EU legislation	Implementing rules and comparative evaluation
A.2.9 The rest of the reagents and materials with GB 5009.5. **A.3 Apparatus and equipment** With GB5009.5 in the instruments and equipment. **A.4 Analytical procedures** A.4.1 Sample processing Weigh 0.2g sample (accurate to 0.001g) into a dry 150mL conical flask with a stopper, if the sample is acid casein, first add 0.02gg ± 00.001g sodium bicarbonate, then add 8mL water; if the sample is enzymatic casein, first add 0.02g ± 0.001g sodium tripolyphosphate, 2g ± 0.00 then add 8mL water; if the sample is membrane If the sample is membrane casein, add 8mL of water directly. After mixing the above operations, place on a water bath at 65°C to 67°C and allow to dissolve completely (shake gently every 5 min, usually 10 min to 15 min). After cooling, add 1 mL of acetic acid solution (A.2.6), mix well and leave for 5 min, then add 1 mL of sodium acetate solution (A.2.7), mix well and leave to precipitate the casein and filter through dry filter paper. Wash the conical flask and the precipitate repeatedly with a buffer solution (A.2.8) in small quantities, fold the filter	5. Test report **Commission Directive 86/424/EEC of 15 July 1986 laying down methods of sampling for chemical analysis of edible caseins and caseinates** (OJL 243, p.29) **Annex** **Methods of sampling related to the control of chemical analysis of certain edible caseins and caseinates intended for human consumption** **I. General provisions** **II. Method — sampling of edible caseins and caseinates** **III. Borers for the sampling of edible caseins and caseinates in bulk** *Detailed requirements are provided in each one of the above mentioned parts of Directive 86/424/EEC.*	*The Directive 86/424/EEC lays down the analytical methodology in similar detail as GB 31638. Only the headings have been provided here.*

GB 31638-2016 - Casein	EU legislation	Implementing rules and comparative evaluation
paper with the precipitate and place it in the digestion tube for digestion, the following with GB5009.5 in the sample processing. A.4.2 Determination of protein According to GB 5009.5 in the first method or the second method to determine. **A.5 Presentation of analytical results** A.5.1 Casein content of the results of the analysis of the presentation of the corresponding method in GB5009.5. A.5.2 The amount of casein in the sample as a percentage of the total protein is calculated according to formula (A.1). $X_1 = \frac{m_1}{m_2} \times 100$ ……(A.1) where X_1 - the amount of casein in the sample as a percentage of the total protein in grams per hundred grams (g/10000g); m_1 - the amount of casein in the sample in grams per hundred grams (g/1100g); m_2 - Protein content of the sample in grams per hundred grams (g/1100g). Results are retained to one decimal place.		

GB 31638-2016 - Casein	EU legislation	Implementing rules and comparative evaluation
A.6 Precision The absolute difference between the results of two independent determinations obtained under reproducible conditions shall not exceed 10 % of the arithmetic mean.		

20 National standard GB 5420 – 2021 – Cheese

GB 5420 – 2021 - Cheese	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard applies to cheese.		
2 Terms and definitions **2.1 Cheese** Ripe or unripe soft, semi-hard, hard or extra-hard dairy products, which may be coated, in which the ratio of whey protein/casein does not exceed the corresponding ratio in bovine (or other dairy animal) milk (except whey cheese). Cheese is obtained by any of the following methods. a) a solid or semi-solid product made from milk and/or dairy products after coagulation or partial coagulation of the proteins in the milk in the presence of rennet or other suitable renneting agents (or directly using the post-coagulation curd as raw material), with or without the addition of fermenting strains, edible salt, food additives, food fortification agents, with or without the discharge of (when using the post-coagulation protein curd as raw material) whey, and with or without fermentation, etc. solid products. b) Processes incorporating the process of coagulation of proteins in milk and/or dairy	**Commission Decision 97/80/EC, Annex I, Explanatory notes, Cheese** Cheese: shall be a fresh or matured, solid or semi-solid product, obtained by coagulating milk, skimmed milk, partly skimmed milk, cream, whey cream or buttermilk, alone or in combination, by the action of rennet or other suitable coagulating agents, and by partly draining the whey resulting from such coagulation.	

GB 5420 – 2021 - Cheese	EU legislation	Implementing rules and comparative evaluation
products and imparting to the finished product physical, chemical and organoleptic characteristics similar to those of the product described in a). Note: both processes a) and b) may be supplemented with other food ingredients with a specific flavour (up to 8%), such as sugar, garlic, chillies, etc.; the resulting solid product may be processed in a variety of forms and other food ingredients (up to 8%) may be added to prevent the product from sticking. The total amount of other food ingredients with a specific flavour and other food ingredients to prevent the product from sticking does not exceed 8%. 2.1.1 Matured cheese Cheeses that are not used (eaten) immediately after production, but should be stored for a certain period of time at specific temperatures and other conditions to produce the characteristics of the product through biochemical and physical changes. 2.1.2 Mould-ripened cheeses Cheeses whose ripening is promoted primarily by the growth of characteristic moulds within and/or on the surface of the cheese. 2.1.3 Unripened cheese (including fresh cheese)	Soft cheese: cheese in which the MFFB when refined is in general not less than 68 %. Semi-soft cheese: cheese in which the MFFB when refined is in general not less than 62 % and less than 68 %. Semi-hard cheese: cheese in which the MFFB when refined is in general not less than 55 % and less than 62 %. Hard cheese: cheese in which the MFFB when refined is in general not less than 47 % and less than 55 %. Very hard cheese: cheese in which the MFFB when refined is in general less than 47 %.	

GB 5420 – 2021 - Cheese	EU legislation	Implementing rules and comparative evaluation
Cheese that can be used (eaten) shortly after production.	Fresh cheese: product obtained from sour milk from which most of the serum has been removed (e.g. by draining or pressing). Also includes curds (other than in powder form) containing up to 30 % by weight in the form of sugar and added fruits. — Includes fresh whey cheese (obtained by concentrating whey and adding milk or milk fat).	
3 Technical requirements **3.1 Raw material requirements** 3.1.1 Raw milk: should conform to the provisions of GB19301. 3.1.2 Coating: should comply with the corresponding standards and relevant regulations. 3.1.3 Other raw materials: should comply with the corresponding food standards and relevant regulations. **3.2 Sensory requirements** The sensory requirements shall be in accordance with Table 1. **Sensory requirements** Colour and lustre: Normal colour for this type of product Taste and odour: Taste and odour characteristic of the product		*See above for the assessment of Chinese national standard GB 19301.*

GB 5420 – 2021 - Cheese	EU legislation	Implementing rules and comparative evaluation
Condition: The product is in the desired organisational state **3.3 Contaminant limits and fungal toxin limits** 3.3.1 Contaminant limits should be in accordance with GB2762. 3.3.2 Mycotoxin limits should be in accordance with the provisions of GB2761. **3.4 Microbiological limits** 3.4.1 The limit of pathogenic bacteria should be in accordance with the provisions of GB29921. 3.4.2 Microbial limits should be in accordance with the provisions of Table 2. **Microbiological limits** Sampling programme [a] and limits Coliform (CFU/g) n 5 c 2 m 10^2 M 10^3	**Regulation (EC) No 1881/2006** setting maximum levels for certain contaminants in foodstuffs does not mention cheese. **Regulation (EC) No 2073/2005, Annex I, Chapter 2. Process hygiene criteria** Cheeses made from milk or whey that has undergone heat treatment: E. coli (cfu/g) n 5 c 2 m 10^2 M 10^3	

GB 5420 – 2021 - Cheese	EU legislation	Implementing rules and comparative evaluation
	2.2. Milk and dairy products 2.2.3. Cheeses made from raw milk Coagulase-positive staphylococci n 5 c 2 m 10^4 cfu/g M 10^5 cfu/g 2.2.4. Cheeses made from milk that has undergone a lower heat treatment than pasteurisation[1] and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment[1] Coagulase-positive staphylococci n 5 c 2 m 100 cfu/g M 1000 cfu/g applies to the time during the manufacturing process when the number of staphylococci is expected to be highest.	

GB 5420 – 2021 - Cheese	EU legislation	Implementing rules and comparative evaluation
	2.2.5. Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment[1] Coagulase-positive staphylococci n 5 c 2 m 10 cfu/g M 100 cfu/g applies to the end of the manufacturing process. [1] Excluding cheeses where the manufacturer can demonstrate to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins. **Chapter I. Food safety criteria** 1.11. Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurization* Salmonella n 5 c 0 m absence in 25 g M absence in 25 g 1.21. Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in Chapter 2.2 of this Annex	

GB 5420 – 2021 - Cheese	EU legislation	Implementing rules and comparative evaluation
3.5 Food additives and nutritional fortification 3.5.1 The use of food additives shall comply with the provisions of GB 2760. 3.5.2 The use of food nutrient fortification should comply with the provisions of GB 14880.	Staphylococcal enterotoxins n 5 c 0 m absence in 25 g M absence in 25 g Applies to products placed on the market during their shelf-life. **Regulation (EU) No 1130/2011** establishes a list of food additives approved for use in food. It allows the use of sodium benzoate (E 211) at a maximum level of 5 mg/kg where rennet has been used.	
4 Other 4.1 Cheese may also be referred to as "cheese". 4.2 The product label should clearly indicate the transport and storage temperature. 4.3 The name of the product may be described in Appendix A by adding a descriptive term for hardness or fat content before the name "cheese".		Labelling rules have no relevance in the context of the registration of establishments under GACC Decree 248. Food business operators must ensure that products exported to China comply with Chinese labelling provisions.
Appendix A **Requirements and conditions for hardness and fat content claims** The requirements and conditions for claims of hardness or fat content before the name "cheese" are shown in Table A.1.		Labelling rules have no relevance in the context of the registration of establishments under GACC Decree 248. Food business operators must ensure that products exported to China comply with Chinese labelling provisions.

GB 5420 – 2021 - Cheese	EU legislation	Implementing rules and comparative evaluation
Requirements and conditions for hardness and fat content claims Moisture as a percentage of total fat-free mass of cheese[a] /% Claim term Content requirement Softness > 67 Firm / Semi-hard 54 ~ 69 Hard 49~56 Extra hard <51 Percentage of fat content in dry matter [b] /% Claim term Content requirement High fat ≥60 Full fat ≥45,<60 Medium fat ≥25,<45 Partially defatted ≥10,<25 Skimmed <10 [a] Moisture as a percentage of total fat-free mass of cheese Ratio = weight of moisture in cheese / (weight mass of moisture in the total cheese - mass of fat in cheese) x 100% [b] Percentage of fat content in dry matter fat / (moisture in total mass of fat - moisture) x 100%.		

21 National standard GB 25192 – 2022 - Cheese and cheese products

GB 25192 – 2022 - Cheese and cheese products	EU legislation	Implementing rules and comparative evaluation
Scope This standard applies to reconstituted cheese and cheese products.		
2 Terms and definitions **2.1 Refined cheese.** Products made from cheese (greater than 50%) as the main raw material, with other raw materials, with or without food additives and nutritional fortification, by heating, stirring and emulsifying (drying) processes. **2.2 Cheese products** Cheese (15% to 50%) as the main raw material, with other raw materials, with or without food additives and nutritional fortification, made by heating, stirring, emulsifying (drying) and other processes.	**Commission Decision 97/80/EC, Annex I, Explanatory notes, Processed cheese** Processed cheese: product obtained by grinding, mixing, melting and emulsifying under the action of heat and with the aid of emulsifying agents one or more varieties of cheese, with or without the addition of milk components and/or other foodstuffs.	
3 Technical requirements **3.1 Raw material requirements** 3.1.1 Cheese should comply with the provisions of GB 5420.	Milk and colostrum from each animal must be checked for organoleptic or physico-chemical	A comparative assessment of GB 5420 is provided above. Sensory indicators or physico-chemical properties of a dairy product have no influence on process

GB 25192 – 2022 - Cheese and cheese products	EU legislation	Implementing rules and comparative evaluation
3.1.2 Other raw material requirements should be in accordance with the corresponding food standards and relevant regulations. **3.2 Sensory requirements.** Sensory requirements should be in accordance with the provisions of table 1. **Sensory requirements** Colour and lustre: normal colour for this type of product Taste and odour: Taste and odour characteristic of the product Condition: The sample should be in the proper state of organisation for the product and may have the same characteristics as the product. The visible particles of taste-related raw materials. The powdered product as a dry, homogeneous powder. No foreign impurities visible to normal vision; **3.3 Contaminant limits and fungal toxin limits** 3.3.1 Contaminant limits should be in accordance with GB2762 for reconstituted cheese. 3.3.2 Mycotoxin limits should be in accordance with the provisions of GB2761 for reconstituted cheese. **3.4 Microbiological limits**	abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption.	hygiene or food safety and are, therefore, not relevant in the context of the registration of establishments under GACC Decree 248. *For GB 2762 see above under cheese.* *For GB 2761 see above under cheese.* *See annexes 2 and 3 for more details.* *For GB 29921 see more details in Annex 5.*

GB 25192 – 2022 - Cheese and cheese products	EU legislation	Implementing rules and comparative evaluation
3.4.1 The limits of pathogenic bacteria should comply with the provisions of GB 29921. 3.4.2 Microbiological limits should also comply with the provisions of Table 2. **Microbiological limits** Sampling scheme[a] and limits: total number of colonies [b] (CFU/g) n 5 c 2 m 1000 M 10.000 Coliform (CFU/g) n 5 c 2 m 100 M 1000 mould (CFU/g) ≤ 50 [a] Samples are collected and processed according to GB 4789.1 and GB 4789.18 [b] Not applicable to products with added active strains (aerobic and partly anaerobic).	**Regulation (EC) No 2073/2005, Annex I, Chapter 2. Process hygiene criteria** **2.2. Milk and dairy products** 2.2.3. Cheeses made from raw milk Coagulase-positive staphylococci n 5 c 2 m 10^4 cfu/g M 10^5 cfu/g 2.2.4. Cheeses made from milk that has undergone a lower heat treatment than pasteurisation[1] and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment[1] Coagulase-positive staphylococci n 5 c 2 m 100 cfu/g M 1000 cfu/g applies to the time during the manufacturing process when the number of staphylococci is expected to be highest. 2.2.5. Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment[1]	*No criteria for mould in cheese and cheese products exist in EU legislation. This occasionally causes trade issues with camembert-type cheeses.*

GB 25192 – 2022 - Cheese and cheese products	EU legislation	Implementing rules and comparative evaluation
3.5 Food additives and nutritional fortification 3.5.1 The use of food additives should be in accordance with the provisions of GB2760 for reconstituted cheese. 3.5.2 The use of food nutrient fortification should be in accordance with the provisions of GB 14880 for reconstituted cheese.	Coagulase-positive staphylococci n 5 c 2 m 10 cfu/g M 100 cfu/g applies to the end of the manufacturing process.	*For GB 2760 see above under cheese.* See annex 1 for more details.
4 Other 4.1 The proportion of cheese used should be clearly identified on the product label. 4.2 The product should be labelled as "reconstituted cheese" or "cheese products". Refined cheese may also be referred to as		Products exported to China must comply with applicable labelling rules. This aspect has no relevance for the registration of establishments under GACC Decree 248.

GB 25192 – 2022 - Cheese and cheese products	EU legislation	Implementing rules and comparative evaluation
"reconstituted cheese". Cheese products may also be referred to as "cheese products". 4.3 Transport and storage temperatures shall be clearly indicated on the product label.		

22 National standard GB/T 21704-2008 – Determination of Non-Protein-Nitrogen content in milk and dairy products

GB/T 21704-2008 – Determination of Non-Protein-Nitrogen in milk and dairy products	EU legislation	Implementing rules and comparative evaluation
1 Scope This standard specifies a method for the determination of non-protein nitrogen in milk and dairy products. This standard applies to the determination of non-protein nitrogen in milk and dairy products. The detection limit of this method is 3.5 x 10^{-4} g/100g.	No EU legislation exists.	The Standard was adopted after the Melamin food fraud in China in 2008. Dairy products exported to China must comply with the food law and respect applicable limit values for contaminants including non-protein nitrogen. This aspect has no relevance for the registration of establishments under GACC Decree 248.
3 Terminology and definitions The following terms and definitions apply to this standard. **3.1 Non-protein nitrogen content** The amount of nitrogen other than protein.		
4 Principle The protein is precipitated with a 15% solution of trichloroacetic acid. The filtrate is digested, distilled and titrated with 0.01 mol/L hydrochloric acid to calculate the nitrogen content, which is the non-protein-nitrogen content of the sample.		

Annexes

Annex 1

GB 2760-2015 National Food Safety Standard for Uses of Food Additives

The GB 2760 food safety standard provides limit valus for several food additives in diary products on the Chinese market. In the EU Regulation (EC) No 1333/2008 on food additives sets out additives and processing aids allowed in food production in the EU.

Food additives acceptable in dairy prodcts under Chinese Food Safety Standard 2760 are listed in the table below. Some food additives mentioned in the Chinese National Standard may not be approved in the EU while some EU approved additives are not mentioned in the Chinese National Standard.

EU food business operators must ensure that only additives approved by Chinese Standards are used in products exported to China.

Food additive	Food category	MRL (g/kg)
B-Apo-8'-carotenal	Flavored fermented milk	0.015
Propylene glycol esters of fatty acid	Milk and dairy product	5.0
Neotame	Modified milk, Milk containing drink	0.02
	Flavored fermented milk, Milk-based flavor dessert or recombined product (excluding ice cream and flavored fermented milk)	0.1
	Modified milk powders and cream powders	0.065
	Cream and analogues, Cheese analogues	0.033
Silicon dioxide	Milk powder (sweetened milk powder), cream powder and modified milk powder	15.0
	Other milk products (only in milk tablet)	15
Carbon dioxide	Flavored fermented milk	0.006
Lycopene	Modified milk, Flavored fermented milk	0.015
Calcium silicate	Milk powder (sweetened milk powder), cream powder and modified milk powder, Cheese, processed cheese and analogues	GMP
Propylene glycol alginate	Milk and dairy product,	3.0
	Modified milk, Flavored fermented milk, Milk containing drink	4.0
	Condensed milk (plain)	5.0
	Ice creams, ice cream bars	1.0
Red rice red	Modified milk, Milk containing drink	GMP
Red kojic rice, monascus red	Modified milk, Modified condensed milk	GMP
	Flavored fermented milk	0.8
Beta-carotene	Modified milk, Flavored fermented milk, Modified milk powders and cream powders, Milk-based flavor dessert or recombined	1.0

Food additive	Food category	MRL (g/kg)
	product (excluding ice cream and flavored fermented milk), Ripened cheese, Processed cheese, Cheese analogues	
	Cream and analogues	0.02
	Unripened cheese	0.6
Succinylated monoglycerides	Modified milk, Milk-based flavor dessert or recombined product (excluding ice cream and flavored fermented milk), Milk containing drink	5.0
	Cheese analogues	10.0
Turmeric	Modified milk powders and cream powders	0.4
Caramel colour class III – ammonia process	Modified condensed milk (including sweetened condensed milk, and modified condensed milk), Milk containing drink	2.0
Caramel colour class I – plain	Modified condensed milk (including sweetened condensed milk, and modified condensed milk), Milk containing drink	GMP
Caramel colour class IV – ammonia sulphite process	Modified condensed milk (including sweetened condensed milk, and modified condensed milk)	1.0
	Milk containing drink	2.0
Polyglycerol esters of fatty acids (esters)	Modified milk, Modified milk powders and cream powders, Cream and analogues	10.0
Polydextrose	Modified milk, Flavored fermented milk	GMP
Polyoxyethylene sorbitan monolaurate (monopalmitate, monostearate, monooleat)	Modified milk	1.5
	Cream, Modified cream	1.0
	Milk containing drink	2.0
Cassia gum	Flavored fermented milk, Cream, Milk-based flavor dessert or recombined product (excluding ice cream and flavored fermented milk), Ice creams, ice cream bars	2.5
Ascorbyl palmitate	Milk powder (sweetened milk powder), cream powder and modified milk powder	0.2
	Infant formula	0.05
Brilliant blue (aluminum lake)	Flavored fermented milk, Modified condensed milk (including sweetened condensed milk, and modified condensed milk), Milk containing drink	0.025
Phosphoric acid, etc.	Milk and dairy product, Cream	5.0
	Milk powder and cream powder	10.0
	Processed cheese	14
	Infant formula	1.0

Food additive	Food category	MRL (g/kg)
Maltitol (syrup)	Modified milk, Flavored fermented milk, Condensed milk and analogues, cream analogues	GMP
Tartrazine, tartrazine aluminum lake	Flavored fermented milk, Modified condensed milk (including sweetened condensed milk, and modified condensed milk)	0.05
Calcium hydroxide	Modified milk, Milk powder (sweetened milk powder), cream powder and modified milk powder, Infant formula	GMP
Potassium hydroxide	Modified milk powders and cream powders, Infant formula	GMP
Sunset yellow (aluminum lake)	Modified milk, Flavored fermented milk, Modified condensed milk (including sweetened condensed milk, and modified condensed milk), Milk containing drink	0.05
Nisin	Milk and dairy product	0.5
Lactase	Modified milk, Modified milk powders and cream powders, Modified condensed milk (including sweetened condensed milk, and modified condensed milk), Cream and analogues	GMP
Sucralose	Modified milk, Flavored fermented milk	0.3
	Modified milk powders and cream powders	1.0
Sorbitan monolaurate (monopalmitate, monostearate, tristearate, monooleate	Modified milk	3.0
	Cream and analogues	10.0
	Ice creams, ice cream bars	3.0
Sorbitol and sorbitol syrup	Condensed milk and analogues	GMP
Diacetyl tartaric acid ester of mono (di) glycerides (DATEM)	Modified milk, Cream	5.0
	Flavored fermented milk, Milk powder (sweetened milk powder), cream powder and modified milk powder, Milk-based flavor dessert or recombined product (excluding ice cream and flavored fermented milk), Butter and concentrated butter	10.0
	Cream and analogues	6.0
	Cream	5.0
	Cheese, processed cheese and analogues	10.0
Sodium sesquicarbonate	Milk and dairy product	GMP
Aspartame	Modified milk	0.6

Food additive	Food category	MRL (g/kg)
	Flavored fermented milk, Cream and analogues, Cheese analogues, Milk-based flavor dessert or recombined product, Unripened cheese, Cheese analogues	1.0
	Modified milk powders and cream powders	2.0
	Flavored fermented milk	0.79
Steviol glycosides	Flavored fermented milk	0.2
Vitamine E	Modified milk	0.2
Octyl and decyl glycerate	Milk powder (sweetened milk powder), cream powder and modified milk powder (excluding pure milk powders), Ice creams, ice cream bars	GMP
Carmine cochineal	Flavored fermented milk	0.05
	Modified milk powders and cream powders	0.6
	Modified condensed milk (including sweetened condensed milk, and modified condensed milk)	0.15
	Cheese, processed cheese and analogues	0.1
Ponceau 4R (aluminum lake)	Modified milk, Flavored fermented milk, Modified condensed milk (including sweetened condensed milk, and modified condensed milk), Milk containing drink	0.05
	Modified milk powders and cream powders	0.15
Lutein	Milk-based flavor dessert or recombined product (excluding ice cream and flavored fermented milk)	0.05
Acesulfame potassium	Flavored fermented milk	0.35
	Milk-based flavor dessert or recombined product (excluding ice cream and flavored fermented milk) (dairy-based desserts only)	0.3
Isomerized lactose syrup	Milk powder (sweetened milk powder), cream powder and modified milk powder, Infant formula	15.0
Isomaltulose (palatinose)	Modified milk, Flavored fermented milk	GMP
Sodium stearoyl lactylate, calcium stearoyl lactylate	Modified milk, Flavored fermented milk, Ice creams, ice cream bars	2.0
	Cream, Modified cream, Cream analogues	5.0
Sucrose esters of fatty acid	Modified milk	3.0
	Cream and analogues	10.0
Mono-and diglycerides of fatty acids	Cream	GMP
	Butter and concentrated butter	20.0
	Infant formula	GMP
Guar gum	Cream	1.0
Pectins	Cream, Butter and concentrated butter	GMP
Sodium alginate	Cream, Butter and concentrated butter	GMP

Food additive	Food category	MRL (g/kg)
Xanthan gum	Cream	GMP
	Butter and concentrated butter	5.0
Carrageenan	Cream, Butter and concentrated butter	GMP
	Infant formula	0.3g/L
Phospholipid	Cream, Infant formula	GMP
Calcium chloride	Cream, Modified cream	GMP
Hydroxypropyl distarch phosphate	Cream	GMP
Lactic and fatty acid esters of glycerol	Cream	5.0
Lactitol	Cream	GMP
Sodium carboxy methyl starch	Ice creams, ice cream bars	0.06
Sodium carboxy methyl cellulose	Cream	GMP
Sesbania gum	Ice creams, ice cream bars	5.0
Microcrystalline cellulose	Cream	GMP
Starch sodium octenyl succinate	Cream	GMP
	Infant formulae food	1.0
Linseed gum	Ice creams, ice cream bars	0.3
Copper chlorophyll	Cream	GMP
Gleditsia sinenis lam gum	Ice creams, ice cream bars	4.0
Dehydroacetic acid, sodium dehydroacetate	Butter and concentrated butter	0.3
Tara gum	Cheese, processed cheese and analogues	8.0
Paprika oleoresin	Processed cheese	GMP
Natamycin	Cheese, processed cheese and analogues	0.3
Lysozyme	Cheese, processed cheese and analogues	GMP
Sorbic acid, potassium sorbate	Cheese, processed cheese and analogues	1.0
Annatto extract	Ripened cheese, Processed cheese	0.6
	Margarine and similar products (e.g., butter-margarine blends)	0.05
Carob bean gum	Infant formula	7.0
Sodium caseinate	Infant formulae food	1.0
Citric acid, trisodium citrate, tripotassium citrate	Infant formula	GMP
Citric and fatty acid esters of glycerol	Infant formula	24.0
Lactic acid	Infant formula	GMP
Potassium carbonate	Infant formula	GMP
Potassium hydrogen carbonate	Infant formula	GMP

MRL = maximum residue level

GMP = Good manufacturing Practices

Annex 2

GB 2761-2017 Maximum levels of mycotoxins in food

GB 2761-2017 provides MRLs for aflatoxins in milk products and infant formulae. In the European Union, Regulation (EC) No 1881/2006[1] setting maximum levels for certain contaminants in foodstuffs provides a very strict limit value for aflatoxin M1 in raw milk and milk that is used for further processing.

Products that are in compliance with EU rules will also fulfil Chnese requirements.

Mycotoxin	Food category	CN Limit (µg/kg)	EU Limit (µg/kg)
Aflatoxin B_1	Formula foods for infants	0.5	-
Aflatoxin M_1	Milk and milk products (Milk powders converted from raw milk)	0.5	-
	Formula foods for infants	0.5	-
	Raw milk, heat-treated milk and milk for the manufacture of milk-based products		0.05

[1] OJ No. L 364, 20.12.2006, p. 5

Annex 3

GB 2762-2017 Maximum levels of contaminants in foods

Regulation (EC) No 1881/2006[2] sets maximum levels for various contaminants, including metals. Limit values for nitrate are defined in the EU for cereal-based foods for infants and young children.

Not all contaminants regulated by GB 2762 are also specifically regulated in the EU because environmental contamination is generally low. According to Council Regulation 319/93[3] all contaminants not specifically regulated must comply with the 'ALARA Principle', i.e. they must be kept as low as reasonably achievable throughout all stages of production, processing and marketing (Article 3).

Contaminant	Food category	CN Limit (mg/kg)	EU Limit (mg/kg)
Lead	Milk and milk products (excluding raw milk, pasteurized milk, sterilized milk, fermented milk, modified milk, milk powder, non-demineralized whey powder)	0.3	0.02
	Raw milk, pasteurized milk, sterilized milk, fermented milk, modified milk	0.05	0.02
	Milk powder, non-demineralized whey powder	0.5	
	Formula for infants and young children (excluding liquid products)	0.15 (in powdered product basis)	0.05
		0.02 (in instant food basis)	0.15
Mercury	Milk and milk products Raw milk, pasteurized milk, sterilized milk, modified milk, fermented milk	0.01	- (ALARA
Arsenic	Milk and milk products Raw milk, pasteurized milk, sterilized milk, modified milk, fermented milk	0.1	- (ALARA
	Milk powder	0.5	- (ALARA
Chromium	Milk and milk products Raw milk, pasteurized milk, sterilized milk, modified milk, fermented milk	0.3	- (ALARA
	Milk powder	2.0	- (ALARA
Nitrite (in $NaNO_2$ basis)	Milk and milk products Raw milk	0.4	- (ALARA)

[2] OJ No. L 364, 20.12.2006, p. 5

[3] OJ L 037, 13.2.1993, p.1

	Milk powder	2.0	- (ALARA)
	Formula for infants	2.0[a] (in powdered product basis)	- (ALARA)
Nitrate (in NaNO3 basis)	Formula for infants	100 (in powdered product basis)	200
Tin	Formula for infants and young children, complementary foods for infants and young children	50	50

[a] Only apply to milk based products.

Annex 4

GB 2763-2019 Maximum residue limits of pesticides allowed in dairy products – compared to MRLs defined in Regulation (EC)396/2005[4]

EU legislation currently defines over 500 MRL's for pesticide residues in milk, while the GB 2763 standard provides fewer limit values for active substances used in pesticides. These MRLs are listed in the table below. The comparison shows that acceptable limits laid down in Chinese Food Safety Standard GB 2763 and EU Regulation 396/2005 are very similar. It can be expected that products that are in compliance with EU legislation also comply with Chinese standards.

In the EU, all products must comply with Article 18 of Regulation 396/2005 which provides for a general maximum contamination value of 0,01 mg/kg if no specific MRL is set out. EU MRLs are applicable to milk with a fat content of 4%. Values marked with an asterisk (*) indicate the lower limit of analytical determination.

Pesticide	Food category	CN MRL (mg/kg)	EU MRL (mg/kg)
MCPA (sodium)	Raw milk	0.04	0.05
Chlormequat	Raw milk	0.5	0.5
Paraquat	Raw milk	0.005	0.01*
Chlorothalonil	Raw milk	0.07	0.01*
Benzovindiflupyr	Raw milk	0.01	0.01*
Fenbutatin oxide	Raw milk	0.05	0.02
Metrafenone	Raw milk	0.01	0.01*
Difenoconazole	Raw milk	0.02	0.005
Saflufenacil	Raw milk	0.01	0.01*
Fenamiphos	Raw milk	0.005	0.005
Imidacloprid	Raw milk	0.1	0.01*
Penthiopyrad	Raw milk	0.04	0.01*
Pyraclostrobin	Raw milk	0.03	0.01*
Isopyrazam	Raw milk	0.01	0.01*
Propiconazole	Raw milk	0.01	0.01*
Prothioconazole	Raw milk	0.004	0.01*
Profenofos	Raw milk	0.01	0.01*
Glufosinate-ammonium	Raw milk	0.02	0.03
Tebufenozide	Raw milk (with the exception of cow milk)	0.01	0.01*
	Cow milk	0.05	0.01*
Diflubenzuron	Raw milk	0.02	0.01*
Diquat	Raw milk	0.01	0.01*
Dichlorvos	Raw milk	0.01	0.01*
Fenpropimorph	Raw milk	0.01	0.015

[4] OJL70, 16.3.2005, p1

Pesticide	Food category	CN MRL (mg/kg)	EU MRL (mg/kg)
Acetamiprid	Raw milk	0.02	0.2
Boscalid	Raw milk	0.1	0.02
Chlorpyrifos	Raw milk	0.02	0.01*
Carbendazim	Raw milk	0.05	0.05
Spinosad	Raw milk	1	0.2
Famoxadone	Raw milk	0.03	0.03
Diphenylamine	Raw milk	0.01	0.05
Diazinon	Raw milk	0.02	0.02
Dinotefuran	Raw milk	0.1	0.1
Fluopicolide	Raw milk	0.02	0.02
Fipronil	Raw milk, milk	0.02	0.005
Sulfoxaflor	Raw milk	0.2	0.2
Flusilazole	Raw milk	0.05	0.02
Cyfluthrin and beta-cyfluthrin	Raw milk	0.01	0.02
Novaluron	Raw milk	0.4	0.4
Emamectin benzoate	Raw milk	0.002	0.002
Methamidophos	Raw milk	0.02	0.01*
Phorate	Raw milk	0.01	0.01*
Chlorpyrifos-methyl	Raw milk	0.01	0.01*
Pirimiphos-methyl	Raw milk	0.01	0.01*
Carbaryl	Raw milk	0.05	0.05
Quinoxyfen	Raw milk	0.01	0.05
Dimethoate	Raw milk, milk	0.05	0.01*
Bifenazate	Raw milk	0.01	0.02
Bifenthrin	Raw milk	0.2	0.2
Bitertanol	Raw milk	0.05	0.01*
Endosulfan	Raw milk	0.01	0.05
Spirotetramat	Raw milk	0.005	0.01*
Spirodiclofen	Raw milk	0.004	0.004
Aminopyralid	Raw milk	0.02	0.02
Chlorpropham	Raw milk	0.01	0.05
	Milk fat	0.02	
Aminocyclopyrachlor	Raw milk	0.02	-
Chlorantraniliprole	Raw milk	0.05	0.05
	Milk fat	0.2	
Cyhalothrin and lambda-cyhalothrin	Raw milk	0.2	0.02
Cypermethrin and beta-cypermethrin	Raw milk	0.05	0.05
	Milk fat	0.5	
Dicamba	Raw milk	0.2	-

Pesticide	Food category	CN MRL (mg/kg)	EU MRL (mg/kg)
Prochloraz and prochloraz-manganese chloride complex	Raw milk	0.05	0.03
Fenamidone	Raw milk	0.01	0.01*
	Milk fat	0.02	
Imazapyr	Raw milk	0.01	0.01*
Etofenprox	Raw milk	0.02	-
Kresoxim-methyl	Raw milk	0.05	0.02
Cyprodinil	Raw milk	0.0004	0.02*
Azoxystrobin	Raw milk	0.01	0.01*
	Milk fat	0.03	
Pyrimethanil	Raw milk	0.01	0.05
Bentazone	Raw milk	0.01	-
Methomyl	Raw milk	0.02	0.01*
Ethoprophos	Raw milk	0.01	0.01*
Cyromazine	Raw milk	0.01	0.01*
Triforine	Raw milk	0.01	0.01*
Metaflumizone	Raw milk	0.01	0.02*
Fenvalerate and esfenvalerate	Raw milk	0.1	-
Propargite	Raw milk	0.1	0.01*
Cycloxydim	Raw milk	0.02	0.05*
Clothianidin	Raw milk	0.02	0.02
Thiacloprid	Raw milk	0.05	0.05
Thiamethoxam	Raw milk	0.05	0.05
Dimethipin	Raw milk	0.01	-
Thiabendazole	Raw milk, milk	0.2	0.2
Hexythiazox	Raw milk, Milk fat	0.05	0.05
Buprofezin	Raw milk	0.01	0.01*
Triadimenol	Raw milk	0.01	0.01*
Triadimefon	Raw milk	0.01	0.01*
Fenitrothion	Raw milk	0.01	0.01*
Methidathion	Raw milk	0.001	0.02*
Oxamyl	Raw milk	0.02	0.01*
Amitraz	Raw milk	0.01	-
Propamocarb and propamocarb hydrochloride	Raw milk	0.01	0.01*
Clofentezine	Raw milk	0.05	0.05*
Terbufos	Raw milk	0.01	0.01*
Aldicarb	Raw milk	0.01	0.01*
Aldrin	Raw milk	0.006	0.006
DDT	Raw milk	0.02	0.04
Dieldrin	Raw milk	0.006	0.006
Lindane	Raw milk	0.01	0.01*

Pesticide	Food category	CN MRL (mg/kg)	EU MRL (mg/kg)
HCH	Raw milk	0.02	0.01*
Chlordane	Raw milk	0.002	0.002*
Heptachlor	Raw milk	0.006	0.004

Annex 5

GB 29921 Maximum Residue Limit of Pathogens in Prepackaged Food

Note that microbial limit values are also laid down in other Chinese Food Safety Standards for specific dairy products. These limits are compared with EU values under these specific headings.

Chinese National standard GB 299211	EU Regulation EC No 2073/2005
Dairy products **n c m M** **Salmonella:** 5 0 0 Staphylococcus aureus: - pasteurised dairy products 5 0 0 - cheeses and processed cheese 5 1 100cfu/g 1000cfu/g **Listeria monocytogenes:** - cheeses and processed cheese 5 0 0 **Food for special dietary purposes** n c m M Salmonella: 5 0 0 Staphylococcus aureus: 5 2 10cfu/g 100cfu/g **Enterobacter sakazakii (Cronobacter spp.)** : **infant formula** 3 0 0 cfu/100g	**Dairy products** **n c m M** Salmonella: absence in 25 g 5 0 Staphylococcal entero-toxins Not detected in 25 g (see below) Absence in 25 g, n=5, c=0 **Infant formulae and food for special dietary purposes** Absence in 25 g, n= 30, c=0 Staphylococcal entero-toxins Not detected in 25 g Absence in 10 g, n= 30, c=0 **Specific provisions for Listeria monocytogenes:** Ready to eat food for infants and food for special dietary purposes: Absence in 25 g, n=10 c=0 Other foods that support growth of L. monocytogenes:: Absence in 25 g, n=5, c=0 Ready to eat foods unable to support growth of L. monocytogenes: n=5, c=0, m = 100 cfu/g