

## **Response of the European Union (EU) on questionnaire of The People's Republic of China related to registration of dairy establishments: Annex II 2 Comparison with the Chinese dairy product manufacturing practices, norms etc.**

The legislation of the EU is based on the relevant international standards, for food safety matters the basis is the International Organisation for food safety, the Codex Alimentarius Commission.

With regard to Food Safety, the General Principles and requirements are laid down in the EU General Food Law, namely Regulation (EC)178/2002<sup>1</sup>.

The aim of the General Food Law Regulation is to provide a framework to ensure a coherent approach in the development of food legislation within the European Union.

It establishes a framework for controlling and monitoring the production, prevention and management of risks. It also creates the European Food Safety Authority (EFSA), which is the reference point for the scientific control and evaluation of food and feed.

A leading principle of the EU is Free Movement of Goods within the 28 Member States based on a harmonised framework legislation which sets the highest standard for consumer protection.

This principle in particular applies in the food and agricultural sector. The EU is an entity with a functioning division of labour based on the most stringent provisions for health and consumer protection.

Milk product specific regulations include EU Regulation (EC) N° 852/2004<sup>2</sup> on the hygiene of foodstuffs and EU Regulation (EC) N° 853/2004<sup>3</sup> laying down specific hygiene rules for food of animal origin.

The Codex Alimentarius standards and related texts particularly relevant for this document are:

- Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004)



CXP\_057e.pdf

- Code of hygienic practice for powdered formulae for infants and young children (CAC/RCP 66 – 2008)



CXP\_066e.pdf

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<sup>1</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:NOT>

<sup>2</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0852:en:NOT>

<sup>3</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0853:en:NOT>

Please fill in the right hand column of the following table listing the provisions of the exporting country national legislation and/or other standards used for manufactures intending to export dairy products to the PRC. If not already covered in this table, please provide a copy of the exporting country national relevant laws, regulations and administrative provisions

Chinese manufacturing practices and standards 中国生产规范标准		<p style="text-align: center;"><b>EU legislation</b> National laws and standard</p> <p>( to be filled in English and/or Chinese )</p>
Dairy product manufacturing best practice ( GB 12693-2010) 乳制品良好生产规范		
Scope 范围	1	<p><b>Regulation (EC)178/2002:</b> Article 1: 1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety. 2. For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level. It establishes the European Food Safety Authority. It lays down procedures for matters with a direct or indirect impact on food and feed safety. 3. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.</p> <p><b>Regulation (EC) N° 852/2004:</b> 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;</p>

(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 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.

2. This Regulation shall not apply to:

(a) primary production for private domestic use;

(b) the domestic preparation, handling or storage of food for private domestic consumption;

(c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;

(d) collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen.

3. Member States shall establish, under national law, rules governing the activities referred to in paragraph 2(c). Such national rules shall ensure the achievement of the objectives of this Regulation.

**Regulation (EC) N° 853/2004:**

Article 1

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. Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of this Regulation.

		<p>3. This Regulation shall not apply in relation to:</p> <ul style="list-style-type: none"> <li>(a) primary production for private domestic use;</li> <li>(b) the domestic preparation, handling or storage of food for private domestic consumption;</li> <li>(c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;</li> <li>(d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat;</li> <li>(e) hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.</li> </ul> <p>4. Member States shall establish, according to national law, rules governing the activities and persons referred to in paragraph 3(c), (d) and (e). Such national rules shall ensure the achievement of the objectives of this Regulation.</p> <p>5. (a) Unless expressly indicated to the contrary, this Regulation shall not apply to retail.</p> <p>(b) However, this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment, unless:</p> <ul style="list-style-type: none"> <li>(i) the operations consist only of storage or transport, in which case the specific temperature requirements laid down in Annex III shall nevertheless apply;</li> <li>or</li> <li>(ii) the supply of food of animal origin from the retail establishment is to other retail establishments only and, in accordance with national law, is a marginal, localised and restricted activity.</li> </ul> <p>(c) Member States may adopt national measures to apply the requirements of this Regulation to retail establishments situated on their territory to which it would not apply pursuant to subparagraphs (a) or (b).</p> <p>6. This Regulation shall apply without prejudice to:</p> <ul style="list-style-type: none"> <li>(a) relevant animal and public health rules, including more stringent rules laid down for the prevention, control and eradication of certain transmissible spongiform encephalopathies;</li> <li>(b) animal welfare requirements;</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>(c) requirements concerning the identification of animals and the traceability of products of animal origin.</li> </ul>
<p>Location and plant environment 选址及厂区环境</p>	<p>4</p>	<p><b>Regulation (EC) N° 852/2004:</b> Article 6</p>

	<p>Official controls, registration and approval</p> <p>1. Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.</p> <p>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.</p> <p>Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.</p> <p>3. However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required:</p> <p>(a) under the national law of the Member State in which the establishment is located;</p> <p>(b) under Regulation (EC) No 853/2004;</p> <p>or</p> <p>(c) by a decision adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).</p> <p>Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.</p> <p><b>Regulation (EC) N° 853/2004:</b></p> <p><b>SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS</b></p> <p><b>CHAPTER I: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION</b></p> <p><b>II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS</b></p> <p><b>A. Requirements for premises and equipment</b></p> <p>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.</p> <p>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.</p> <p>3. Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils,</p>
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		<p>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.</p> <p>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.</p>
<p>Plant and workshop 厂房和车间</p>	<p>5</p>	<p><b>Regulation (EC) N° 852/2004:</b></p> <p>ANNEX I: PRIMARY PRODUCTION PART A: GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS</p> <p>I. Scope</p> <p>1. This Annex applies to primary production and the following associated operations:</p> <p>(a) the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;</p> <p>(b) the transport of live animals, where this is necessary to achieve the objectives of this Regulation;</p> <p>and</p> <p>(c) in the case of products of plant origin, fishery products and wild game, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.</p> <p>II. Hygiene provisions</p> <p>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.</p> <p>3. Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production and associated operations, including:</p> <p>(a) measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary</p>

	<p>medicinal products, plant protection products and biocides and the storage, handling and disposal of waste; and</p> <p>(b) measures relating to animal health and welfare and plant health that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.</p> <p>4. Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:</p> <p>(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;</p> <p>(b) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels;</p> <p>(c) as far as possible to ensure the cleanliness of animals going to slaughter and, where necessary, production animals;</p> <p>(d) to use potable water, or clean water, whenever necessary to prevent contamination;</p> <p>(e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;</p> <p>(f) as far as possible to prevent animals and pests from causing contamination;</p> <p>(g) to store and handle waste and hazardous substances so as to prevent contamination;</p> <p>(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;</p> <p>(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;</p> <p>and</p> <p>(j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.</p> <p>5. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:</p> <p>(a) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels;</p> <p>(b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products;</p> <p>(c) to use potable water, or clean water, whenever necessary to prevent contamination;</p>
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(d) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;

(e) as far as possible to prevent animals and pests from causing contamination;

(f) to store and handle wastes and hazardous substances so as to prevent contamination;

(g) to take account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health;

and

(h) to use plant protection products and biocides correctly, as required by the relevant legislation.

6. Food business operators are to take appropriate remedial action when informed of problems identified during official controls.

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:

(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.

9. Food business operators producing or harvesting plant products are, in particular, to keep records on:

(a) any use of plant protection products and biocides;

(b) any occurrence of pests or diseases that may affect the safety of products of plant origin;

and

(c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.

10. The food business operators may be assisted by other persons, such as veterinarians, agronomists and farm technicians, with the keeping of records.

**PART B: RECOMMENDATIONS FOR GUIDES TO GOOD HYGIENE**



**PRACTICE**

1. National and Community guides referred to in Articles 7 to 9 of this Regulation should contain guidance on good hygiene practice for the control of hazards in primary production and associated operations.

2. Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production and associated operations and actions to control hazards, including relevant measures set out in Community and national legislation or national and Community programmes. Examples of such hazards and measures may include:

(a) the control of contamination such as mycotoxins, heavy metals and radioactive material;

(b) the use of water, organic waste and fertilisers;

(c) the correct and appropriate use of plant protection products and biocides and their traceability;

(d) the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;

(e) the preparation, storage, use and traceability of feed;

(f) the proper disposal of dead animals, waste and litter;

(g) protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the competent authority;

(h) procedures, practices and methods to ensure that food is produced, handled, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control;

(i) measures relating to the cleanliness of slaughter and production animals;

(j) measures relating to record-keeping.

**ANNEX II**

**GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS (EXCEPT WHEN ANNEX I APPLIES)**

**INTRODUCTION**

Chapters V to XII apply to all stages of production, processing and distribution of food and the remaining Chapters apply as follows:

— Chapter I applies to all food premises, except premises to which Chapter III applies

— Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas and premises to which Chapter III applies

— Chapter III applies to those premises listed in the heading to the Chapter

— Chapter IV applies to all transportation.

CHAPTER I

General requirements for food premises (other than those specified in chapter iii)

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;
  - (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.
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.
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.
7. Food premises are to have adequate natural and/or artificial lighting.
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.

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.

#### CHAPTER II

Specific requirements in rooms where foodstuffs are prepared, treated or processed (excluding dining areas and those premises specified in chapter III) 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:

(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;

(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;

(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 mould and the shedding of particles;

(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 non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate;

and

(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, unless food business operators can satisfy the competent authority that other materials used are appropriate.

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.

3. Adequate provision is to be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Chapter VII and be kept clean and, where necessary, disinfected.

#### CHAPTER III

Requirements for movable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), premises used primarily as a private dwelling-house but where foods are regularly prepared for placing on the market and vending machines

1. Premises and vending machines are, so far as is reasonably practicable, to be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contamination, in particular by animals and pests.

2. In particular, where necessary:

(a) appropriate facilities are to be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);

(b) surfaces in contact with food are to be 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, unless food business operators can satisfy the competent authority that other materials used are appropriate;

(c) adequate provision is to be made for the cleaning and, where necessary, disinfecting of working utensils and equipment;

(d) where foodstuffs are cleaned as part of the food business' operations, adequate provision is to be made for this to be undertaken hygienically;

(e) an adequate supply of hot and/or cold potable water is to be available;

(f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) are to be available;

(g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions are to be available;

(h) foodstuffs are to be so placed as to avoid the risk of contamination so far as is reasonably practicable.

**Regulation (EC) N° 853/2004:**

		<p>SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS</p> <p>CHAPTER I: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION</p> <p>II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS</p> <p>A. Requirements for premises and equipment</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
Facility 设施	5.3	See above
Ventilation facilities 通风设施	5.3.5	<p><b>Regulation (EC) N° 852/2004</b></p> <p>...</p> <p>ANNEX II</p> <p>GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS (EXCEPT WHEN ANNEX I APPLIES)</p> <p>...</p> <p>5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.</p> <p>6. Sanitary conveniences are to have adequate natural or mechanical ventilation.</p> <p>...</p>

Lighting facilities 照明设施	5.3.6	See above
<p>The plant should have sufficient natural or artificial lighting. The lighting in the workshop should at least meet standard IV requirements. For the area where the quality control is performed lighting should meet 540 lx or above. The working area should reach no less that 220 lx while the remain area, with the exception of the one where sensitive tests are performed, should reach at least 110 xl. The lighting source should not change the food colour.</p> <p>厂房内应有允足的自然采光或人工照明,车间采光系数不应低于标准 IV 级.质量监控场所工作面的混合度不宜低于 540LX,加工场所工作面不宜低于 220LX,其他场所不宜低于 110LX,对光敏感测试区域除外.光源不应改变食品的颜色.</p>	5.3.6.1	<p><b>Regulation (EC) N° 852/2004</b> ... ANNEX II GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS (EXCEPT WHEN ANNEX I APPLIES) ... 7. Food premises are to have adequate natural and/or artificial lighting. ...</p>
Equipment 设备	6	<p>See also above.</p> <p><b>Regulation (EC) N° 853/2004:</b> SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS CHAPTER I: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS</p>

		<p>A. Requirements for premises and equipment</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ol>
<p>Hygiene management 卫生管理</p>	<p>7</p>	<p>See also above</p> <p><b>Regulation (EC)178/2002:</b></p> <p>Article 17</p> <p><b>Responsibilities</b></p> <ol style="list-style-type: none"> <li>1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.</li> <li>2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.</li> </ol> <p>For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing</p>

and distribution.

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.

#### Article 18

##### **Traceability**

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).



		<p>Article 19</p> <p><b>Responsibilities for food: food business operators</b></p> <p>1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.</p> <p>2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.</p> <p>3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.</p> <p>4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.</p>
<p>Personnel health and hygiene requirements 人员健康与卫生要求</p>	<p>7.4</p>	<p><b>Regulation (EC) N° 852/2004:</b></p>

ANNEX I:  
PRIMARY PRODUCTION  
PART A: GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

...

II. Hygiene provisions

...

(e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;

...

5. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:

...

(d) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;

...

6. Food business operators are to take appropriate remedial action when informed of problems identified during official controls.

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:

(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.

9. Food business operators producing or harvesting plant products are, in particular, to keep records on:

(a) any use of plant protection products and biocides;

		<p>(b) any occurrence of pests or diseases that may affect the safety of products of plant origin; and (c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.</p> <p>10. The food business operators may be assisted by other persons, such as veterinarians, agronomists and farm technicians, with the keeping of records.</p> <p>...</p> <p><b>Regulation (EC) N° 853/2004:</b> SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS 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 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.</p> <p>...</p>
<p>Raw and packaging material requirements 原料和包装材料的要求</p>	<p>8</p>	<p>See also above</p>

<p>Purchase and acceptance requirements for raw and packaging material 原料和包装材料的采购和验收要求</p>	<p>8.2</p>	<p><b>Regulation (EC) N° 853/2004:</b> SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS CHAPTER I: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION</p> <p>II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS</p> <p>A. Requirements for premises and equipment</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ol> <p>B. Hygiene during milking, collection and transport</p> <ol style="list-style-type: none"> <li>1. Milking must be carried out hygienically, ensuring in particular: <ol style="list-style-type: none"> <li>(a) that, before milking starts, the teats, udder and adjacent parts are clean;</li> <li>(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;</li> <li>(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;</li> <li>(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</li> <li>(e) that teat dips or sprays are used only after authorisation or registration in accordance with the</li> </ol> </li> </ol>
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		<p>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 ( 1 ):</p> <p>(f) that colostrum is milked separately and not mixed together with raw milk.</p> <p>2. Immediately after milking, milk and colostrum must be held in a clean place designed and equipped to avoid contamination.</p> <p>(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;</p> <p>(b) Colostrum must be stored separately and immediately cooled to not more than 8 o C in the case of daily collection, or not more than 6 o C if collection is not daily, or frozen.</p> <p>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 o C.</p> <p>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:</p> <p>(a) the milk is processed within two hours of milking; or</p> <p>(b) a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises.</p>
<p>Transportation and storage requirements for raw and packaging material</p> <p>原料和包装材料的运输和贮存</p>	8.3	See above
<p>Transportation and storage for raw milk</p> <p>生乳的运输和贮存</p>	8.3.2	<p><b>Regulation (EC) N° 853/2004:</b></p> <p>SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS</p> <p>CHAPTER I: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION</p> <p>II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS</p> <p>...</p> <p>B. Hygiene during milking, collection and transport</p> <p>1. Milking must be carried out hygienically, ensuring in particular:</p> <p>(a) that, before milking starts, the teats, udder and adjacent parts are clean;</p> <p>(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</p>

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 ( 1 ):

(f) that colostrum is milked separately and not mixed together with raw milk.

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;

(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.

...

**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

(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

	<p>inform the competent authority and take measures to correct the situation.</p> <p><b>CHAPTER III: WRAPPING AND PACKAGING</b></p> <p>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.</p> <p><b>CHAPTER IV: LABELLING</b></p> <p>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:</p> <p>(a) in the case of raw milk intended for direct human consumption, the words ‘raw milk’;</p> <p>(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’;</p> <p>(c) in case of colostrum, the word ‘colostrum’;</p> <p>(d) in case of products made with colostrum, the words ‘made with colostrum’.</p> <p>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.</p> <p><b>CHAPTER V: IDENTIFICATION MARKING</b></p> <p>By way of derogation from the requirements of Annex II, Section I:</p> <p>1. rather than indicating the approval number of the establishment, the identification mark may include a reference to where on the wrapping or packaging the approval number of the establishment is indicated;</p> <p>2. in the case of the reusable bottles, the identification mark may indicate only the initials of the consigning country and the approval number of the establishment.</p> <p>...</p>
<p>Raw milk within two hours from milking should be brought to a temperature between 0 e 4 °C, then transported with thermal insulated truck. The truck should be equipped with well kept/complete certification and records.</p> <p>生乳在挤奶后 2 小时内应降温至</p>	<p>8.3.2.2</p> <p><b>Regulation (EC) N° 853/2004:</b></p> <p><b>SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS</b></p> <p><b>CHAPTER I: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION</b></p> <p><b>II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS</b></p> <p>...</p> <p><b>B. Hygiene during milking, collection and transport</b></p>

<p>0°C~4°C.采用保温奶罐车运输.运输车辆应具备完善的证明和记录.</p>		<p>...</p> <p>2. Immediately after milking, milk and colostrum must be held in a clean place designed and equipped to avoid contamination.</p> <p>(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;</p> <p>(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.</p> <p>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.</p> <p>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:</p> <p>(a) the milk is processed within two hours of milking; or</p> <p>(b) a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises.</p> <p>...</p> <p><b>CHAPTER II: REQUIREMENTS CONCERNING DAIRY AND COLOSTRUM-BASED PRODUCTS</b></p> <p><b>I. TEMPERATURE REQUIREMENTS</b></p> <p>1. Food business operators must ensure that, upon acceptance at a processing establishment,</p> <p>(a) milk is quickly cooled to not more than 6 o C;</p> <p>(b) colostrum is quickly cooled to not more than 6 o C or maintained frozen, and kept at that temperature until processed.</p> <p>2. However, food business operators may keep milk and colostrum at a higher temperature if:</p> <p>(a) processing begins immediately after milking, or within four hours of acceptance at the processing establishment; or</p> <p>(b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy or colostrum-based products.</p>
<p>Food safety control during the manufacturing process 生产过程的食品安全控制</p>	<p>9</p>	<p>See also above</p>
<p>Macrobial contamination control 微生物污染的控制</p>	<p>9.1</p>	<p><b>Regulation (EC) N° 853/2004:</b></p> <p>...</p>



SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS

...

CHAPTER II: REQUIREMENTS CONCERNING DAIRY AND COLOSTRUM-BASED PRODUCTS

...

III. CRITERIA FOR RAW MILK AND COLOSTRUM

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.

(b) National criteria for colostrum, as regards plate count, somatic cell count or antibiotic residues, apply pending the establishment of specific Community legislation.

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 o C (per ml)

$\leq 100\ 000$  (\*)

Somatic cell count (per ml)

$\leq 400\ 000$  (\*\*)

(\*) 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, unless the competent authority specifies another methodology to take account of seasonal variations in production levels.

(ii) for raw milk from other species: Plate count at 30 o C (per ml)

$\leq 1\ 500\ 000$  (\*)

(\*) Rolling geometric average over a two-month period, with at least two samples per month.

	<p>(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 o C (per ml)  <math>\leq 500\ 000</math> (*)  (*) Rolling geometric average over a two-month period, with at least two samples per month.  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 ( 1 ), exceeds the levels authorised under that Regulation; or  (b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.  5. When raw milk fails to comply with point 3 or 4, the food business operator must inform the competent authority and take measures to correct the situation.</p>
<p>Level of air cleanliness within the production area  生产区域空气清洁度</p>	<p>9.1.3 ..  <b>Regulation (EC) N° 852/2004:</b>  ANNEX II  GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS (EXCEPT WHEN ANNEX I APPLIES)  INTRODUCTION  Chapters V to XII apply to all stages of production, processing and distribution of food and the remaining Chapters apply as follows:  — Chapter I applies to all food premises, except premises to which Chapter III applies  — Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas and premises to which Chapter III applies  — Chapter III applies to those premises listed in the heading to the Chapter  — Chapter IV applies to all transportation.  CHAPTER I  General requirements for food premises (other than those specified in chapter iii)  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</p>

	<p>contamination, and provide adequate working space to allow for the hygienic performance of all operations;</p> <p>(b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;</p> <p>(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control;</p> <p>and</p> <p>(d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.</p> <p>3. An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.</p> <p>4. An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.</p> <p>5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.</p> <p>6. Sanitary conveniences are to have adequate natural or mechanical ventilation.</p> <p>7. Food premises are to have adequate natural and/or artificial lighting.</p> <p>8. Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.</p> <p>9. Where necessary, adequate changing facilities for personnel are to be provided.</p> <p>10. Cleaning agents and disinfectants are not to be stored in areas where food is handled.</p> <p><b>CHAPTER II</b></p> <p>Specific requirements in rooms where foodstuffs are prepared, treated or processed (excluding dining areas and those premises specified in chapter III) 1. In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including</p>
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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:

- (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;
- (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;
- (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 mould and the shedding of particles;
- (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 non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate;

and

- (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, unless food business operators can satisfy the competent authority that other materials used are appropriate.

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.

3. Adequate provision is to be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Chapter VII and be kept clean and, where necessary, disinfected.

		<p><b>CHAPTER III</b>  Requirements for movable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), premises used primarily as a private dwelling-house but where foods are regularly prepared for placing on the market and vending machines</p> <p>1. Premises and vending machines are, so far as is reasonably practicable, to be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contamination, in particular by animals and pests.</p> <p>2. In particular, where necessary:</p> <p>(a) appropriate facilities are to be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);</p> <p>(b) surfaces in contact with food are to be 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, unless food business operators can satisfy the competent authority that other materials used are appropriate;</p> <p>(c) adequate provision is to be made for the cleaning and, where necessary, disinfecting of working utensils and equipment;</p> <p>(d) where foodstuffs are cleaned as part of the food business' operations, adequate provision is to be made for this to be undertaken hygienically;</p> <p>(e) an adequate supply of hot and/or cold potable water is to be available;</p> <p>(f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) are to be available;</p> <p>(g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions are to be available;</p> <p>(h) foodstuffs are to be so placed as to avoid the risk of contamination so far as is reasonably practicable.</p>
<p>Standard GB/T18204.1 is about determination of natural sedimentation , it forsees that the maximum total concentration of colonies in the air within the working area should not exceed 30 CFU/dish.  按 BG/T18204.1 中的自然沉降法测</p>	<p>9.1.3.2</p>	<p><b>Regulation (EC) N° 852/2004:</b>  ..</p> <p><b>ANNEX II</b>  <b>GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS (EXCEPT WHEN ANNEX I APPLIES)</b>  <b>INTRODUCTION</b></p>

定,清洁作业区空气中的菌落总数应控制在 30CFU/皿以下.

Chapters V to XII apply to all stages of production, processing and distribution of food and the remaining Chapters apply as follows:

— Chapter I applies to all food premises, except premises to which Chapter III applies

— Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas and premises to which Chapter III applies

— Chapter III applies to those premises listed in the heading to the Chapter

— Chapter IV applies to all transportation.

#### CHAPTER I

General requirements for food premises (other than those specified in chapter iii)

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;

(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.

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.

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.
7. Food premises are to have adequate natural and/or artificial lighting.
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.
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.

#### CHAPTER II

Specific requirements in rooms where foodstuffs are prepared, treated or processed (excluding dining areas and those premises specified in chapter III) 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:

- (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;
- (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;
- (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 mould and the shedding of particles;
- (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 non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate;

and

(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, unless food business operators can satisfy the competent authority that other materials used are appropriate.

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.

3. Adequate provision is to be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Chapter VII and be kept clean and, where necessary, disinfected.

**CHAPTER III**

Requirements for movable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), premises used primarily as a private dwelling-house but where foods are regularly prepared for placing on the market and vending machines

1. Premises and vending machines are, so far as is reasonably practicable, to be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contamination, in particular by animals and pests.

2. In particular, where necessary:

(a) appropriate facilities are to be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);

(b) surfaces in contact with food are to be 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, unless food business operators can satisfy the competent authority that other materials used are appropriate;

(c) adequate provision is to be made for the cleaning and, where necessary, disinfecting of working utensils and equipment;

(d) where foodstuffs are cleaned as part of the food business' operations, adequate provision is to be made for this to be undertaken hygienically;

(e) an adequate supply of hot and/or cold potable water is to be available;

(f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or



	<p>inedible substances and waste (whether liquid or solid) are to be available;  (g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions are to be available;  (h) foodstuffs are to be so placed as to avoid the risk of contamination so far as is reasonably practicable.</p>
<p>Test  检验</p>	<p>10</p> <p><b>Regulation (EC) N° 853/2004:</b>  ...  SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS  ...  CHAPTER II: REQUIREMENTS CONCERNING DAIRY AND COLOSTRUM-BASED PRODUCTS  ...    <b>III. CRITERIA FOR RAW MILK AND COLOSTRUM</b>  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.  (b) National criteria for colostrum, as regards plate count, somatic cell count or antibiotic residues, apply pending the establishment of specific Community legislation.  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 o C (per ml)  ≤ 100 000 (*)  Somatic cell count (per ml)</p>

	<p> <math>\leq 400\ 000</math> (**)  (*) 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, unless the competent authority specifies another methodology to take account of seasonal variations in production levels.  (ii) for raw milk from other species: Plate count at 30 o C (per ml)  <math>\leq 1\ 500\ 000</math> (*)  (*) Rolling geometric average over a two-month period, with at least two samples per month.  (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 o C (per ml)  <math>\leq 500\ 000</math> (*)  (*) Rolling geometric average over a two-month period, with at least two samples per month.  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 ( 1 ), exceeds the levels authorised under that Regulation; or  (b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.  5. When raw milk fails to comply with point 3 or 4, the food business operator must inform the competent authority and take measures to correct the situation. </p>
Products transportation and storage 产品的贮存和运输	11 See also above <b>Regulation (EC) N° 853/2004:</b> SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS 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

		<p>separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment.</p> <p>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.</p> <p>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.</p>
<p>Products traceability and recall 产品追溯和召回</p>	<p>12</p>	<p>See above</p> <p><b>Regulation (EC)178/2002:</b></p> <p>Article 17</p> <p><b>Responsibilities</b></p> <p>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.</p> <p>2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.</p> <p>For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.</p> <p>Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.</p>

Article 18

**Traceability**

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

Article 19

**Responsibilities for food: food business operators**

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

		<p>requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.</p> <p>2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.</p> <p>3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.</p> <p>4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.</p>
<p>Training 培训</p>	<p>13</p>	<p><b>Regulation (EC) N° 852/2004:</b></p> <p>CHAPTER XII Training Food business operators are to ensure:</p> <p>1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;</p>

		<p>2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles; and</p> <p>3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors</p>
<p>Administration and personnel 管理机构和人员</p>	<p>14</p>	<p><b>Regulation (EC) N° 852/2004:</b></p> <p>CHAPTER II FOOD BUSINESS OPERATORS' OBLIGATIONS</p> <p>Article 3 General obligation Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.</p> <p>Article 4 General and specific hygiene requirements</p> <p>1. Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I and any specific requirements provided for in Regulation (EC) No 853/2004.</p> <p>2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No 853/2004.</p> <p>3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:</p> <ul style="list-style-type: none"> <li>(a) compliance with microbiological criteria for foodstuffs;</li> <li>(b) procedures necessary to meet targets set to achieve the objectives of this Regulation;</li> <li>(c) compliance with temperature control requirements for foodstuffs;</li> <li>(d) maintenance of the cold chain;</li> <li>(e) sampling and analysis.</li> </ul> <p>4. The criteria, requirements and targets referred to in paragraph 3, and associated sampling and analysis methods shall be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).</p>

5. When this Regulation, Regulation (EC) No 853/2004 and their implementing measures do not specify sampling or analysis methods, food business operators may use appropriate methods laid down in other Community or national legislation or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.

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.

#### Article 5

##### Hazard analysis and critical control points

1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.
2. The HACCP principles referred to in paragraph 1 consist of the following:
  - (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
  - (b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
  - (c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
  - (d) establishing and implementing effective monitoring procedures at critical control points;
  - (e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
  - (f) establishing procedures, which shall be carried out regularly, to verify that the 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.
3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.
4. Food business operators shall:
  - (a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food

		<p>business;</p> <p>(b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;</p> <p>(c) retain any other documents and records for an appropriate period.</p> <p>5. Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 14(2). Such arrangements may facilitate the implementation of this Article by certain food business operators, in particular by providing for the use of procedures set out in guides for the application of HACCP principles, in order to comply with paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents and records in accordance with paragraph 4(c).</p> <p>Article 6</p> <p>Official controls, registration and approval</p> <p>1. Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.</p> <p>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.</p> <p>Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.</p> <p>3. However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required:</p> <p>(a) under the national law of the Member State in which the establishment is located;</p> <p>(b) under Regulation (EC) No 853/2004;</p> <p>or</p> <p>(c) by a decision adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).</p> <p>Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.</p>
<p>Records and documents management 记录和文件的管理</p>	<p>15</p>	<p>See also above</p>



		<p><b>Regulation (EC) N° 852/2004:</b></p> <p>III. Record-keeping</p> <p>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.</p> <p>8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:</p> <ul style="list-style-type: none"> <li>(a) the nature and origin of feed fed to the animals;</li> <li>(b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods;</li> <li>(c) the occurrence of diseases that may affect the safety of products of animal origin;</li> <li>(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;</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>(e) any relevant reports on checks carried out on animals or products of animal origin.</li> </ul> <p>9. Food business operators producing or harvesting plant products are, in particular, to keep records on:</p> <ul style="list-style-type: none"> <li>(a) any use of plant protection products and biocides;</li> <li>(b) any occurrence of pests or diseases that may affect the safety of products of plant origin;</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>(c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.</li> </ul> <p>10. The food business operators may be assisted by other persons, such as veterinarians, agronomists and farm technicians, with the keeping of records.</p>
<p>Requirements for computer system applications 计算机系统应用的要求</p>	<p>All A</p>	<p><b>Regulation (EC) N° 852/2004:</b></p> <p>CHAPTER II FOOD BUSINESS OPERATORS' OBLIGATIONS Article 3</p>

	<p>General obligation Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.</p> <p>Article 4 General and specific hygiene requirements</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No 853/2004.</li> <li>3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:       <ol style="list-style-type: none"> <li>(a) compliance with microbiological criteria for foodstuffs;</li> <li>(b) procedures necessary to meet targets set to achieve the objectives of this Regulation;</li> <li>(c) compliance with temperature control requirements for foodstuffs;</li> <li>(d) maintenance of the cold chain;</li> <li>(e) sampling and analysis.</li> </ol> </li> <li>4. The criteria, requirements and targets referred to in paragraph 3, and associated sampling and analysis methods shall be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).</li> <li>5. When this Regulation, Regulation (EC) No 853/2004 and their implementing measures do not specify sampling or analysis methods, food business operators may use appropriate methods laid down in other Community or national legislation or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.</li> <li>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.</li> </ol> <p>Article 5 Hazard analysis and critical control points</p> <ol style="list-style-type: none"> <li>1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</li> </ol>
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2. The HACCP principles referred to in paragraph 1 consist of the following:

- (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
- (b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
- (c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
- (d) establishing and implementing effective monitoring procedures at critical control points;
- (e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
- (f) establishing procedures, which shall be carried out regularly, to verify that the 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.

3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.

4. Food business operators shall:

- (a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;
- (b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;
- (c) retain any other documents and records for an appropriate period.

5. Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 14(2). Such arrangements may facilitate the implementation of this Article by certain food business operators, in particular by providing for the use of procedures set out in guides for the application of HACCP principles, in order to comply with paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents and records in accordance with paragraph 4(c).

Article 6  
Official controls, registration and approval

	<p>1. Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.</p> <p>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.</p> <p>Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.</p> <p>3. However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required:</p> <ul style="list-style-type: none"><li>(a) under the national law of the Member State in which the establishment is located;</li><li>(b) under Regulation (EC) No 853/2004;</li></ul> <p>or</p> <ul style="list-style-type: none"><li>(c) by a decision adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).</li></ul> <p>Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.</p>
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