

# Industry Guide to Good Hygiene Practice

# Milk and Dairy Products





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# **Milk and Dairy Products**

Regulation (EC) 852/2004 The hygiene of foodstuffs

Regulation (EC) 853/2004 *Hygiene rules for food of animal origin* 

Regulation (EC) 2073/2005 *Microbiological criteria for foodstuffs* (as amended by EC Regulation No. 1441/2007 and Regulation No. 365/2010)

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#### Preface

This Industry Guide to Good Hygiene Practice gives advice to the dairy industry on how to comply with the EU legislation.

This is an official guide to the Regulations which has been developed in accordance with Articles 7-8 of the EC Regulation on the hygiene of foodstuffs (Regulation No 852/2004).

The guidance also includes an annex on non-exhaustive list of establishments subject to approval under Regulation (EC) 853/2004.

Whilst the guidance given in this Guide is not legally binding, Food Authorities must give its content due consideration when enforcing the Regulations.

Therefore Food Business Operators whilst not legally bound to follow the guidance, must be prepared to justify if they do not do so.

#### **Acknowledgements**

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#### Introduction

This Guide has been produced by Dairy UK on behalf of the Dairy Sector and is intended to assist, milk producers, processors and all other dairy manufacturing establishments to meet the legal requirements of Regulation (EC) 852/2004 on the hygiene of foodstuffs and Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin. The latter regulation has been amended by Regulations (EC) 1662/2006, (EC) 1664/2006, (EC) 2074/2005, (EC) 2076/2005 and (EC) 1020/2008 and these modifications have been taken into account in this guide.

In order to make this guide self contained it contains relevant extracts from Regulation (EC) 2073/2005 and from the Food Standards Agency general guidance on it.

## Scope

This Guide is intended to apply to Milk and Dairy Products.

#### Structure of the Guide

This guide has been structured into four different major parts

- Hazard Analysis and Critical Control Point (HACCP)
- Regulation (EC) 852/2004 on the hygiene of foodstuffs
- Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin
- Regulation (EC) 2073/2005 Microbiological Criteria for foodstuffs

This guide has been arranged in the order of each of the regulations themselves.

Each section includes reference to the regulation which is the legal requirement, followed by guidance to compliance, which is advice on how to comply, and advice on good practice which goes further than the law requires which you can follow if you wish.

Some sections applying to Regulation (EC) 853/2004 include a short introduction which may help to explain the relevance of the legal requirement.

This guidance contains a glossary giving the meaning of some of the terms used.

## LEGAL BACKGROUND

From 1 January 2006, new EU food hygiene legislation has applied throughout the UK.

The package of legislation:

- Modernises, consolidates and simplifies the previous EU food hygiene legislation
- Applies effective and proportionate controls throughout the food chain, from primary production to sale or supply to the final consumer
- Focuses controls on what is necessary for public health protection
- Clarifies that it is the primary responsibility of food business operators to produce food safely

As EU regulations, the legislation is directly applicable law. The regulations are:

- Regulation (EC) 852/2004 (as amended) on the hygiene of foodstuffs
- Regulation (EC) 853/2004 (as amended) laying down specific hygiene rules for food of animal origin
- Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

The general hygiene requirements for all food business operators are laid down in Regulation 852/2004. Regulation 853/2004 supplements Regulation 852/2004 in that it lays down specific requirements for food businesses dealing with foods of animal origin. Regulation 854/2004 relates to the organisation of official controls on products of animal origin intended for human consumption.

The legislation introduces a 'farm to fork' approach to food safety, by including primary production (that is, farmers and growers) in food hygiene legislation, for the first time in the majority of cases.

All food businesses should be registered with or approved by the relevant competent authority, normally the local authority environmental health department. The new legislation also requires food business operators (except farmers and growers) to put in place, implement and maintain a permanent procedure, or procedures, based on HACCP principles – although the legislation is structured so that it can be applied flexibly and proportionately according to the size and nature of the food business.

The Food Hygiene (England) Regulations 2006 provide for the execution and enforcement of the above European Regulations in England. Similar Regulations apply in Wales, Scotland and Northern Ireland.

# Hazard Analysis and Critical Control Points (HACCP)

HACCP is science based and systematic; it identifies specific hazards and measures for their control to ensure the safety of a process. HACCP is a tool to identify and assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system should be capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from primary production to final consumption and its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits, for example the application of HACCP can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include, where appropriate, expertise in agronomy, veterinary hygiene, production, microbiology, medicine, public health, food technology, environmental health, chemistry and engineering.

Prior to application of HACCP to any business the food business operator should have implemented the prerequisite food hygiene requirements. Prerequisite is also referred to as basic good hygiene conditions and practices. This will include procedures for cleaning and sanitation, maintenance, personal hygiene and training, pest control, plant and equipment, premises and structure, storage, distribution and transport, waste management etc. Management commitment is necessary for implementation of an effective HACCP. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The intent of HACCP is to focus control at critical control points (CCP's). HACCP should be applied to each specific operation separately. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step. It is important when applying HACCP

to be flexible where appropriate, given the context of the application and taking into account the nature and the size of the operation.

#### Legal requirements for HACCP

Article 5 of Regulation 852/2004 sets down the following requirements:

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 of Regulation 852/2004.

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.

#### **Further Guidance**

Further Guidance on HACCP can be found on the Food Standards Agency website at <u>www.food.gov.uk</u> or from the European Commission at <u>www.europa.eu</u>

#### Dairy Specific Guidance

Further guidance on the application of HACCP to dairy products has been issued (Dairy UK Guidelines for Good Hygienic Practice in the Manufacture of Dairy-Based Products May 1995) for the following products:

- Liquid Milk
- Milk Powders
- Soft Cheeses
- Hard pressed Cheese
- Cream
- Butter
- Condensed and Evaporated Milk
- Yogurts
- Desserts
- Processed Cheese

Dairy UK has also issued a Code of Practice on High Temperature Short Time (HTST) Pasteurisation. Pasteurisation is a critical control point for many dairy products. This Code of Practice contains pre-requisites for pasteurisation.

## Regulation 852/2004 The hygiene of foodstuffs

## Hazard analysis and critical control points

Legal Requirement	Guide to Compliance	Advice on Good Practice
<ol> <li>Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</li> <li>The HACCP principles referred to in paragraph 1 consist of the following:         <ul> <li>(a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;</li> <li>(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;</li> <li>(c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;</li> <li>(d) establishing and implementing effective monitoring procedures at critical control points;</li> <li>(e) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and</li> <li>(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).</li> </ul> </li> </ol>	The processes which could affect food safety must be identified within each dairy process and controlled via the HACCP process. This includes processing time and temperature for biological risk as well as package integrity for ambient products. It must also include assessment of microbiological, physical and chemical food safety hazards. This risk assessment does not include quality points and these must be dealt with as a separate study.	The European Commission has issued a guidance document (HACCP Guidance Document 16 November 2005) on the implementation of procedures based on the HACCP principles and on the facilitation of the implementation of the HACCP principles in certain food businesses. High temperature short time (HTST) pasteurisation is a critical control point for many dairy products have other specific critical control points. Dairy UK has produced a Code of Practice on HTST pasteurisation. This can be considered to contain pre- requisites for HACCP. A good documented flow chart system is needed to demonstrate the processes involved. This forms the basis for documented assessments of food safety risks.

Legal Requirement	Guide to Compliance	Advice on Good Practice
<ul> <li>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.</li> <li><b>3.</b> 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.</li> <li><b>4.</b> Food business operators shall: <ul> <li>(a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;</li> <li>(b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;</li> <li>(c) retain any other documents and records for an appropriate period.</li> </ul> </li> <li><b>5.</b> 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</li> </ul>		Records should be kept for a minimum of 1 year depending on the life of the product.
accordance with paragraph 4(c).		

## Regulation 852/2004 The hygiene of foodstuffs

### Chapter I

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

Legal Requirement	Guide to Compliance	Advice on Good Practice
1. Food premises are to be kept clean and maintained in good repair and condition.	<ul> <li>The outer fabric of the building including the roof must be structurally maintained in sound condition.</li> <li>External doors must be well fitted and proofed to prevent bird, rodent or insect entry.</li> <li>The inside of the buildings must be maintained in a high state of repair, decoration and cleanliness.</li> <li>This relates to the structure of the building and also to fixtures such as lighting and ventilation.</li> <li>A high standard of cleanliness and hygiene must be maintained throughout the premises.</li> <li>With regard to the cleaning of production equipment, refer to Chapter II, 2.</li> <li>Such features as bare blocks or brick walls will be suitable in some parts of the premises as long as being able to be maintained clean.</li> </ul>	It is important to extend good housekeeping practice to the perimeter of the site, keeping grass cut and litter cleared. Maintaining a tidy exterior will reduce the risk of rodent activity. External doors should be kept closed whenever possible, only opening them for receipt of materials or for loading out finished products. Automatic doors are available and can assist in protection. If there is frequent traffic preventing keeping the doors closed, then the opening should be protected by strip curtains or other suitable means to prevent pest entry to the premises. It is good practice to "clean as you go" but food contact surfaces should always be cleaned at a defined regular period at appropriate intervals Non food contact surfaces and those that are not subject to a significant risk of contamination e.g. high wall surfaces, extract ventilation should receive periodic cleaning. Cleanliness standards should be audited and monitored by internal supervisory/managerial staff to ensure that schedules are appropriate and effectively applied.

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Advice on Good Practice

<b>2.</b> 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;	The criterion is ability to clean. Layout and design must allow access for effective cleaning and disinfection. Alternatively equipment must be mobile to enable adequate cleaning and disinfection. The amount and type of cleaning needed will relate to the area of the premises and the use to which it is put.	The building should be able to accommodate a continuous process flow with materials receipt and storage at one end, finished goods and despatch at the other end and the processing stages in order of procedure in between. The frequency and type of cleaning for different areas will relate to their designated use.
(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;	Construction must be designed to avoid build up of condensation. Toxic materials must not be used for food contact use. See Chapter II,1(f) Design and construction, especially of high level surfaces, must avoid finishes that may lead to shedding of particles such as flaking paint, plaster or fibres. Design, construction, layout and size of the premises must be planned to avoid the build up of condensation. Special attention must be given to areas where steam and humidity are generated.	Packaging materials in particular can generate a lot of dust and care should be taken not to contaminate packing and wrapping. Areas should be defined for designated use to prevent cross contamination. It is good practice to avoid sharp corners at wall or floor junctions by coving.
(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control; and	Assess the environment where food handling takes place and provide a well controlled environment particularly where open processes are used. e.g. Allocate a particular area for the critical stage of packing and wrapping so that a controlled environment can be provided All personnel must maintain a high standard of personal hygiene. Facilities must be provided for good personal hygiene. The fabric of the building must be designed to minimise the ingress of pests ( See Chapter IX, 4)	This may simply entail providing physical barriers around this area but may involve air filtration. Covering of conveyors from bottle supply to after capping is recommended for open wrapping. It is advisable for both materials and finished goods storage areas to have a designated section and identification system for any quarantined goods. Prevent potential incoming sources of contamination from footwear e.g. by using entry mats. Appropriate supervision/ instruction and training as outlined in Chapter XII. A suitable pest control service should

Legal Requirement	Guide to Compliance	Advice on Good Practice
<ul> <li>(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.</li> <li>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.</li> </ul>	Heat treatment of liquid milk requires specific time temperature combinations to be maintained and demonstrated. Design and construction of process plants must prevent under temperature milk being processed and packed. Handling systems for milk and product derivatives must be capable of providing a suitable temperature to prevent unwanted bacterial and mould growth within the products durability life. Workplace (Health, Safety & Welfare) Regulations 1992 and British Standards BS 6465 make provision for lavatories requirements according to number of employees. Also there must be no direct access to lavatories from processing areas and food storage areas. Lavatories must be well separated from production areas and other food handling areas by a suitable intervening space such as corridors or lobbies.	be used. (See Chapter IX, 4). A suitable pest control service will advise on proofing requirements as well as the means of control. Secondary defences against pests may include pest baits and electronic fly killers. It is recommended, and essential with some customers, that maintenance storage, workshops and laboratories are required to provide engineering and technical services. These should be well separated from production areas. Good chiller maintenance procedures are recommended. Maintenance procedures should be in place for all critical temperature and pressure monitoring equipment. Automated continuous recording systems are the preferred choice. Lavatories should be in a suitable hygienic condition and kept clean. They should be connected to a drainage system through traps. Provision should be made to hang protective clothing.
<b>4.</b> 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.	Washbasins must be located i) within toilet facilities; & ii) at strategic places within premises. Washbasins designated for hand washing should be used for that purpose only. Mixer taps are acceptable.	Non-hand operable taps should be used in food production areas, the operation mechanism can be floor, knee or elbow. Hand operable taps can be used in toilets and non-food production areas. The number of washbasins required will depend on both the number of staff and the nature of work being carried out. It is recommended to site wash hand basins also at entry points to food handling areas

Legal Requirement	Guide to Compliance	Advice on Good Practice
Where necessary, the facilities for washing food are to be separate from the hand-washing facility.	Soap must be provided. Drying facilities may include: • Single use hand towels • Washable fabric roller towels • Roller paper cabinet towels • Warm air hand dryers • Ultra violet or similar technology	Mixed water at a temperature of 50°C is recommended. It is good practice to have signs which identify designated HAND WASH ONLY basins. Wash Hands Now notices should be located in toilet areas. Unperfumed, bactericidal soap/detergent should be provided by dispensers. Antiseptic rubs (applied to clean hands) can provide a supplement to bactericidal soap. If warm air hand dryers are elected it is important that they are effective and efficient. The most important features of a hand dryer are Motor Speed ;( revs per minute (rpm)) and Volume of Air; (cubic feet of air per minute (cf/m)). It is these two features which dictate how quickly hands can be dried.
<b>5.</b> 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.	Natural or mechanical ventilation must be provided to ensure that heat and or humidity do not build up to levels that could compromise the safety of food. Where external windows are used for ventilation they must be fitted with cleanable fly screens. Ventilation systems must be suitably screened to prevent rodent and insect access. Mechanical ventilation, other than filtered positive pressure systems, should be designed to extract air away from process and filling plant	It is recommended external windows should not open into production/processing areas. Schedules for regular maintenance of filtration systems should be made which incorporate requirements for changing of cartridges/filter medium at appropriate frequencies to ensure effective control.
<b>6.</b> Sanitary conveniences are to have adequate natural or mechanical ventilation.	Mechanical systems must be designed to discharge away from production areas and must be separate from any ventilation systems within the factory.	Schedules for regular maintenance of filtration systems should be made which incorporate requirements for changing of cartridges/filter medium at appropriate frequencies to ensure effective control. Natural ventilation can be via air bricks, open windows and louvers.

Legal Requirement	Guide to Compliance	Advice on Good Practice
7. Food premises are to have adequate natural and/or artificial lighting.	Lighting may be natural or artificial but must be good enough to allow safe food handling, effective cleaning, the monitoring of cleaning standards and inspection.	Light fittings should all have unbreakable diffusers or covers (not glass), and where fluorescent tubes are fitted the diffusers should have covered ends. Where possible, light fittings should be flush with the ceilings.
		Individual companies should assess whether their particular plant may require "waterproof" fittings to IP65 standard or "splashproof" fittings, IP54 standard. See the link below on IP Codes. <u>http://www.beamainstallation.org.uk/</u> <u>assets/pdfs/IPCodes.pdf</u> Lighting should be adequate for safe work. Recommended illumination levels range from 150 lux in store rooms to 500 lux in production inspection areas.
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.	Floors must be constructed so that any liquid spillages flow to a drain to prevent pooling of water. Any floor gullies or equipment connected to the drainage system must be provided with an effective trap Any external drain outlets must be covered to minimise ingress of rodents or other pests.	Drains should have a greater capacity than processing requirements and be fitted with perforated traps of easily cleanable material to retain extraneous matter, e.g. caps. Recommended fall 1 in 100. The cleaning and disinfection of drains on a routine basis should be provided for in the cleaning schedules. If open floor drains are provided, corrosion resistant grids should be provided and be easy to clean. Depending on the size of operation consideration should be given to environmental cleaning. Inspection chambers inside the premises should have secure sealed airtight double cover which is accessible.
<b>9.</b> Where necessary, adequate changing facilities for personnel are to be provided.	Provision must be made to allow food handlers to change and to store their street clothes and personal effects away from the production area.	There should be no direct access to locker rooms from processing areas. Intervening space such as corridors or wash stations should provide access.

Legal Requirement	Guide to Compliance	Advice on Good Practice
		Locker areas need to be inspected for cleanliness. Lockers should be made available to each employee and be of such a design to prevent accumulation of debris inside and out e.g. if lockers are free standing they should have sloping tops. Areas provided for changing should not be used for consuming food. Consideration should be given to separate collection sources for dirty and clean laundry. A receptacle for dirty work wear should be provided.
<b>10.</b> Cleaning agents and disinfectants are not to be stored in areas where food is exposed.	Use of approved disinfectants to prevent food contamination at workstations is permissible providing such agents are held in a leak proof container and cannot contaminate the food in any way. <u>http://www.coshh-</u> <u>essentials.org.uk/assets/live/indg136.pdf</u>	Generally disinfectants and cleaning agents should be kept away from food handling areas but there are some processes where aseptic conditions need to be met and the controlled use of non toxic disinfectants is permissible in these circumstances. Consideration to be given to automatic dosage but sufficient maintenance is required to ensure contamination is prevented.

#### Chapter II

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

Legal Requirement	Guide to Compliance	Advice on Good Practice
<b>1.</b> 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;	The flooring material must be suitably durable to remain intact and easy to clean. Suitable materials include:- • ceramic tiles • terrazzo tiles • concrete suitably sealed or treated with a waterproof epoxy resin based floor paint • epoxy resins • metal plate • natural minerals (slate, marble) Not so hard wearing but suitable for some purposes are:- • vinyl tiles • vinyl sheet Floor surfaces must be maintained in good condition, any necessary repairs being carried out promptly.	All floors should be sealed and easily cleanable. In product areas coving with walls is recommended to prevent debris harbourage in corners. For safety reasons floors should have a non-slip finish. Floors should be such that they can withstand the use they are put to, including fork lift truck traffic where used.
	Floors must be designed to provide surface flow to drainage, and drains must be of suitably large enough capacity to prevent floor flooding during high volume discharge from plant or equipment. Frequent disinfection of floors is not essential but a high standard of cleanliness must be maintained particularly for gullies or drains.	Recommended fall of 1 in 100 for floor surfaces. Where drainage is not of a type to allow free flow of liquids to drain, mechanical means of removing waste water/ liquid should be provided e.g. squeegees, wet vacuum cleaners or scrubber driers.

Legal Requirement	Guide to Compliance	Advice on Good Practice
(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;	Walls must be of a smooth impervious nature and easily cleanable. They must be kept in a good state of repair. Wall surfaces do not have to be of one material or type but all joints must be waterproof and impervious. Surfaces that comply with this requirement include: • ceramic tiles • washable painted smooth brick, plaster or rendering • epoxy resin or similar coatings • smooth fibre glass • plastic cladding • plastic coated fibreboard or chipboard • refrigeration panelling • metal sheeting Frequent disinfection of walls is not essential in low risk areas but must be periodically carried out in high risk areas. A high standard of cleanliness must be maintained.	In processing areas, walls should be light in colour to reflect as much light as possible and so that any soiling is easily visible for cleaning. Walls should be coved to junctions with ceilings and floors. Ledges, ridges and recesses should be avoided where possible to prevent dirt accumulation and convenient dumping ground for odds and ends. It is recommended to protect wall corners or areas behind moveable equipment to prevent damage. This can be in the form of metal protective sheeting or barrier rails.
(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;	Ceiling and overhead fixtures in production areas must be of a smooth and impervious nature and easily cleanable Surfaces that comply with this requirement include: • Smooth washable painted plaster • Direct fixed ceiling systems • Suspended ceilings • Non porous sheet material. They must be properly maintained They must not allow the growth of mould, accumulation of dust or condensation or shedding of particles.	Ceilings should be light in colour to reflect as much light as possible and so that any soiling is easily visible for cleaning. Polystyrene or fibre tiles would not be suitable in high humidity locations and these are not suitable finishes where open food is handled. The choice and design of ceiling may be important in reducing condensation. If false or lowered ceilings are fitted, access to the space above should be available to facilitate servicing and maintenance. Consideration should be given to pest controls. Any roof windows, if fitted should be shatterproof.

Legal Requirement	Guide to Compliance	Advice on Good Practice
(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;	<ul> <li>Windows must be close-fitting and allow for effective cleaning.</li> <li>All openable external windows where food is handled must be fitted with insect-proof screens to prevent ingress of insects and pests.</li> <li>The design of screens must enable easy cleaning.</li> <li>Screens must also be considered essential for openings for ventilation systems to prevent the ingress of birds, insects or rodents. Air bricks if fitted must be checked to ensure they open to an internal cavity wall and not directly into production areas. These need not be screened unless they open to production areas.</li> </ul>	<ul> <li>Windows in processing areas should be constructed of clear, shatterproof material or protected so as to prevent the risk of glass or hard plastic fragments entering foodstuffs.</li> <li>Window surrounds should be impervious and easily cleaned.</li> <li>Where possible in production areas, sills should be sloped to discourage their use as shelves.</li> <li>Screened external windows should open to the outside if they can be opened.</li> <li>It is good practice in new food production buildings to either have sealed non opening windows or no windows.</li> </ul>
(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	Doors should be close fitting and self- closing where possible. If wooden doors are used, these must have a well-maintained painted or sealed finish so that they are impervious and easily cleaned. Unsealed wood does not comply. Disinfection of doors is not essential but a high standard of cleanliness must be maintained.	Where windows or viewing safety panels are fitted to doors, these should be of clear shatterproof material. Swing doors with kick plates or push plates are preferable to doors with handles. Protective kick plates should also be fitted to the base of the doors where there is risk of damage. Where fitted, door furniture should be easy to clean and resistant to chemical damage.

Legal Requirement	Guide to Compliance	Advice on Good Practice
(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 nontoxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.	Equipment must be carefully selected, of good design with accessibility for cleaning. The material and equipment used must be capable of being suitably sanitised. All support surfaces are recommended be enclosed or easily cleaned to prevent dust build up. Care must be taken that there are no deadlegs in the pipework or equipment where product or sanitiser can remain and thus be the cause of undetected contamination at a later stage.	Good quality stainless steel should be used for all process pipework, tanks and filling equipment. Stainless steel fittings should be used on stainless steel pipework which is designed for use with CIP systems. Any welding should be specified as tungsten inert gas (TIG). Welds should be smooth finish both inside and outside. Other fittings and valves should be of a hygienic design.
	Food contact surfaces must be maintained in good condition so that they are easily cleaned. All surfaces that come into contact with foods must be able to be disinfected regularly. Surfaces which would comply with this requirement(assuming that they are properly fixed, applied or installed and maintained) include: • Stainless steel • Ceramics • Food grade plastics	Compliance with the European Hygienic Design Equipment Group recommendations can be used to demonstrate that machinery hygiene has been considered during the design stage.
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.	All tools and utensils must be of sanitary design Cleaning must be carried out, as appropriate to the type of product manufactured and to the risks identified in the equipment used. The chemicals must penetrate all areas of product flow. Traces of chemical must be removed prior to the line returning to production. Care must be taken to ensure that the rinsing water is of a suitable hygienic potable standard. Safe use of all chemicals must be assessed to comply with the Control of Substances Hazardous to Health	Hygienic storage of all utensils and tools used for food duties should be provided and a colour coded system to segregate the specific use of these instruments is recommended. There should be measures in place to avoid the risk of cross contamination of clean and dirty utensils. The frequency and method with which the filling line, tanks and any other equipment is sanitised should be set to ensure microbiological loading does not reach unacceptable levels, as well as preventing physical contamination. Due regard for any environmental impact of cleaning duties should be

Legal Requirement	Guide to Compliance	Advice on Good Practice
	Regulations 1999 SI 1999/437. Where small parts are sanitised separately from CIP, designated sinks or other equipment should be used which are not shared with tasks such as cleaning of labelling parts for the removal of glue.	considered. Any new plant and equipment should receive a thorough cleaning prior to use to remove residual grease, lubricant or solvent used in its manufacture. The use of any cleaning chemicals should be carefully logged. It is important to have a procedure to ensure the absence of cleaning chemicals such as sodium hydroxide, peracetic acid in the product. Non-shedding, non wood tools should be used and replaced on an appropriate frequency.
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.	Separate facilities to be provided for hot and cold potable water. Construction to be suitable to allow cleaning and disinfection to be carried out. Good hygienic practice must be observed as for primary food production.	A HACCP risk assessment should be carried out to ensure facilities and personnel do not create additional risk in the washing of food. Good hygienic practice is essential, i.e. washing of hands and equipment prior to handling food for washing.

#### 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

Mobile retail premises include market stalls, farmers markets and vehicles built as, or converted for use as shops. Temporary stands include marquees at trade shows

Legal Requirement	Guide to Compliance	Advice on Good Practice
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.	The basic requirement is qualified here by the phrase "so far as is reasonably practicable". This will depend on the nature of the premises and the type of dairy foods sold. Any premises and vending equipment must not be located in any area where the environment would offer any risk of contamination of the food. The design, materials and construction must be in compliance with the relevant standards as amended from time to time.	The distributor should provide each new customer with advice, explaining care and hygiene requirements of the vending unit and as to a suitable location.
<ul> <li>2. In particular, where necessary:</li> <li>(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);</li> </ul>	Where open food is handled a washbasin or bowls specifically for handwashing must be provided with a means of cleaning, washing and drying hands.	<ul> <li>Drying facilities may include: <ul> <li>Single use hand towels</li> <li>Washable fabric roller towels</li> </ul> </li> <li>If only pre-packed food is being sold, it is not necessary to provide handwashing or sanitary facilities at the premises.</li> <li>Unperfumed, bactericidal soap/detergent should be provided by dispensers. Antiseptic rubs (applied to clean hands) can provide a supplement to bactericidal soap.</li> </ul>
(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;	For temporary premises and stalls it is acceptable to use plastic sheets or impervious cloths. They must be clean and in good condition. If utensils are provided these must meet the requirements of relevant legislation e.g. Materials and Articles in Contact with Food Regulations.	Disposable equipment, utensils and drinking cups should be wrapped to protect them from risk of contamination and should be stored in a clean dry place until required.

Legal Requirement	Guide to Compliance	Advice on Good Practice
(c) adequate provision is to be made for the cleaning and, where necessary, disinfecting of working utensils and equipment;	The use of suitable bowls instead of fixed facilities is sufficient. As an alternative to providing cleaning facilities, an adequate supply of clean utensils can be provided, soiled utensils being regularly replaced.	Stainless steel basins are recommended due to ease of cleaning
	Vending machines must be designed in such as a way to allow access for cleaning and sanitizing as required	Due to the variation in available systems the distributor should supply detailed instructions as to what cleaning requirement is needed and how this undertaken.
(d) where foodstuffs are cleaned as part of the food business' operations, adequate provision is to be made for this to be undertaken hygienically;	This section is considered not applicable.	
(e) an adequate supply of hot and/or cold potable water is to be available;	Where a piped supply is unavailable, suitable containers filled with potable water will suffice. If it is necessary to wash utensils or equipment, or hands hot water must be available.	These containers should be kept clean and sanitized as appropriate
(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;	Many temporary premises will be connected to mains drainage. Where this is not provided liquid waste must be fed to suitable containers for later disposal. Other waste must be placed in covered or enclosed bags or containers. For stalls etc it is unacceptable to allow waste to flow or fall onto the ground. Special provisions maybe made in fixed markets.	
(g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions are to be available;	Where foods are required to be kept below a particular temperature, insulated containers or ice packs can be used but in warmer weather proper refrigeration equipment will probably be needed. A means of monitoring temperatures must be provided and documenting and keeping of records is essential.	It is good practice not to have on display more chilled foods than is strictly necessary. Vending equipment should be sited out of direct sunlight in an area away from other direct sources of heat. It is recommended that chilled products be kept at a maximum of 8°C and frozen products below minus 15°C.

Legal Requirement	Guide to Compliance	Advice on Good Practice
(h) foodstuffs are to be so placed as to avoid the risk of contamination so far as is reasonably practicable.	In temporary premises foods may be exposed to a greater degree than in a conventional outlet. This is acceptable provided it does not pose a risk to consumers. Care must be taken to place open food so that it will be protected from contamination.	It is advised that preparation of foods be minimized in mobile or temporary premises. The use of barriers or screens to protect exposed foods from contact or contamination by customers is recommended

## Chapter IV

### Transport

Legal Requirement	Guide to Compliance	Advice on Good Practice
1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.	Vehicles and containers must be in good repair and condition. Must be clean and free from odorous substances. Bulk liquid transport vehicles and containers must have no excessive residual wash water present in the container. Bulk powder and dry goods vehicles and containers must be dry. Bulk liquid vessels must be subject to at least one CIP during the working day. It is recommended that CIP is documented.	All vehicles and containers destined to carry foodstuffs should be inspected on a regular basis to ensure they are fit for purpose. A system of hygiene monitoring should be used for all containers used for direct product contact. An ideal method of monitoring is by the use of swabbing the food contact surfaces prior to loading to check for cleanliness. This may be done weekly as a routine screening for trending or on an individual container/tanker basis dependant on risk identified in HACCP. Also a visual inspection should be carried out if possible. CIP systems used for liquid milk vessels should be designed and managed to ensure a milk stone removing reagent is used on a regular basis. Containers and vessels should receive a maintenance check to a schedule appropriate for their use. Records of these checks should be kept. CIP units should be designed with the appropriate specifications to provide the right temperature, chemical strength, flow rate and wash programme to give effective cleaning. Additional measures such as a disinfection cycle may be required when the vessels are used for transporting finished processed products. Consideration should be given to tanker design to ensure pipework and spray ball/spinner configurations are suitable for the task e.g. cleaning liquid must be spread onto all inside vessel surfaces.

Legal Requirement	Guide to Compliance	Advice on Good Practice
2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination.	Bulk liquid vessels and containers must be designated for food use only and marked accordingly to confirm to the appropriate legislation. Cleaning materials may be carried on the vehicle provided precautions are taken to avoid the possibility of any contamination of food. Consideration must be given to any potential allergen cross contamination.	The receptacles and or containers should only be used for transporting foodstuffs. There should be separate designated receptacles and or containers for other items. The history of previous use should be known and cleaning records should be available if appropriate. If the history of previous use is unknown then cleaning records, if appropriate, should be inspected to ascertain suitability for use of vehicle or container as a foodstuff. This is especially important for tankers and liquid containers but a detailed visual inspection of a dry goods flatbed vehicle or container to check that it is clean should be sufficient if transporting wrapped or sealed products.
3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.	Where transport of other goods in addition to foodstuffs is unavoidable the other goods must be of an inert non contaminating nature. If bulk tankers are used which have separate compartments for transporting different grades of milk or dairy products then each compartment must be securely separated. Some vehicles with both ambient and chilled compartments must have each type securely separate from the other to avoid loss of temperature control.	Transporting other goods in addition to foodstuffs in the same vehicle or container is not encouraged. Transport of non food chemicals and foodstuffs would not be allowed, but transport of packaging to be used for foodstuffs and foodstuffs would be allowed if there was no risk of either contaminating the other. Transport of different types of food stuffs is perfectly acceptable as long as there is no risk of cross contamination or allergen transfer. Traceability should be maintained for all product type and cleaning records.
<b>4.</b> Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs.	Milk collection tankers must be for food use only and identified as such. Such marking must conform to relevant transport legislation.	

Legal Requirement	Guide to Compliance	Advice on Good Practice
Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked 'for foodstuffs only'.	Where a container or vessel carrying milk has changed status to an animal by-product, this must be indicated on documentation.	
5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.	Records of all cleans must be made and be available with the vehicle or container. All such cleans must be validated for effectiveness. Cleaning of lorries or dry goods containers must be effective in removing any traces of previous goods.	If the "different" foodstuff, to be carried in a tanker, is from the same generic type, e.g. milk and cream, then a common CIP facility with re- use of chemicals may be used. Where foodstuffs are contained in boxes or containers and protected from external environments then a thorough inspection of the transport vehicle for lack of debris will suffice. It is recommended that bulk liquid vessels be cleaned between milk types (e.g. Standard milk, Channel Island milk, Organic milk, Kosher milk) and following carriage of loads declared as animal by-products or where bio-security between loads is at risk.
<b>6.</b> Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination.	Bulk liquid tanker manways must be kept closed except to allow for cleaning, filling and sampling. If the vehicle or container contains foodstuffs, and is left unattended, all access points must be sealed with tamperproof tags or other suitable method with records kept and traceable.	Consideration should be given to the parking and storage of transport vehicles and containers to minimise any security or tampering risks. Random security checks and simulated breaches are recommended in order to ensure that requirements under the terms of the relevant legislation are being complied with.
7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored.	Bulk liquid tankers / containers must be insulated to a suitable standard to minimise temperature variation in the transported product.	Bulk liquid tanker insulation should be sufficient so as to not permit a rise in temperature of the product of more than 1℃ within a 24 hour period.

Legal Requirement	Guide to Compliance	Advice on Good Practice
	Temperature monitoring must be carried out by recording devices fitted to the vehicle / container, or must be monitored by a hand held instrument at point of dispatch and delivery. Vehicles used for transporting packaged chilled dairy products must be insulated, refrigerated and fitted with a temperature recording device. Milk floats are exempted from temperature control except for the special refrigeration boxes where fitted. Insulated boxes used for transportation of chilled products must have suitable insulation and refrigeration packs relevant to length of journey, volume of product carried and conditions expected during transportation (e.g. thicker insulation would be required for transporting in hot environments.) Ambient dairy products are exempted from the requirements of temperature control.	Bulk liquid vessels and containers will ideally have a means of recording temperature during loading, transit and delivery. Where not available the use of hand held thermometers is recommended. Use of consignment notes can also be used to track temperature from loading to delivery. Lorries or containers used for transporting packaged chilled dairy products should be fitted with a refrigeration unit which can maintain the required temperature of the product during transport. Ambient products can be distributed on normal taut liner trailers or unrefrigerated containers. Ideally refrigerated vehicles or containers should be fitted with a refrigeration device which can reduce product temperature to allow for potential temperature rises during loading and unloading activities.

### Equipment requirements

Legal Requirement	Guide to Compliance	Advice on Good Practice
<b>1.</b> All articles, fittings and equipment with which food comes into contact are to:		
(a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;	All food processing, filling and packaging equipment product surfaces must be capable of being suitably cleaned and disinfected, if necessary. This includes any fitments and fittings which are likely to come into contact with the food product e.g. agitators, bowl choppers, and temporary utensils. Cleaning frequency must be determined by doing a HACCP risk assessment. Non food contact surfaces outside or inside complex plant or fillers will require periodic cleaning to prevent any food safety risk, depending on the rate and severity of soiling.	Cleaning can be either by Cleaning in Place (CIP) where equipment design allows for adequate cleaning by this method, e.g. pasteurisers, pipework etc or by thorough effective manual cleaning to ensure no product residues remain in or on the equipment after cleaning. Only appropriate disinfectants should be used following manufactures guidance. The frequency of cleaning is determined by risk dependant on the particular product type and equipment type, and frequency will be guided by microbiological, physical, and environmental monitoring e.g. it is recommended a raw milk silo should be cleaned after use and before use on a daily basis but a sterile process plant may run much longer before cleaning is required. All cleaning equipment should have planned maintenance procedures which are well documented and carried out regularly enough to prevent risk of food contamination. Equipment should be monitored and inspected at regular intervals and cleaning routines established and validated for efficiency by means of chemical concentration checks, swabbing or other inspection means. All such checks should be recorded.
(b) Be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;	If a material used has a high risk of causing a food contamination issue it must not be used. The use of HACCP to identify risks must be used.	The use of stainless steel or food contact plastic materials should be used in all food handling equipment. Surfaces should be kept clean and smooth.

Legal Requirement	Guide to Compliance	Advice on Good Practice
	All materials must be non toxic and not capable of transferring odour or taste to the product, this is especially important with cream based products. Any damaged areas must be repaired before next production. If it is not possible to maintain surfaces in a clean condition they should be replaced or treated. Construction materials must be inert non corrosive in nature. Product must not come into contact with motors, drive mechanisms which must be encased or placed in such positions that they cannot cause food contamination from lubricant drips etc. All nuts, bolts, fasteners etc must be kept secure. All cleaning equipment must be effectively maintained and cleaning cycles monitored and verified.	Stainless steel is highly desirable and recommended. If coated materials are used, the coating should be non toxic and resistant to abrasion. If plastic materials are used it is preferable to use a break resistant grade and a HACCP should be carried out detailing an adequate monitoring frequency to ensure food safety.
(c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected; and	The design of the equipment must be so as to prevent any accumulation of debris which could give rise to food contamination. There must be no cracks or crevices and surfaces must not be unduly scratched. Damaged equipment must as soon as possible be repaired or discarded, or assessed to ensure there is no food safety risk to products in or around the damaged item.	All new equipment should be designed, and the installation supervised, by persons or companies having a good regard and understanding of hygiene and food handling requirements. Such design should facilitate easy effective cleaning on a regular basis and should also consider sealing to prevent contamination ingress.
(d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.	There must be adequate design features to allow disassembly to carry out regular deep cleaning procedures and maintenance.	Filler and conveyor covers should be demountable to allow access to the underside and insides of machinery for cleaning purposes. However, such guards must also be maintained to provide equipment safety when in use, e.g. guards secured to prevent inadvertent and unauthorized removal. Good access should be provided around and under equipment to facilitate effective cleaning.
Legal Requirement	Guide to Compliance	Advice on Good Practice
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2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives.	As identified by HACCP study, equipment must be fitted with suitable control devices which may include temperature control probes, thermographs, pressure devices, conductivity probes and automatic divert control systems. These devices will be used to control both production processes and CIP controls where fitted.	Divert systems should be regularly maintained and calibrated, and checked daily for correct operation. All liquid dairy processing plant should have automatic divert control systems in place to prevent incorrectly processed product reaching the filling and packing equipment. Further advice is given in the Dairy UK HTST pasteurisation guide.
3. Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice.	All such chemicals must be appropriate for use in food handling equipment and areas, and if traces may be left on product contact surfaces of equipment then such chemicals must be suitable for food use. Consideration must be given to making sure the use of such chemicals is effective and this will include strength, flow rate, contact time and temperature.	Where possible additives should not be used but where unavoidable then data should be obtained from the manufacturer as to the suitability for intended purpose, including any risk to product type and allergen content, e.g. Disinfectant sanitisers should be used to manufacturers recommended levels to ensure effective disinfection but not to exceed safe dosage levels. In this situation careful regard to the Maximum Residue Levels must be taken into consideration. It is essential to be satisfied that any lubricants used are suitable for food use.

## Food waste

Legal Requirement	Guide to Compliance	Advice on Good Practice	
<b>1.</b> Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.	Food handling will generate material which may either be used as rework or waste. If a product is designated as waste it must be controlled as such and stored in appropriately identified vessels or containers and must not remain in the production environment for longer than is necessary.	There should be segregated waste systems, colour coded where possible, and defined written procedures on how to deal with the waste. Procedures should include emptying of containers when full and removal from food handling areas.	
	The use of food waste containers or transport system is required so as to remove such waste in a hygienic manner to prevent contamination of	All waste should be removed from production areas at the end of each working day.	
	other food being handled or prepared. The nature of the processes will generate some debris during the working day, but this must not be allowed to build up to unacceptable levels.	Production records should be kept to be able to clearly identify food waste from good quality material. These records should be auditable.	
2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.	Bins and other waste containers must be constructed of material which permits them to be easily cleaned and disinfected and fitted with lids. If after use over a period of time they become corroded and present a food safety risk in the environment they are being used, they must be replaced.	Waste of a potentially contaminating nature should be placed in covered bins and/or removed immediately from sensitive areas. As a principle, non-hand operable waste bin lids are good practice. Skips should be of the enclosed type, excluding the access of pests. Disposable plastic bags are acceptable and should be removed	
		daily.	
<b>3.</b> Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.	A designated waste collection area must provide well managed storage which will not have a detrimental effect in any way on product integrity. The requirements for the 'Duty of Care' must also be taken into account for the storage of waste. Storage of waste must not be an attraction to or be accessible to pests, and must be away from doors or openable windows or separate from the building. Food waste must be labelled as per the animal by products Regulations.	Bins and other waste containers should be emptied at least daily and cleaned on a daily basis. Skips should be emptied or replaced regularly, probably on a minimum of a weekly basis. Waste segregated and stored for recycling should be kept to a minimum and should be well secured. Any bulk liquid waste should be kept in isolated storage containers, or silos, and clearly labelled as such. A good pest control contract should be maintained to ensure roving pests are not attracted to waste handling areas.	

Legal Requirement	Guide to Compliance	Advice on Good Practice
4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.	All such waste handling activity must conform to Environment Agency regulations. All dairy waste is encompassed by the Animal By-Products Regulations 2005 as amended and must be clearly categorized and controlled according to these regulations. See internet link to ABP milk guidance on the Defra website at: www.defra.gov.uk/foodfarm/byproducts/ documents/milk.pdf Waste manufactured milk or milk products can either be disposed of through a well controlled effluent system or transported for disposal through competent contractors having the necessary "Waste Carriers" and Waste Handlers" licences according to EU legislation.	Tankers of milk, if rejected by a dairy establishment, are not automatically deemed as waste until a decision is made as to the disposal route and they reach the final destination. Products no longer intended for human consumption should be disposed of by reference to the "Animal By Products Regulations" It is the responsibility of the waste producing site to ensure their chosen contractors have the correct licences.

# Water supply

Legal Requirement	Guide to Compliance	Advice on Good Practice
<b>1. (a)</b> There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;	To meet this requirement water must be to a potable standard to be used for: <ul> <li>cleaning of equipment;</li> <li>hand washing</li> <li>a food ingredient</li> <li>packaging contact</li> </ul> <li>However in some circumstances Article 5 will mean a higher standard must be applied.</li>	Water should be routinely sampled and tested to ensure it is of suitable quality and meets the water regulations as laid down.
(b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When such water is used, adequate facilities are to be available for its supply.	Water Supplied to premises in which food is produced must be wholesome as defined by Chapter III of The Water Supply (Water Quality) Regulation 2000. It is not envisaged that this will be applicable to dairy products but if there are any applications then the water must be of potable quality.	
2. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non- potable water is not to connect with, or allow reflux into, potable water systems.	Where water supply is not potable quality it must be clearly marked e.g. hoses intended for use in the event of fire must be clearly marked for fire fighting and must not be used for general cleaning purposes. There should be clear segregation of any waters used for potable and non potable purposes. If water supplies of both types are available in any production areas they must be clearly identified by marking the pipes and containers accordingly.	It is recommended to use potable water for all water supplies. For microbiological reasons water from non potable sources e.g. fire hoses, should not be used for washing down equipment.
<b>3.</b> Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.	Validation and verification of suitability of water for specific uses such as processing or as an ingredient must be carried out by testing. All test results must be recorded and kept in an auditable form.	It is good practice to re-use final rinse water from CIP systems as the initial rinse in the next clean.

Legal Requirement	Guide to Compliance	Advice on Good Practice
<b>4.</b> Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.	It is not envisaged that this will be applicable to dairy products but if there are any applications then the water must be of potable quality.	
5. Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.		<ul> <li>The following substances may be present in water used for direct application of steam, as follows:</li> <li>(a) any such compound necessary to make it wholesome;</li> <li>(b) any of the following boiler feed water treatment compounds:— Potassium alginate, Sodium alginate Potassium carbonate, Sodium carbonate, Sodium hydroxide, Sodium dihydrogen orthophosphate, diSodium hydrogen orthophosphate, triSodium orthophosphate, Sodium oplyphosphates, tetraSodium diphosphate, Sodium sulphate, Magnesium sulphate Neutral or alkaline sodium sulphite, Unmodified starch, Sodium aluminate Polyoxyethylene glycol (minimum molecular weight 1000).</li> </ul>
<b>6.</b> Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.	Cooling water used for in-container sterilised milk must be monitored. Such water supply is to be tested at suitable intervals to ensure it is suitable for use as potable quality.	

# Chapter VIII

# Personal hygiene

Legal Requirement	Guide to Compliance	Advice on Good Practice
1. Every person working in a food- handling area is to maintain a high degree of personal clean liness and is to wear suitable, clean and, where necessary, protective clothing.	All personnel must maintain a high standard of personal hygiene. Hands must be kept clean. Hands must be washed after use of toilet facilities, after eating, smoking and whenever entering open production areas. No jewellery or false nails should be worn that may present a risk to contamination A plentiful supply of clean protective clothing must be provided and worn within production areas. There must be no eating, drinking or smoking in production areas and while handling food. A similar policy must be applied to visitors to food production sites and these requirements must be communicated to them before entering any food production or preparation areas.	<ul> <li>Personal Hygiene</li> <li>Provide clear and simple instructions to all staff on personal hygiene (in various languages if necessary) before they start to handle food.</li> <li>Fingernails should be kept clean and short. No nail varnish should be worn.</li> <li>Long hair should be neatly contained with no grips outside the hair covering. If working in a production area it is a requirement to cover hair and beards with a net or snood.</li> <li>Invasive use of perfume or aftershave should not be permitted.</li> <li>Personal items</li> <li>No jewellery should be worn with the exception of plain wedding rings and sleeper earrings.</li> <li>Equally it is not permissible to wear wrist watches or cufflinks in production areas. If other jewellery is worn for medical or religious purposes then a HACCP should be carried out to ensure there is no risk of food contamination from the person working in a particular area.</li> <li>Protective clothing</li> <li>Protective clothing should be restricted for use on site only. It is recommended that clothing should have no external pockets; however where necessary pockets should be restricted to below the waist and should only accommodate items required for work.</li> <li>Contract cleaning of protective clothing should be discouraged from home laundering of these garments.</li> <li>In addition to protective clothing and</li> </ul>

hats, gloves and masks provided use in open bottle areas may furth assist in maintaining integrity of th product.	for her he
Gloves will only assist in protectin product if they are frequently repla as needed and clean.	ig aced
A canteen or rest room should be provided for any meal breaks.	
Smoking materials and foods sho not be taken into production areas	uld s

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#### **Guide to Compliance**

#### Advice on Good Practice

2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.

Any sickness or injury must be reported to supervisory staff and noted where they know or suspect they are suffering or a carrier of a disease likely to be transmitted through food or are suffering from infected wound, sores, diarrhoea or stomach upset / vomiting. Cover all wounds likely to cause risk of contamination of foods (on hands or other parts of the body) with waterproof dressing

Management are legally responsible to ensure protection of the food from risks through listed medical conditions. This may include exclusion of the member of staff, visitor or contactor from the premises whilst the condition lasts, or exclusion from working in certain areas.

See also guidance in "Food Handlers Fitness to Work" documents prepared by The Department of Health, see Bibliography. The food business operator should, on appointment of any employees, instruct the employee that if they are suffering from any of the ailments that they are to notify their manager or supervisor. It is also good practice to give this instruction in writing.

Employees should also inform Manager / supervisor at the start of their shift

Sores, cuts or grazes should be covered with a conspicuously coloured waterproof dressing

It is good practice for the manager to consult EHO or medical practitioner on advice on exclusion.

A medical questionnaire could be used on appointment and return to work from illness.

Sores, cuts or grazes should be covered with a conspicuously coloured waterproof dressing.

Any dressings should be accounted for at the end of each shift and replaced with a new one before each shift, and as required.

This should include visitors and contractors.

# Provisions applicable to foodstuffs

Legal Requirement	Guide to Compliance	Advice on Good Practice
1. A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.	Routine checks must be made periodically on deliveries of food. These checks must show that the product conforms to the agreed specification. Different foods will need to be checked more frequently depending on the degree of risk identified from HACCP principles. Critical steps and controls will be identified by the systems described in the chapter on HACCP. The consignment or a representative sample must be examined to ensure that it is fit for the purpose intended. Checks will determine the general condition and may include more specific checks such as date marks or temperature. Unfit items or 'use by' expired product must not be accepted. It must be immediately returned on the delivery vehicle or set aside and clearly marked for later disposal.	For chilled or frozen items, checks should be made that the item is delivered at the correct temperature and all food meets the requirements of the product specification. Consideration should be given to the anticipated shelf life of the food. Establishments should be aware of any heat treatment requirements on raw milk due to the high risk of pathogenic contamination, e.g. listeria.
2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.	The stores must be appropriate to the type of product or material. Ambient stores must be clean and dry, free from pest infestation. Chilled stores must be run at suitable temperatures to comply with temperature control guidelines. Note that regulations relate to the temperature of the food, not the air temperature of the storage equipment	A system of monitoring to check operating temperatures should be in place, if applicable. Note that regulations relate to the temperature of the food, not the air temperature of the storage equipment. Appropriate stock segregation and stock rotation should be demonstrated.
<b>3.</b> At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.	<ul> <li>A HACCP study must be carried out on all stages of production, processing, storage and distribution.</li> <li>Protection against risks will depend on- <ul> <li>the potential hazard,</li> <li>the type of food and how it will be handled</li> </ul> </li> <li>Some hazards e.g. toxic material or glass may immediately render the food unfit or injurious to health. For these hazards, steps must be taken to avoid</li> </ul>	Milk is vulnerable to picking up taste and or odour taints as well as undergoing compositional alterations. It is well worth using stainless steel for all pipework, tanks and filling equipment.

Legal Requirement	Guide to Compliance	Advice on Good Practice
	<ul> <li>primary contamination. As there may be no further processing after pasteurization great care must be taken to prevent microbial contamination and pollution</li> <li>For many other hazards, especially food poisoning bacteria, preventing risk will have two elements- <ul> <li>protection from initial contamination</li> <li>protection from multiplication to high numbers that may be infective or toxic.</li> </ul> </li> <li>Protection may be achieved by control of either or both of the elements. That is, food may either be protected from contamination and/ or held for a short period of time, kept chilled or heat treated and packaged to prevent the development of pathogenic bacteria.</li> </ul>	Good stock rotation is advocated on all materials and finished product. It is important to ensure that materials are adequately protected at the point of unloading, and finished product is protected at the point of despatch.
4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).	A suitable pest control system must be used. Monitor any proofing requirements which may otherwise have been overlooked. This provision includes control of the following pests: insects, rats, mice and birds. Also domestic animals must be excluded from any food production or preparation areas.	It is recommended that a site be registered with a pest control service. Bait stations should be clearly specified and identified. Open dishes of granular bait should not be used in production or warehousing areas. It is recommended that baits in solid block form should be used, contained in sealed boxes. Electronic insect killer trays should be large enough to catch falling insects. The units should be, appropriately positioned to ensure best operation and no contamination, regularly maintained and cleaned out. Regular routine pest control visits with additional field biologist's reports and corrective actions arising should all be recorded and available on site. It may be found advantageous to have a member of staff trained in aspects of pest control. The pest control service can be undertaken internally.

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5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro- organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health. Food businesses manufacturing, handling and wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials from processed material and sufficient separate refrigerated storage.	The quality characteristics of certain dairy products are created by holding the product at elevated temperatures. These conditions must be clearly understood and defined to ensure safety, and shelf life quality, are not adversely affected. They must be covered by the HACCP procedures.	Cooling curves and temperature loggers can be used to confirm acceptable time periods where the milk or product can be held outside temperature control. Shelf life verification should be carried out. These temperatures may work alongside other parameters such as Ph, salt or water activity. These links should be understood and demonstrated.
<b>6.</b> Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.	Pasteurisation plants must have a means of displaying both the process temperature and also the post process temperature.	Further information is referenced in the Dairy UK Code of Practice on HTST Pasteurisation.
7. The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic micro organisms or the formation of toxins in the foods. During thawing, foods are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic micro organisms or the formation of toxins.	HACCP principles must be used to assess the time temperature implications of any frozen ingredients Processes and procedures should be developed to ensure that there is no risk of cross contamination after thawing	
8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.	Separate storage areas are required for cleaning materials, lubricants and greases and for any other substance or chemical used within the plant. A risk assessment must be completed for the handling of these materials, and	A designated area should be provided for adhesives or coding inks, which must be appropriately labelled. Storage areas should ideally be under lock and key, with only authorised, trained personnel having access to

Legal Requirement	Guide to Compliance	Advice on Good Practice
	must include a risk assessment for allergens including cross contamination risks.	them. Chemical containers should only be stored in food handling areas when actually in use. Back up storage should be kept in a secure area away from the production or food preparation area.

# Chapter X

Provisions applicable to the	e wrapping and	packaging of	foodstuffs
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Legal Requirement	Guide to Compliance	Advice on Good Practice
<b>1.</b> Material used for wrapping and packaging are not to be a source of contamination.	Materials used must be non-toxic, leave no harmful or undesirable deposits on the product, or otherwise contaminate it. Materials must adequately protect the product. Consideration must also be given to printing inks used in the production of the packaging to ensure there is no migration of harmful solvents. http://www.food.gov.uk/foodlabelling/foodcontactmaterials2/	Recommend to use only approved packaging suppliers (BRC Packaging standards) who can demonstrate conformance to meet relevant legislation and specification requirements. Visual checks of products on receipt should be carried out for damage/contamination and batch codes logged. Verify suitability of packaging prior to use and monitor packaging complaints.
2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.	Materials must be stored in a clean, dry, dust free place away from the manufacturing area where possible, and be effectively protected against pest contamination. In the case of small establishments, storage is acceptable in designated areas of processing rooms as long as there is no risk of contaminating the product or deterioration of wrapping materials. Wrapping and packaging materials must be transported to the establishment in a protective cover. Returnable packaging is exempt, but needs to be stored to prevent contamination.	Where possible, wrapping materials should be stored in a separate room.
<b>3.</b> Wrapping and packaging operations are to be carried out so as to avoid contamination of the products.	Wrapping and packaging operations must not be conducted in an area where raw milk operations are carried out. Where there is a serious risk of contamination from the factory environment, packaging shall take place in a separate room. Wrapping and packaging may take place in the same room as other operations as long as there is no risk of	Secondary packaging operations where possible should be away from filling areas. The air supply to the primary wrapping area should be free of dust, fumes and vapours. Micro organisms should be excluded as determined by HACCP.

Legal Requirement	Guide to Compliance	Advice on Good Practice
Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.	HACCP assessments shall be carried out on construction and cleanliness requirements of packaging. Mechanical washing equipment (e.g. bottle washers) shall be installed for all recyclable wrapping (filling) equipment, except where risks are identified as low, when manual cleaning methods can be used. Bottle washing and storage may take place in the same area as wrapping (filling) providing there is no risk of product contamination.	If product being packed can be adversely affected by temperature increases (safety/quality), consideration should be given to controlling the temperature of the wrapping and packaging area for physical, microbiological and chemical requirements. Secondary packaging operations where possible should be away from filling areas. All cleaning operations for these areas should be verified as per site approved methods. Automatic/manual monitoring of all mechanical cleaning operations (e.g. bottle washing) are recommended including time, temperature, detergent / disinfectant strength. Routine bottle/container rinses should be taken to assess levels of cleaning. HACCP assessment of any other automatic / manual cleaning equipment e.g. inversion, air jetting used recommended. Wrapping and packaging should be purchased from approved suppliers against agreed specifications. Visual check of materials for cleanliness and damage before use recommended, with glass bottle scanners recommended when glass containers used.
<b>4.</b> Wrapping and packaging material re- used for foodstuffs is to be easy to clean and, where necessary, to disinfect.	Reusable wrapping shall be smooth and impervious, resistant to cleaning temperatures and chemicals, capable of being suitably rinsed and designed to facilitate visual or automatic inspection for cleanliness. Reusable packaging shall be assessed and where a risk of cross contamination is identified, packaging shall be capable of being cleaned / disinfected. Where/if returnable bottles are used, washing and sanitising facilities must render the containers fit for this purpose.	Wrapping containers should preferably be clear. Where low risks identified with packaging this can be re-used e.g. product can be segregated by reusable cardboard etc.

# Chapter XI

## Heat treatment

Legal Requirement	Guide to Compliance	Advice on Good Practice
<ul> <li>The following requirements apply only to food placed on the market in hermetically sealed containers:</li> <li>1. any heat treatment process used to process an unprocessed product or to process further a processed product is:</li> <li>(a) to raise every party of the product treated to a given temperature for a given period of time; and</li> <li>(b) to prevent the product from becoming contaminated during the process;</li> <li>2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices;</li> </ul>	In the Codex CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS CAC/RCP 57–2004 the following definitions occur: Pasteurization is a microbiocidal heat treatment aimed at reducing the number of any pathogenic microorganisms in milk and liquid milk products, if present, to a level at which they do not constitute a significant health hazard. Pasteurization conditions are designed to effectively destroy the organisms Mycobacterium tuberculosis and Coxiella burnettii. High temperature pasteurisation may be used similarly to pasteurisation to remove all potential vegetative bacteria to extend the shelf life. It will render the product safe from pathogenic bacteria but will not destroy all food spoilage organisms.	<ul> <li>Dairy UK has produced a Code of Practice on HTST pasteurisation.</li> <li>Heat-treatment equipment should be fitted with: <ul> <li>An automatic temperature control</li> <li>A recording thermometer</li> <li>An automatic device preventing insufficient heating</li> <li>An adequate safety system preventing the mixture of pasteurised or sterilised milk with incompletely heated milk, and</li> <li>An automatic recording device which records the operation of the safety system referred to in the preceding indent.</li> </ul> </li> </ul>
an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation).	of milk and liquid milk products is the application of heat to a continuously flowing product using such high temperatures for such time that renders the product commercially sterile at the time of processing. When the UHT treatment is combined with aseptic packaging, it results in a commercially sterile product. Sterilised products are typically filled and sealed into containers in an unprocessed state and then heat treated in sealed containers for such a time temperature combination to render the entire product commercially sterile. Such processing usually takes place at a lower temperature but longer time than UHT in order to prevent container damage.	

# Chapter XII

# Training

Legal Requirement	Guide to Compliance	Advice on Good Practice
Food business operators are to ensure: 1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.	<ul> <li>All persons involved in food handling (see advice in good practice column) must be supervised and instructed, and or trained, in food safety and hygiene.</li> <li>Before any food handler is allowed to start work in the production area they must receive written or verbal instruction in food hygiene practices essential to the safety of the product.</li> <li>Induction training will include:- <ul> <li>Keep yourself clean and wear clean clothing</li> <li>Always wash your hands thoroughly before handling food, after using the toilet, handling waste, before starting work, after every break, after blowing your nose, and after eating</li> <li>Tell your supervisor before commencing work of any skin, nose, throat, stomach or bowel trouble or infected wound.</li> <li>Ensure cuts and sores are covered with a waterproof dressing.</li> <li>Do not smoke, eat or drink in a food room and never cough or sneeze over food.</li> <li>Follow any food safety instructions from your supervisor.</li> <li>Report any sightings of pest activity.</li> </ul> </li> <li>All staff should be properly supervised and instructed to ensure that they work hygienically. A greater degree of supervision may be needed: for new staff awaiting formal training; and for less experienced staff. Even if staff have received formal</li> </ul>	Records of all training should be kept and documented. Different levels of food hygiene training can be undertaken dependant on the job being carried out and responsibility All staff should be taken through induction training on commencement of employment in order to gain a basic understanding of food safety principles. Do not overlook temporary or agency workers. It is equally important to involve these in training appropriate to the duties being carried out. Training in this instance need not be formal but documented evidence should be maintained. New staff must be supervised until it is clear they are able to handle food. Training/instruction may be required if there are major changes in working practices, procedures, equipment or legislation. For further information and a list of food safety qualifications currently offered which are targeted at either food handlers or supervisor/manager level and a list of awarding bodies see link below www.food.gov.uk/multimedia/pdfs/fstg.p df

Legal Requirement	Guide to Compliance	Advice on Good Practice
	training, supervision must depend upon the competence and experience of the individual food handler. All staff must be trained in Health & Hygiene to a stage appropriate to their food handling activities.	
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	Relevant staff need to have appropriate training in HACCP principles	
<b>3.</b> compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.		

# **Regulation 853/2004** Hygiene rules for food of animal origin

#### Raw Milk, Colostrum, Dairy Products and Colostrum-Based Products

#### Legal Requirement

For the purpose of this Section,

- 1. "Colostrum" means the fluid secreted by the mammary glands of milk-producing animals up to three to five days post parturition that is rich in antibodies and minerals, and precedes the production of raw milk.
- 2. "Colostrum-based products" means processed products resulting from the processing of colostrum or from the further processing of such processed products.

#### Chapter I

#### Raw Milk and Colostrum— Primary Production

#### Introduction

It is important that milk producing holdings are registered with the relevant authorised body. This helps to provide confidence about the production methods, safety and quality of the milk leaving the farm premises or processing establishments.

Consumers and retailers need to be reassured that standards are being achieved.

Legal Requirement	Guide to Compliance	Advice on Good Practice
Food business operators producing or, as appropriate, collecting raw milk and colostrum must ensure compliance with the requirements laid down in this Chapter.	All milk production holdings must be registered with the relevant authorised body: in England & Wales Animal Health Dairy Hygiene; in Scotland the Environmental Health Office; in Northern Ireland DARD	Milk production holdings can be audited and accredited to dairy farm assured schemes such as the Assured Dairy Farms (ADF) or recognized assurance scheme.

#### Part I

#### Health Requirements for Raw Milk & Colostrum Production

#### Introduction

The health and welfare of animals is fundamental to the hygienic operation and production in a dairy farm. To produce an abundant, safe supply of high quality milk, dairy cows must be healthy. This can be achieved through good animal husbandry, safe and responsible use of vet medicines and the control and monitoring of health and welfare parameters. Animals with infectious diseases can lead to contamination of the milk if not treated properly.

Legal Requirement	Guide to Compliance	Advice on Good Practice
<ol> <li>Raw milk and colostrum must come from animals:</li> <li>(a) that do not show any symptoms of infectious diseases communicable to humans through milk and colostrum</li> </ol>	Milk from infected cows must not enter the bulk storage tank or be used for human consumption.	
(b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and colostrum and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;		
(c) that do not have any udder wound likely to affect the milk and colostrum;		
(d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC; and	All medicines must be authorised medicines and used under the direction of a vet. All treatments must be recorded. Minimum Acceptable Records of Veterinary Products Use are – • Date of administration • Identification of animal(s) • Product name • Quantity used • Milk withdrawal period • Meat withdrawal period	
(e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.	Milk from treated cows must be withheld from the bulk tank and must not be marketed until at least the withdrawal periods have lapsed in accordance with manufacturer instructions or veterinary advice Withdrawal period must be specified by the prescribing vet. These periods must	
	be recorded and detailed in medicine records including the date when milk	

Legal Requirement	Guide to Compliance	Advice on Good Practice
	and meat is fit for consumption. If a medicine is prescribed for off label use or in conjunction with some other treatment the milk must be withheld for a minimum of 7 days and the milk tested before being put in the tank.	
<ul> <li>2. (a) In particular, as regards brucellosis, raw milk and colostrum must come from:</li> <li>(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC<sup>1</sup>, is free or officially free of brucellosis;</li> <li>(ii) sheep or goats belonging to a holding officially free or free of brucellosis within the meaning of Directive 91/68/EEC<sup>2</sup>; or</li> <li>(iii) females of other species belonging, for species susceptible to brucellosis, to herds regularly checked for that disease under a control plan that the competent authority has approved.</li> <li>(b) As regards tuberculosis, raw milk and colostrum must come from:</li> <li>(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis; or</li> <li>(ii) females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for that disease under a control plan that the competent authority has approved.</li> <li>(b) As regards tuberculosis, raw milk and colostrum must come from:</li> <li>(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis; or</li> <li>(ii) females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for this disease under a control plan that the competent authority has approved.</li> <li>(c) If goats are kept together with cows, such goats must be inspected and tested for tuberculosis.</li> </ul>	A herd loses its OBF of OTF status when a positive brucellosis or tuberculosis reactor is detected	Immediately the farmer is aware the animals should be isolated from the rest of the herd until removed for culling. Movement restrictions are applied to the animals on the farm. Both the milk producer and competent authority should notify the milk purchaser immediately. First purchasers should maintain records of the OBF and OTF status for their contracted milk supplies.

<sup>&</sup>lt;sup>1</sup> Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977/64). Directive as last amended by the 2003 Act of Accession. <sup>2</sup> Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

Legal Requirement	Guide to Compliance	Advice on Good Practice
<ul> <li>3. However, raw milk from animals that do not meet the requirements of point 2 may be used with the authorisation of the competent authority:</li> <li>(a) in the case of cows or buffaloes that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, after having undergone a heat treatment such as to show a negative reaction to the phosphatase test;</li> </ul>	In a herd which has lost its OTF status, milk from non reactor animals may enter the bulk storage tank but must be subject to heat treatment before going for human consumption. See above re inconclusive reactors	Both the milk producer and competent authority should notify the milk purchaser immediately
(b) in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, or which have been vaccinated against brucellosis as part of an approved eradication programme, and which do not show any symptom of that disease, either:		
(i) for the manufacture of cheese with a maturation period of at least two months; or		
(ii) after having undergone heat treatment such as to show a negative reaction to the phosphatase test; and		
(c) in the case of females of other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, but belong to a herd where brucellosis or tuberculosis has been detected after the checks referred to in point $2(a)(iii)$ or $2(b)(ii)$ , if treated to ensure its safety.		
<b>4.</b> Raw milk and colostrum from any animal not complying with the requirements of points 1 to 3 — in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC — must not be used for human consumption.	Milk from positive brucellosis reactors must be withheld from the bulk storage tank and not used for human consumption	

Legal Requirement	Guide to Compliance	Advice on Good Practice
	milk from positive TB reactors must be	
	withheld from the bulk storage tank and not used for human consumption	
	See above re inconclusive reactors.	
<b>5.</b> The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in point 1 or 2 must be effective to avoid any adverse effect on other animals' milk and colostrum.	Immediately the farmer is aware the animals must be isolated from the rest of the herd until removed for culling. Isolation facilities must be available for positive reactors.	The food business operator should ensure that as individual reactor animals are identified, that they are marked or their numbers noted, so that they can be isolated immediately and the milk not put into the bulk tank.

Part II

## **II. Hygiene on Milk and Colostrum Production Holdings**

#### Introduction

It is important to maintain a high standard of hygiene during milk production and processing. Contamination of milk occurs during and after milking.

#### SOURCES OF MILK CONTAMINATION



Contamination can be avoided by sticking to good hygiene milking. For the purpose of good hygienic milking process, it is important to maintain udders free from infection (e.g. mastitis); manage cows so that their udders and teats are clean; as unclean teats and udders can be a source of contamination and subsequent food poisoning. Also it is important to milk cows in such a way that minimises bacterial contamination; store the milk in clean containers and, wherever possible, at temperatures which below 6 °C until collected.

Personal hygiene of the operator and cleanliness of all equipment, surfaces and the premises during milking and processing is also essential.

Comprehensive guidance on hygiene on milk production holdings is set out in the booklet 'A Practical Guide for Milk Producers' prepared by the Animal Health Dairy Inspectorate and distributed to all registered establishments. Milk producers should find this a valuable guide for day to day operations.

In England and Wales see

http://www.defra.gov.uk/animalhealth/inspecting-and-licensing/dairies/index.htm

In Northern Ireland http://www.dardni.gov.uk/hygiene-dairy-farm-2008

Legal Requirement	Guide to Compliance	Advice on Good Practice
A. Requirements for premises and equipment		
<b>1.</b> Milking equipment and premises where milk and colostrum is stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk and colostrum.	Premises must be of suitable construction and secure when unattended. The bulk storage tank must have access points which are secure when unattended.	It is advisable to use only reputable companies with appropriately qualified staff for repair and maintenance of milking equipment.
	The milking area must be sited and constructed to ensure satisfactory hygienic conditions during milking. The milking area and immediate surroundings must be kept clean. Sufficient clean or potable water must be available in the milking area for the cleaning of soiled teats and udders, equipment, hands, fittings and floors, during and after milking.	Any chemicals should be segregated from the milking equipment area.
	Floors and wall surfaces must be maintained in good condition and easy to clean.	
	Equipment must be made from appropriate food-grade material and must be kept clean and in good condition at all times.	
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.	The dairy must be separate from animal housing and be free from birds and vermin. Storage tanks must be sited and constructed so as to limit the risk of contamination of the milk	<ul> <li>Vermin entry points to focus on are:</li> <li>Around doors</li> <li>Drains / drain pipes</li> <li>False ceilings</li> <li>Pipelines from the parlour to the dairy</li> <li>Wiring holes</li> </ul>
	Storage tanks must be adequately enclosed to prevent physical contamination of the milk.	Milk producers should have vermin control policy. Milk producers should keep records of bait-changing dates to confirm vermin
	Retrigeration equipment must be capable of cooling milk to required levels.	control policy.

Legal Requirement	Guide to Compliance	Advice on Good Practice
<b>3.</b> 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 be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.	All equipment must be of sound construction and be recognised as suitable for use in food production areas.	
<b>4.</b> 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 raw milk and colostrum must be cleaned and disinfected in an appropriate manner before re-use.	The milk vat, including mobile vats, must be emptied and cleaned after each use. Milk collection tankers and reload tankers must be cleaned and disinfected at least once a day.	Detailed advice is given in Dairy UK's code of practice on cleaning in place. Containers and tanks which have been cleaned but taken out of service may need to be re-cleaned and disinfected prior to use. Tankers will normally be cleaned once in a 24 hour period. If the tanker has been out of service for more than 24 hours from the last CIP then the tanker can be re – disinfected rather than giving a full CIP. Subject to contractual arrangements, this could be extended to 48 hours if the tanker has been sealed and the seals have not been broken. The requirement to clean tankers once in a 24 hour period does not apply if the tanker still contains milk at the end of the 24hr period. In this case the tanker should be cleaned as soon as it is practicable after emptying.

Legal Requirement

Buide to Compliance

Advice on Good Practice

B. Hygiene during milking, collection and transport		
<ul> <li>1. Milking must be carried out hygienically, ensuring in particular:</li> <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 is not used for human consumption otherwise than in</li> </ul>	<ul> <li>Animals must have clean teats, udders and adjacent parts (flanks, hindquarters, tails and abdomen) before milking</li> <li>Housing must be managed to avoid soiling of the animals</li> <li>Milking equipment must be kept clean at all times</li> <li>Milk from each animal must be examined at each milking</li> <li>When identified, abnormal milk must be kept separate and not used for human consumption</li> <li>Milk from animals showing clinical signs of udder disease must be kept separate and not used for human consumption</li> <li>Animal producing milk that is unfit for human consumption must be clearly identified</li> <li>Hands must be cleaned before milking and milk handling. Exposed skin wounds must be hygienically covered.</li> </ul>	Milk producers should carry out a regular check of udder health
(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 is not used for human consumption; and	In the case of robotic milking there must be a system for preventing milk with abnormalities from entering the milk supply. All treated cows must be clearly identified and milk from such animals must be segregated from bulk storage tank.	last with the milking equipment subsequently cleaned and sanitised. Treated animals should be marked with at least two forms of marker, e.g. leg band and tail tape.

Legal Requirement	Guide to Compliance	Advice on Good Practice
<ul> <li>(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.</li> <li>(f) that coloctrum is milked concretely.</li> </ul>	Teat dips/sprays – Use only products in accordance with manufacturer's instructions or as directed by the Vet.	
and not mixed together with raw milk.		
<ul> <li>2. Immediately after milking, milk and colostrum must be held in a clean place designed and equipped to avoid contamination.</li> <li>(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.</li> <li>(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.</li> </ul>	The cooling and storage equipment must be capable of cooling the milk to the required temperature. The bulk tank (including external silos) and any ancillary equipment must be regularly and thoroughly cleaned internally.	Its good practice to check that the milk has been cooled to the required temperature at the end of milking. Milk purchasers in their commercial contracts may require temperatures of 5 °C or lower to safeguard the quality and shelf-life of their products. Milk collection drivers should check the temperature of the milk offered for sale prior to starting to upload milk from the bulk tank and collection tickets detailing collection temperature should be left on farm.
<b>3.</b> During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk and colostrum must not be more than $10 \ C$ .	To maintain required temperatures tanker design specifications must include adequate insulation. Temperature must be maintained at or below 10°C throughout cold chain.	Receiving customers should check the temperature of the tanker load of milk prior to offloading into silo and records should be kept. Milk purchasers in their commercial contracts may require milk to be delivered below 6 °C.
<ul> <li>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:</li> <li>(a) the milk is processed within two hours of milking; or</li> </ul>	If making use of this provision, the local authority must authorise.	Producer - processors making use of this requirement should keep records of the time of milking and processing.

Legal Requirement	Guide to Compliance	Advice on Good Practice
(b) a higher temperature is necessary		
for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises.		
C. Staff hygiene		
<b>1.</b> Persons performing milking and/or handling raw milk and colostrum must wear suitable clean clothes.		Waterproof clothing (wellingtons, gloves, hair covers and milking apron) should be available and clean at the start of milking and be capable of being cleaned or changed if they become heavily soiled.
2. Persons performing milking must maintain a high degree of personal cleanliness. Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk and colostrum to wash their hands and arms.	Operator's hands and forearms must be thoroughly washed before milking and these parts as well as gloves, if worn, kept clean during milking and milk handling.	Wearing of rubber gloves is recommended.

## Part III

## Criteria for Raw Milk and Colostrum

Legal Requirement	Guide to Compliance	Advice on Good Practice
<ol> <li>(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.</li> <li>(b) National criteria for colostrum, as regards plate count, somatic cell count or antibiotic residues, apply pending the</li> </ol>		
legislation		
<ul> <li>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:</li> <li>(a) the food business operator producing the milk;</li> <li>(b) the food business operator collecting or processing the milk;</li> <li>(c) a group of food business operators; or</li> <li>(d) in the context of a national or regional control scheme.</li> </ul>	Sampling and testing regimes must be in place to demonstrate compliance with raw milk quality criteria. Records of test results must be retained.	It is recommended that a sample of milk for each consignment offered for sale is to be taken prior to collection. Milk purchasers should store these samples for traceability purposes. Payment systems for raw milk should encourage low counts of bacteria and somatic cell count Samples of milk from each holding should be tested randomly at least weekly as per milk purchaser contracts. Testing should be carried out by laboratories with proven competencies and accredited to UKAS or equivalent standards. The first purchaser will normally be responsible for this.

Legal Requirement	Guide to Compliance	Advice on Good Practice
<b>3. (a)</b> Food business operators must initiate procedures to ensure that raw milk meets the following criteria: (i) for raw cows' milk: Plate count at 30 °C (per ml) $\leq 100\ 000^3$ Somatic cell count (per ml) $\leq 400\ 000^4$ (ii) for raw milk from other species: Plate count at 30 °C (per ml) $\leq 1\ 500\ 000^3$	Food Business Operator must ensure that systems are in place to ensure that raw milk meets the plate count and somatic cell count criteria. Bactoscan or impedence methods can be used as an indirect measurement of plate count. Regulation (EC) 854/2004 Annex IV provides that food business operator's failing to meet this criteria must correct the situation within 3 months of first	Milk producers should follow good hygiene and animal husbandry practices. Robust sampling and testing regimes should be in place. First purchasers should operate quality assurance payment systems to encourage compliance to the plate count and somatic cell count criteria.
<b>(b)</b> However, if raw milk from species other than cows is intended for the manufacture of products made with raw milk by a process that does not involve any heat treatment, food business operators must take steps to ensure that the raw milk used meets the following criterion: Plate count at 30 °C (per ml) $\leq$ 500 000 <sup>3</sup>	notifying non compliance.	

<sup>&</sup>lt;sup>3</sup> Rolling geometric average over a two-month period, with at least two samples per month.

 <sup>&</sup>lt;sup>4</sup> 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.
 Regulation 853/2004 Chapter I Part III
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Legal Requirement	Guide to Compliance	Advice on Good Practice
<b>4.</b> 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:	Food Business Operator must operate systems to ensure that antibiotic limits are not exceeded. Food Business Operators are milk producers, milk purchasers and milk processors.	Milk producers should ensure that withdrawal periods are respected and veterinary advice followed. Milk producers should advise milk purchasers if accidental contamination is a possibility.
(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 <sup>5</sup> , exceeds the levels authorised under that Regulation;		Milk purchasers should operate a quality assurance payment scheme for ex-farm samples to encourage compliance with legal limits.
(b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.		Milk processors should operate a quality control scheme whereby a sample of tankers and / or silos are tested for antibiotics
		Procedures in the FSA guidance should be followed. See FSA – INFORMATION AND GUIDANCE ON THE TESTING OF MILK FOR ANTIBIOTIC RESIDUES APRIL 2009 http://www.food.gov.uk/foodindustry/ guidancepotes/bygguid/guidancemilk
		testantibioticres
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	The appropriate competent authority is in the FSA guidance on antibiotics and depends on the location of the milk producer and the place of testing.	First purchasers should have procedures to advise producers on compliance.
situation.		First purchasers may cease collecting milk which exceeds the criteria.

 <sup>&</sup>lt;sup>5</sup> Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 546/2004 (OJ L 87, 25.3.2004, p. 13).
 Regulation 853/2004 Chapter I Part III

Chapter II:

## Requirements concerning dairy and colostrum-based products

Part I

#### **Temperature Requirements**

#### Introduction

Temperature is the most important single factor affecting the growth of bacteria. Cooling milk to less than 6 °C is a very good method to keep the quality of milk at a high level. If the temperature of stored milk is lowered, chemical processes as well as microbiological growth will slow down. Two main reasons why it is important to cool milk to less than 6 °C is to inhibit bacteria spoilage and also to extend the shelf life of the milk.



Legal Requirement	Guide to Compliance	Advice on Good Practice
<ol> <li>Food business operators must ensure that, upon acceptance at a processing establishment,         <ul> <li>(a) milk is quickly cooled to not more than 6 °C</li> <li>(b) colostrum is quickly cooled to not more than 6 °C or maintained frozen, and kept at that temperature until processed</li> </ul> </li> </ol>	Milk, on receipt at the dairy must be cooled to 6 °C or less, unless already at or below this temperature where no further cooling is required. Where milk is held in jacketed or insulated vessels these vessels can be used to maintain the raw milk temperature.	Raw milk quality including temperature requirements should be specified in contract/specification with supplier(s). Cooling of milk to below 6°C will aid in improving processed milk/product quality All incoming/stored raw milk loads should be checked for temperature either manually or automatically and recorded, with controlled stock rotation also in place.
<ul> <li>2. However, food business operators may keep milk and colostrum at a higher temperature if:</li> <li>(a) processing begins immediately after milking, or within four hours of acceptance at the processing establishment;</li> <li>or</li> <li>(b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy or colostrum – based products.</li> </ul>	<ul> <li>Higher temperatures than 6 °C may be used if:</li> <li>a. processing begins without undue delay after milking or within four hours of acceptance at the processing establishment.</li> <li>or</li> <li>b. higher temperatures have been authorised by the local authority.</li> </ul>	Records should be kept of the time between milking and processing or time between acceptance and processing. It is recommended to minimise the time raw milk is being kept warm, and time/temperature routinely monitored.

#### Chapter II:

## Requirements concerning dairy and colostrum-based products

Section II

#### **Requirements for Heat Treatment**

#### Introduction

The most important control measure in dairy processing establishments is the process of heat treating the milk which is known as pasteurisation. Pasteurisation is a critical control point in ensuring the safety of milk and dairy products. The hazard is that if milk is not pasteurized correctly, it will allow the survival of pathogenic bacteria which may grow to large numbers and/or produce toxins. Heat treatment of milk is aimed at destroying any pathogenic bacteria in the milk and to prolong the shelf life of the milk.

## Definition of Pasteurisation.

Pasteurisation has been defined in Regulation 853/2004 as a treatment involving:

(i) a high temperature for a short time (at least 72°C for 15 seconds);

(ii) a low temperature for a long time (at least 63°C for 30 minutes); or

(iii) any other combination of time-temperature conditions to obtain an equivalent effect, such that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment.

Although 72°C for 15 seconds or equivalent is the legal minimum for pasteurisation for drinking milk, it is recommended that at least 72°C for 25 seconds is used as a precaution against Mycobacterium paratuberculosis (MAP).

#### **Prevention of Post – Pasteurisation Contamination**

The contamination of milk and milk based products after the pasteurisation process can be the greatest risk of a breakdown in hygiene. There are various sources from which milk which had already been pasteurised can get contaminated again. Below is a schematic diagram to show where contamination could come from.


### Sources of post pasteurisation contamination.

Examples of how to prevent post-pasteurisation contamination are:

- There should be adequate supplies of hot and cold potable water available, with precautions against contamination and pollution.
- Special care must be taken to clean and disinfect all utensils that have been present in raw milk areas before use. Such tools should preferably be kept in raw milk areas only and not be used elsewhere.
- Air supply in high risk areas should be filtered to microbiological standards (filters in high risk areas should conform to BS EN 1822 Minimum MPPS % standard, supplied at positive pressure and at a rate to avoid condensation).
- Layout designed to ensure no cross contamination from raw milk and other source of contamination.
- Regular environmental monitoring to ensure cleaning systems are effective
- Packing should be conducted in an area separate from raw milk operations and completed as quickly as possible to minimize exposure of the product to contamination.
- Personnel involved in post pasteurisation processes should be aware of the possibilities of recontamination through their own person as well as other reasons.
- Personnel involved in the handling of raw milk should not, as far as is reasonably practicable, have duties in any post pasteurisation area. If they do they should wash hands and change clothing. Footwear should either be changed or a footbath used.

Legal Requirement	Guide to Compliance	Advice on Good Practice
1. When raw milk, colostrum, dairy or colostrum-based products undergo heat treatment, food business operators must ensure that this satisfies the requirement of laid down in Chapter XI of Annex II to Regulation (EC) No 852/2004. In particular, they shall ensure, when using the following	The food business operator's HACCP should identify controls required for equipment used for heat treatment for milk and milk products.	The Dairy UK Code of Practice on HTST pasteurisation contains pre- requisites for HACCP.
processes, that they comply with the specifications mentioned:		High Temperature Pasteurisation is achieved by processing at a temperature greater than
(a) Pasteurisation is achieved by a treatment involving:		pasteurisation and gives a time temperature combination suitable to
(i) a high temperature for a short time (at least 72℃ for 15 seconds);		destroy all vegetative bacteria and the majority of the spores. Such products will need to be kept chilled and should
(ii) a low temperature for a long time (at least 63℃ for 30 minutes); or		pass a total viable plate count of less than 100 microorganisms immediately
(iii) any other combination of time- temperature conditions to obtain an equivalent effect, such that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment."	Regulation1664/2006 defines a negative reaction to an alkaline phosphatase test as a measured activity in cow's milk not higher than 350 mU/I.	after processing. Products of this type will give a negative peroxidase but may not show negative reaction to the alkaline phosphatase test due to reactivation of the enzyme at higher temperatures.
<b>(b)</b> Ultra High Temperature (UHT) treatment is achieved by a treatment:	The reference method for the alkaline phosphatase testing method for heat	
(i) involving a continuous flow of heat at a high temperature for a short time (not less than $135$ °C in combination with a suitable holding time) such that there are no viable microorganisms or spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature, and	treated milk (ALP) activity is ISO 11816- 1 An ALP test is considered to give a negative result if the measured activity in cow's milk is not higher than 350mU/L	
(ii) sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at $30^{\circ}$ C in closed containers or for 7 days at $55^{\circ}$ C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.		

Legal Requirement	Guide to Compliance	Advice on Good Practice
<ul> <li>2. When considering whether to subject raw milk and colostrum to heat treatment, food business operators must:</li> <li>(a) have regard to the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) No 854/2004; and</li> </ul>	Operator's HACCP shall identify controls required for milk/product processing, and for the equipment used.	It is recommended that fully documented HACCP based systems are in place with a continuous improvement programme to ensure ongoing compliance. Further advice is given in "EU Guidance document on the implementation of procedures based on the HACCP principles and the facilitation of the implementation of the HACCP principles in certain food businesses".
(b) comply with any requirements that the competent authority may impose in this regard when approving establishments or carrying out checks in accordance with Regulation (EC) No 854/2004.		

### Chapter II:

## Requirements concerning dairy products

Part III

### Criteria For Raw Cows' Milk

Le	gal Requirement	Guide to Compliance	Advice on Good Practice
<b>1.</b> If ma initiant initiant initiant initiant initiant initiant initiant exce	Food business operators nufacturing dairy products must iate procedures to ensure that, nediately before being heat treated d if its period of acceptance defined he HACCP-based procedures is seeded:	If raw and heat-treated cows' milk is heat treated within the time period specified in the HACCP -based procedures, the plate count requirements do not apply.	It is recommended that HACCP- based procedures are in place, including maximum storage time periods prior to heat-treatment for raw and heat-treated milks, to avoid the necessity for carrying out these tests prior to utilising milk supplies.
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, N laic	When milk fails to meet the criteria I down in point 1, the food business	Records must be kept of non compliance and the corrective	
ope	erator must inform the competent	measures taken and these records	
aut the	nority and take measures to correct situation.	must be made available to the local authority.	

## Chapter III:

# Wrapping and Packaging

Legal Requirement	Guide to Compliance	Advice on Good Practice
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.	Containers for milk and other liquid dairy products must be capped immediately after filling. Tamper evident closures must be used which identify if a package has been opened.	The actual sealing mechanism can be heat, physical or mechanical means. Routine tests should be undertaken to demonstrate that the sealing integrity has been maintained.

## Chapter IV:

# Labelling

Legal Requirement	Guide to Compliance	Advice on Good Practice
<ol> <li>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:</li> <li>(a) in the case of raw milk intended for direct human consumption, the words 'raw milk';</li> <li>(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'.</li> <li>c) in case of colostrum, the word "colostrum";</li> <li>d) in case of products made with colostrum.</li> </ol>	Raw milk sold direct to consumers must be labelled with the wording "raw milk" In addition, the Food Labelling Regulations 1996 require that any raw milk (other than buffaloes milk) should be labelled with the words "This milk has not been heat-treated and may therefore contain organisms harmful to health". In Scotland, the sale of raw milk direct to consumer is prohibited. In England, Wales and Northern Ireland the sale of raw milk is permitted under strict marketing conditions and providing it carries a health warning label. Products made from raw milk which have not received treatments to reduce possible microbiological hazards must be labelled "made with raw milk".	
2. The requirements of point 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.	The need to label products as "raw milk" or "made with raw milk" apply to products destined for the ultimate consumer or to a catering establishment. The prescribed wording can appear on the label or other notices accompanying the product. In relation to raw milk dairy products which are not pre-packed or are pre- packed for direct sale by the retailer, for example those on display at a cheese/delicatessen counter, the prescribed information must be made available at the place where the consumer makes their choice – typically the cheese/delicatessen counter. Where the labelling requirement is met up to the point of sale, once chosen by the consumer, the product need not be labelled with prescribed wording.	In relation to raw milk dairy products which are not pre-packaged retailers may voluntarily provide the information 'made with raw milk' on post-sale labelling.

## Chapter V:

# Identification Marking

Legal Requirement	Guide to Compliance	Advice on Good Practice
By way of derogation from the requirements of Annex II, Section I:		
<b>1.</b> 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;	For generic packaging, the site approval number can be referenced, via the identification mark, which shall identify the location on the wrapping or packaging of the approval number, e.g. UK SEE CODE PANEL EC	As an alternative more than one identification mark may appear on the label together with an indication of the identification mark applying to the specific establishment.
2. in the case of the reusable bottles, the identification mark may indicate only the initials of the co-signing country and the approval number of the establishment.	In the case of re-useable bottles the identification mark can be reduced to the consigning country, and the site approval number e.g. UK LLNNN NOTE: L – Letter, N – Number	

# **Regulation 2073/2005** *Microbiological criteria for foodstuffs*

# **Microbiological Criteria for Milk and Dairy Products**

### **Introduction**

EC Regulation No. 2073/2005 sets down microbiological criteria for foodstuffs, including milk and dairy products and establishes two types of criterion requiring food business operators to take corrective actions when these criteria are not met. These two types are:

• food safety criteria which should be used to assess the safety of a product or batch of foodstuffs; and

• **process hygiene criteria** which should be used to ensure the production processes are operating properly.

### **Compliance**

It is recognised the safety of food is neither guaranteed, nor controlled by microbiological testing, and this new legislation <u>does not impose a general requirement for increased end</u> <u>product microbiological testing or positive release</u> but to ensure compliance, the following should be actioned:

- Microbiological criteria shall be used to validate and verify the food business's food safety management procedures
- The sampling and testing plan shall be proportionate to the risk and to the nature and size of the business.
- Alternate indicators can be used such as time/temperature profiles / good hygiene and cleaning practices to demonstrate how the same end result is achieve.

### **Enforcement**

- 1. Local Food Authority e.g. Environmental Health Departments are responsible for ensuring compliance with microbiological criteria throughout the food production and distribution chain.
- 2. This is achieved either by audit of a business's food safety management procedures where supporting evidence to show criteria are being met will be required, or by sampling product.
- 3. If criteria are exceed, food business operators must carry out corrective actions as outlined in Appendix 1 & 5, together with those specified as part of their food safety management procedures.

### Food Safety Criteria - Legal Requirement

- 1. Food Safety Criteria Microbiological Testing Standards (listed in Appendix 1) See also decision trees to determine the testing regime for:
- 1.1. Listeria Monocytogenes in ready to eat foods (Appendix 2)
- 1.2. Coagulase positive-Staphylocci in dairy products (Appendix 2)
- 1.3. Enterobacteriaceae, Salmonella and E-sakazakii in dried infant formula and foods (Appendix 4)

#### **Guide to Compliance**

 Food safety criteria shall be used to assess the safety of a product or batch of foodstuffs. These apply throughout the shelf-life – See Appendix 1
 If a food safety criterion is not met, this usually means the food business operator will not be able to place the foodstuff on the market or will need to remove the food from the market (as provided in Regulation 178/2002 laying down general food safety requirements) and take steps to ensure future production meets the criterion. In certain circumstances, a recall of the food may be required. The food safety management procedures shall be reviewed to ensure the products are likely to comply in the future.

#### 1.1. Decision tree 1

Although pasteurised milk, pasteurised cream, pasteurised flavoured milks, and other dairy products produced from pasteurised milk are able to support the growth of *L. monocytogenes* the pasteurisation process will effectively destroy *Listeria*.

A limit of 0 cfu/g applies before the food has left the immediate control of the producing food business operator.

#### 1.2. Decision tree 2

Batches only need to be tested for enterotoxins if a result of > 100,000 cfu/g is initially obtained for any of the sample units when testing against the coagulase-positive staphylococci process hygiene criterion. Under these circumstances it is advisable not to release the product on to the market until the enterotoxin results are obtained. If staphylococcal enterotoxin is present the batch would present an unacceptable risk to human health and must not be placed on the market.

#### 1.3. Decision tree 3

This decision tree should be applied to milk and whey powders intended for use in dried infant formulae or dried infant foods.

#### Advice on Good Practice

It is recommended that products are tested at the development stage to ensure the relevant food safety requirements can be achieved at point of production and end of shelf life, and then on an ad-hoc rouitine basis as defined by the food business's management system.

1.1 The HACCP procedure should address pasteurisation, preventing post-pasteurisation contamination, and ensure pre-requisite controls are in place. Under these circumstances there is no need for product testing before the product leaves the factory, however it is recommended that on initial development of the product this is established during shelf life trials.

### Process Hygiene Criteria - Legal Requirement

Process hygiene criteria Microbiological Testing Standards (listed in Appendix 5)

### Guide to Compliance

Process hygiene criteria are used to show that the production processes are working properly. These apply throughout every stage of manufacturing and handling.

If a process hygiene criterion is not met the product can be placed on the market, but the food business operator must review the production processes and procedures and improve process hygiene to ensure future production will meet the criteria.

The Regulation does not specify minimum requirements for testing. Nor does it require food business operators to carry out routine microbiological testing or to wait for the results of any testing carried out before the food is placed on the market. The criteria shall be used to ensure that the food safety management procedures are functioning correctly.

In cases whereby further testing may be required, for example presence of Enterobacteriaceae and Coagulase positive staphylococci in dairy products (appendix 3) or infant formula (appendix 4). The action taken in either case shall be included in the food safety management procedures, which shall also include relevant actions to be taken. In both cases, enforcement authorities will require sufficient evidence that the food business operator has taken the appropriate corrective action.

### **Advice on Good Practice**

Routine testing of product is recommended to demonstrate cleaning and disinfection practices are satisfactory, with a recommendation of testing each batch of product at start of run or to site agreed guidelines.

It is good practice for sites to set higher targets than those defined for Enforcement purposes to demonstrate ongoing compliance, but using a smaller test size, normally one test per sample. Regulation stipulates that FBOs producing RTE food which present a risk to public health from

L.monocytogenes **shall** conduct monitoring of the production environment for Listeria Monocytogenes. It is also recommended environmental, and staff hygiene monitoring systems are implemented, such as equipment swabbing, hand swabs, water testing etc.

# Appendix 1 – Food Safety criteria Milk and dairy products

Food category	Micro- organisms/	Sampl plan <sup>1</sup>	ing-	Limits <sup>2</sup>		Analytical reference	Stage where the criterion applies
	their toxins, metabolites	n	С	m	Μ	method	
1.1 Ready-to-eat foods intended for infants and ready-to eat foods for special medical purposes <sup>4</sup>	Listeria monocytogenes	10	0	Absence 25 g	e in	EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2 Ready-to-eat foods able to support the growth of L. monocytogenes, other than		5	0	100 cfu/	⁄g⁵	EN/ISO 11290-2 <sup>6</sup>	Products placed on the market during their shelf-life
those intended for infants and for special medical purposes	Listeria monocytogenes	5	0	Absence 25 g <sup>7</sup>	e in	EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
1.3 Ready-to-eat foods unable to support the growth of L. <i>monocytogenes</i> , other than those intended for infants and for special medical purposes <sup>4</sup> , <sup>8</sup>	Listeria monocytogenes	5	0	100 cfu/	⁄g	EN/ISO 11290-2 <sup>6</sup>	Products placed on the market during their shelf-life
1.11 Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat- treatment than pasteurisation <sup>10</sup>	Salmonella	5	0	Absence 25 g	e in	EN/ISO 6579	Products placed on the market during their shelf-life
1.12 Milk powder and whey powder <sup>10</sup>	Salmonella	5	0	Absence 25 g	e in	EN/ISO 6579	Products placed on the market during their shelf-life
1.13 Ice cream <sup>11</sup> , excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	Salmonella	5	0	Absence 25 g	e in	EN/ISO 6579	Products placed on the market during their shelf-life
1.21 Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in Chapter 2.2 of this Annex	Staphylococcal enterotoxins	5	0	Not detected 25g	d in	European screening method of the CRL for coagulase positive staphylococci <sup>13</sup>	Products placed on the market during their shelf-life

Food category	Micro- organisms/	Sampl plan <sup>1</sup>	ing-	Limit	s <sup>2</sup>	Analytical reference	Stage where the criterion applies
	their toxins, metabolites	n	С	m	М	method	
1.22. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Salmonella	30	0	Absei 25 g	nce in	EN/ISO 6579	Products placed on the market during their shelf-life
1.23 Dried follow-on formulae	Salmonella	30	0	Absei 25 g	nce in	EN/ISO 6579	Product placed on the market during their shelf-life
1.24. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age <sup>14</sup>	Cronobacter spp. (Enterobacter sakazakii)	30	0	Absei 10 g	nce in	ISO/TS 22964	Products placed on the market during their shelf-life

 $(^{1})$  n = number of units comprising the sample; c = number of sample units giving values over m or between m and M.

(<sup>2</sup>) For points 1.1-1.24 m=M.

(<sup>3</sup>) The most recent edition of the standard shall be used.

 $\mathbf{\dot{4}}$  Regular testing against the criterion is not useful in normal circumstances for the following ready-toeat foods: Those which have received heat treatment or other processing effective to eliminate L. *monocytogenes*, when recontamination is not possible after this treatment (e.g. products heat treated in their final package),

(<sup>5</sup>) This criterion applies if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that should be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of the shelf-life.

(<sup>6</sup>) 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

(<sup>7</sup>) This criterion applies to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.

(<sup>8</sup>) Products with pH  $\leq$  4.4 or  $a_w \leq$  0,92, products with pH  $\leq$  5,0 and  $a_w \leq$  0,94, products with a shelf-life of less than five days are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.

(<sup>10</sup>) Excluding products when the manufacturer can demonstrate to the satisfaction of the competent authorities that, due to the ripening time and a<sub>w</sub> of the product where appropriate, there is no salmonella risk.

(<sup>11</sup>) Only ice creams containing milk ingredients.

(<sup>13</sup>) Reference: Community reference laboratory for coagulase postive staphylococci. European screening method for detection of staphylococcal enterotixins in milk and milk products.

(<sup>14</sup>) Parallel testing for Enterobacteriaceae and *E.sakazakii* shall be conducted, unless a correlation between these micro-organisms has been established at an individual plant level. If Enterobacteriaceae are detected in any of the product samples tested in such a plant, the batch must be tested for *E. Sakazakii*. It shall be the responsibility of the manufacturer to demonstrate to the satisfaction of the competent authority whether such a correlation exist between Entrobacteriaceae and *E. Sakazakii*.



# Decision tree 1: Which Listeria monocytogenes criteria should I be using for ready to eat foods?<sup>2</sup>

<sup>2</sup> Regular testing not useful for the following ready to eat foods:

• foods processed sufficiently to eliminate *Listeria monocytogenes* when recontamination not possible e.g. foods heat-treated in final packaging

3 Includes products with:

• pH less than or equal to 4.4

- Water activity aw less than or equal to 0.92
- pH less than or equal to 5.0 and awless than or equal to 0.94

<sup>4</sup> if shelf life studies show 100cfu/g is likely to be exceeded before the end of the shelf life, options include reviewing shelf life, reviewing food safety management procedures, of ensuring absence in 25g before the food leaves the immediate control of food business operator.





5 A 2-tiered approach is to be used for staphylococcal enterotoxins. Batches only need to be tested against this food safety criterion if a result of > 100,000 cfu/g is initially obtained for any of the sample units when testing against the coagulase-positive staphylococci process hygiene criterion.

### **Appendix 4**

#### Decision tree 3: What do I do if I find Enterobacteriaceae, Salmonella or Enterobacter sakazakii in dried infant formulae and dried infant foods?



Remove product from the market and recall failed batches.

## Appendix 5 – Process hygiene criteria

## 2.2 Milk and dairy products

Food category	Micro- organisms	Sam g pla	plin an <sup>1</sup>	Limits <sup>2</sup>		Analytical reference	Stage where the criterion	Action in case of unsatisfactory
		n	с	m	м	method <sup>°</sup>	applies	results
EXAMPLE Pasteurised Milk Entero- bacteriaceae	For enforcement n = number of uni c = number of sam e.g. For enforcem tests per sample s level greater than Sites can determin above.	<b>purpo</b> ts com nple ui ent pu shall be 10 cfu ne thei	prising prising nits giv rposes carri /ml. ir own	g the sampl ving values s, pasteuris ed, up to 5 testing regi	e; between n ed milk sh can have l me and st	n and M. all comply with the Enteros of up to 10 andards but must .	following Enteroba ) cfu/ml, and no sam be able to demonstra	cteriaceae standard - 5 ple can have an Entero ate compliance with the
2.2.1 Pasteurised milk and other pasteurised liquid dairy products <sup>4</sup>	Entero- bacteriaceae	5	0	10 cfu/ml	10 cfu/ml	ISO 21528-2	End of the manufacturing process	Check on the efficiency of heat- treatment and prevention of recontamination as well as the quality of raw materials
2.2.2 Cheeses made from milk or whey that has undergone heat treatment	<i>E.</i> coli⁵	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	At the time during the manufacturing process when the <i>E. coli</i> count is expected to be highest <sup>6</sup>	Improvements in production hygiene and selection of raw materials
2.2.3 Cheeses made from raw milk	Coagulase- positive staphylococci	5	2	10 <sup>4</sup> cfu/g	10 <sup>5</sup> cfu/g	EN/ISO 6888-2	At the time during the manufacturing	Improvements in production hygiene and selection of raw
2.2.4 Cheeses made from milk that has undergone a lower heat treatment than pasteurisation <sup>7</sup> and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment <sup>7</sup>	Coagulase- positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2	process when the number of staphylococci is expected to be highest	materials. If values >10 <sup>5</sup> cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.5 Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment	Coagulase- positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > $10^5$ cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.

Food category	Micro- organisms	Sam g pla	plin an <sup>1</sup>	Limits <sup>2</sup>		Analytical reference	Stage where the criterion	Action in case of unsatisfactory
		n	с	m	м	method <sup>3</sup>	applies	results
2.2.6 Butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	<i>E.</i> coli <sup>5</sup>	5	2	10 cfu/g	100 cfu/g	ISO16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and selection of raw materials
2.2.7 Milk powder and whey powder <sup>4</sup>	Enterobacteria ceae	5	0	10 cfu/g		ISO 21528- 1	End of the manufacturing process	Check on the efficiency of heat treatment and prevention of recontamination
	Coagulase- positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > $10^5$ cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins.
2.2.8 Ice cream <sup>8</sup> and frozen dairy desserts	Enterobacteria ceae	5	2	10 cfu/g	100 cfu/g	ISO 21528- 2	End of the manufacturing process	Improvements in production hygiene
2.2.9 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Enterobacteria ceae	10	0	Absence	in 10 g	ISO 21528-1	End of the manufacturing process	Improvements in production hygiene to minimise contamination <sup>9</sup>
2.2.10 Dried follow-on formulae	Enterobacteria ceae	5	0	Absence	in 10 g	ISO 21528-1	End of the manufacturing process	Improvement in production hygiene to minimise contamination
2.2.11 Dried infant formulae and dried dietary food for special medical purposes intended for infants below six months of age	Presumptive Bacillus cereus	5	1	50 cfu/g	500 cfu/g	EN/ISO 7932 <sup>10</sup>	End of manufacturing process	Improvements in production hygiene. Prevention of recontamination. Selection of raw materials.

1. n = number of units comprising the sample; c = number of sample units giving values between m and M.

2. For point 2.2.7 m=M

3. The most recent edition of the standard shall be used.

 The most recent earlier of the standard shall be used.
 The criterion does not apply to products intended for further processing in the food industry.
 E. coli is used here as an indicator for the level of hygiene.
 For cheeses which are not able to support the growth of E.coli, the E.coli count is usually the highest at the beginning of the ripening period, and for cheeses which are able to support the growth of E.coli, it is normally at the end of the ripening period.

- 7. Excluding cheeses where the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.
- 8. Only ice creams containing milk ingredients.
- 9. Parallel testing for Enterobacteriaceae and *E.sakazakii* shall be conducted, unless a correlation between these micro-organisms has been established at an individual plant level. If Enterobacteriaceae are detected in any of the product samples tested in such a plant, the batch must be tested for *E. Sakazakii*. It shall be the responsibility of the manufacturer to demonstrate to the satisfaction of the competent authority whether such a correlation exist between Entrobacteriaceae and *E. Sakazakii*.
- 10. I ml of inoculum is plated on a Petri dish of 140 mm diameter or on three dishes of 90 mm diameter

## References

The Food Hygiene (England) Regulations 2006

The Food Hygiene (Scotland) Regulations 2006

The Food Hygiene (Wales) Regulations 2006

The Food Hygiene Regulations (Northern Ireland) 2006

Regulation (EC) 852/2004 The hygiene of foodstuffs

Regulation (EC) 853/2004 Hygiene rules for food of animal origin

Regulation (EC) 2073/2005 Microbiological *criteria for foodstuffs* (as amended by EC Regulation No. 1441/2007)

Regulation (EC) No 1020/2008 amending Annexes II and III to Regulation (EC) No 853/2004

Dairy UK Guidelines for Good Hygienic Practice in the Manufacture of Dairy-Based Products May 1995 <u>www.dairyUK.org</u>

Dairy UK Code of Practice on High Temperature Short Time (HTST) Pasteurisation May 2006 <u>www.dairyUK.org</u>

Dairy UK CIP Code of Practice

Regulation (EC) 1774/2002 Animal by-Products

Food Standards Agency: Information and guidance on the testing of milk for antibiotic residues

Food Standards Agency: General guidance for food business operators (EC Regulation No. 2073/2005 on Microbiological Criteria for foodstuffs).

Regulation (EU) No 365/2010 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs as regards Enterobacteriaceae in pasteurised milk and other pasteurised liquid dairy products and *Listeria monocytogenes* in food grade salt

# Glossary

TERM	MEANING
ADF	Assured Dairy Farms
Ambient Temperature	The temperature of the surrounding environment, usually meaning room temperature.
Animal Health Dairy Hygiene	Formerly known as the Dairy Hygiene Inspectorate (DHI) responsible
(AHDH)	for the registration and inspection of production holdings
Bacteria	A group of single cell living organisms, some of which may spoil food or cause illness.
Bactericidal Detergent (Hand	Detergents used either for hand washing or equivalent cleaning, not only to remove dirt but also to destroy micro-organisms
BRC	British Retail Consortium
Chiller / Refrigerator / Chilled	Equipment used to keep food cool – normally between 0°C and 8°C.
Cabinet	
CIP	Cleaning in place
Cleaning	The removal of food residues, dirt, grease, and other undesirable debris.
Codex Competent Authority	The Codex Alimentarius Commission was created in 1963 by FAO (the Food and Agriculture Organisation of the United Nations) and WHO (the World Health Organisation) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. The Codex Alimentarius website can be accessed at the following link: http://www.codexalimentarius.net/web/index_en.jsp The Food Standards Agency (FSA) is the competent authority for food hygiene legislation. In England and Wales Animal Health (Dairy Hygiene) acts on behalf of the FSA in monitoring and verifying compliance with, and enforcing food hygiene legislation at milk production holdings. In Northern Ireland the Quality Assurance Branch of the Dept. of agriculture and Rural development for Northern Ireland carry out this role. In Scotland local authorities are responsible for inspecting milk production holdings.
	In addition, in practice local authorities throughout the UK are responsible for monitoring and verifying compliance with, and enforcing the requirements of the main body of food law. Therefore where there is a reference to 'competent authority' this y Guide indicates which authority is being referred to.
Contamination	The introduction or occurrence in food of any microbial pathogens, chemicals, foreign materials, spoilage agents, taints, unwanted or diseased matter, which may compromise its safety or wholesomeness.
Coved; Coving	Rounded finish to junctions between walls and floors or between two

	walls to make cleaning easier.
Critical Control Points (CCP)	Points at which hazards must be eliminated or reduced to an
	acceptable level.
Cross Contamination	The transfer of bacteria from contaminated surfaces, or foods (usually
	raw) to other foods. This maybe by:
	a) Food handlers, who do not wash their hands between handling
	different products, or after using the toilet, etc.
	b) Direct contact, they are stored next to each other
	c) Drip, one is stored above another
	d) Equipment and surfaces, not cleaning and disinfecting effectively or
	efficiently especially between use for raw and cooked food.
Disinfection	Reduction in the levels of contamination on food equipment, food
	surfaces and food premises, normally by the use of chemicals to
	reduce micro-organisms to a safe level.
Due Diligence	The legal defence, available in Section 21 of the Food Safety Act 1990.
	That a person (or corporate body) took all reasonable precautions and
	exercised all Due Diligence to avoid the commission of the offence
Duty of Care	Food businesses have a duty to ensure any waste produced is handled
	safely and within the law. It applies to anyone who produces, imports,
	transports, stores, treats or disposes of controlled waste from business
	or industry
European Hygienic Equipment	The European Hygienic Engineering and Design Group (EHEDG)
& Design Group (AHEDC)	is a consortium of equipment manufacturers, food industries,
	research institutes and public health authorities, founded in 1989
	with the aim to promote hygiene during the processing and
	packing of food products
E.H.O	Environmental Health Officer, employed by the local authority to
E.H.O	Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation.
E.H.O Electronic Fly Killers	Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation. Equipment to control flying insects, usually by means of UV lamps and
E.H.O Electronic Fly Killers	Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation. Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected.
E.H.O Electronic Fly Killers Fly screen	Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation. Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected. Fine mesh screen fitted to windows and other openings such as doors,
E.H.O Electronic Fly Killers Fly screen	Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation. Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected. Fine mesh screen fitted to windows and other openings such as doors, to prevent ingress of flying insects, and birds.
E.H.O Electronic Fly Killers Fly screen Food / Foodstuffs	<ul> <li>Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation.</li> <li>Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected.</li> <li>Fine mesh screen fitted to windows and other openings such as doors, to prevent ingress of flying insects, and birds.</li> <li>The definition of which is specified in the Food Safety Act 1990.</li> </ul>
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E.H.O Electronic Fly Killers Fly screen Food / Foodstuffs	<ul> <li>Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation.</li> <li>Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected.</li> <li>Fine mesh screen fitted to windows and other openings such as doors, to prevent ingress of flying insects, and birds.</li> <li>The definition of which is specified in the Food Safety Act 1990. Includes;</li> <li>a) drink,</li> </ul>
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E.H.O Electronic Fly Killers Fly screen Food / Foodstuffs	<ul> <li>Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation.</li> <li>Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected.</li> <li>Fine mesh screen fitted to windows and other openings such as doors, to prevent ingress of flying insects, and birds.</li> <li>The definition of which is specified in the Food Safety Act 1990.</li> <li>Includes; <ul> <li>a) drink,</li> <li>b) articles and substances of no nutritional value which are used for human consumption,</li> </ul> </li> </ul>
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E.H.O Electronic Fly Killers Fly screen Food / Foodstuffs Food Business	<ul> <li>Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation.</li> <li>Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected.</li> <li>Fine mesh screen fitted to windows and other openings such as doors, to prevent ingress of flying insects, and birds.</li> <li>The definition of which is specified in the Food Safety Act 1990.</li> <li>Includes; <ul> <li>a) drink,</li> <li>b) articles and substances of no nutritional value which are used for human consumption,</li> <li>c) chewing gum and other products of like nature and use,</li> <li>d) articles and substances used as ingredients in the preparation of food</li> </ul> </li> <li>Any undertaking, whether for profit or not and whether public or private,</li> </ul>
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E.H.O Electronic Fly Killers Fly screen Food / Foodstuffs Food Business	<ul> <li>Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation.</li> <li>Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected.</li> <li>Fine mesh screen fitted to windows and other openings such as doors, to prevent ingress of flying insects, and birds.</li> <li>The definition of which is specified in the Food Safety Act 1990.</li> <li>Includes; <ul> <li>a) drink,</li> <li>b) articles and substances of no nutritional value which are used for human consumption,</li> <li>c) chewing gum and other products of like nature and use,</li> <li>d) articles and substances used as ingredients in the preparation of food</li> </ul> </li> <li>Any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food</li> </ul>
E.H.O Electronic Fly Killers Fly screen Food / Foodstuffs Food Business Food Business Operator	<ul> <li>Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation.</li> <li>Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected.</li> <li>Fine mesh screen fitted to windows and other openings such as doors, to prevent ingress of flying insects, and birds.</li> <li>The definition of which is specified in the Food Safety Act 1990.</li> <li>Includes; <ul> <li>a) drink,</li> <li>b) articles and substances of no nutritional value which are used for human consumption,</li> <li>c) chewing gum and other products of like nature and use,</li> <li>d) articles and substances used as ingredients in the preparation of food</li> </ul> </li> <li>Any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food</li> <li>Any person responsible for ensuring that the requirements of food law</li> </ul>
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E.H.O Electronic Fly Killers Fly screen Food / Foodstuffs Food Business Food Business Operator Food Handler	<ul> <li>Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation.</li> <li>Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected.</li> <li>Fine mesh screen fitted to windows and other openings such as doors, to prevent ingress of flying insects, and birds.</li> <li>The definition of which is specified in the Food Safety Act 1990.</li> <li>Includes; <ul> <li>a) drink,</li> <li>b) articles and substances of no nutritional value which are used for human consumption,</li> <li>c) chewing gum and other products of like nature and use,</li> <li>d) articles and substances used as ingredients in the preparation of food</li> </ul> </li> <li>Any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food</li> <li>Any person responsible for ensuring that the requirements of food law are met within the food business under their control</li> </ul>
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E.H.O Electronic Fly Killers Fly screen Food / Foodstuffs Food Business Food Business Operator Food Handler Food Poisoning	<ul> <li>Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation.</li> <li>Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected.</li> <li>Fine mesh screen fitted to windows and other openings such as doors, to prevent ingress of flying insects, and birds.</li> <li>The definition of which is specified in the Food Safety Act 1990.</li> <li>Includes; <ul> <li>a) drink,</li> <li>b) articles and substances of no nutritional value which are used for human consumption,</li> <li>c) chewing gum and other products of like nature and use,</li> <li>d) articles and substances used as ingredients in the preparation of food</li> </ul> </li> <li>Any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food</li> <li>Any person responsible for ensuring that the requirements of food law are met within the food business under their control</li> </ul> <li>Anyone engaged in an activity which involves handling food, whether open or wrapped / packed</li> <li>Illness transmitted by food, caused usually by infection or intoxication,</li>
E.H.O Electronic Fly Killers Fly screen Food / Foodstuffs Food Business Food Business Operator Food Handler Food Poisoning	<ul> <li>Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation.</li> <li>Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected.</li> <li>Fine mesh screen fitted to windows and other openings such as doors, to prevent ingress of flying insects, and birds.</li> <li>The definition of which is specified in the Food Safety Act 1990.</li> <li>Includes; <ul> <li>a) drink,</li> <li>b) articles and substances of no nutritional value which are used for human consumption,</li> <li>c) chewing gum and other products of like nature and use,</li> <li>d) articles and substances used as ingredients in the preparation of food</li> </ul> </li> <li>Any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food</li> <li>Any person responsible for ensuring that the requirements of food law are met within the food business under their control</li> </ul> <li>Anyone engaged in an activity which involves handling food, whether open or wrapped / packed</li> <li>Illness transmitted by food, caused usually by infection or intoxication, may be bacterial, chemical etc</li>
E.H.O Electronic Fly Killers Fly screen Food / Foodstuffs Food Business Food Business Operator Food Business Operator Food Handler Food Poisoning Food Safety Criteria	<ul> <li>Environmental Health Officer, employed by the local authority to enforce Food Safety Legislation.</li> <li>Equipment to control flying insects, usually by means of UV lamps and high voltage grid. UV lamps must be shatterproof type or protected.</li> <li>Fine mesh screen fitted to windows and other openings such as doors, to prevent ingress of flying insects, and birds.</li> <li>The definition of which is specified in the Food Safety Act 1990.</li> <li>Includes; <ul> <li>a) drink,</li> <li>b) articles and substances of no nutritional value which are used for human consumption,</li> <li>c) chewing gum and other products of like nature and use,</li> <li>d) articles and substances used as ingredients in the preparation of food</li> </ul> </li> <li>Any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food</li> <li>Any person responsible for ensuring that the requirements of food law are met within the food business under their control</li> <li>Anyone engaged in an activity which involves handling food, whether open or wrapped / packed</li> <li>Illness transmitted by food, caused usually by infection or intoxication, may be bacterial, chemical etc</li> <li>Used to assess the safety of a product or batch of foodstuffs</li> </ul>

	factors, such as moisture, temperature and time. Growth may allow small initial contamination to reach levels which make the food upsafe
	or unfit
H.A.C.C.P	Hazard Analysis Critical Control Point. Recognised internationally as "an effective system for the control of food safety"
Hazard	Anything that many cause harm to a person who eats the food
Hazard Analysis	Identifying hazards, the steps at which they could occur and the
	introduction of controls (measures) to either eliminate or control them
Hermetically Sealed Pack	Food sealed into a pack designed to protect it from further
	contamination. Packs may be cans, jars, plastic pouches, and plastic
	and board cartons. Food may be pasteurised or sterilised after sealing
	In the pack or may be sterilised before hand and packed asceptically
	(in a stelle environment). In many cases the pack sear must remain
нтят	High Temperature Short Time A time/temperature ration for the
	effective pasteurisation of milk. Usually involves heating milk to 72°C
	for 15 seconds or 63° for 30 minutes. Other equivalent
	time/temperature ratios are allowed as long as they achieve the same
	effect.
Hygiene	Measures to ensure the safety and wholesomeness of food
Impervious	Surfaces impenetrable to contamination by either micro-organisms,
	chemical or other substances, easily cleaned and disinfected
Medical Questionnaire	A form to be completed by all new staff giving details of their recent
	medical history and that of close household contacts. Contact with
	certain infectious diseases may be transmitted by food handlers
Micro organisms	Any small living organisms, aspecially besterie vesster moulds and
Micro-organisms	viruses
mU/L	Milliunits per litre
National Legislation	In terms of food hygiene include the :
	<ul> <li>Food Hygiene (England) Regulations 2006</li> </ul>
	<ul> <li>Food Hygiene (Scotland) Regulations 2006</li> </ul>
	<ul> <li>Food Hygiene (Wales) Regulations 2006</li> </ul>
	<ul> <li>Food Hygiene Regulations(Northern Ireland) 2006</li> </ul>
Pathogen	A micro-organism that may cause illness
Pasteurisation	Most commonly used heat-treatment for liquid milk in the UK.
	Eliminates non-spore forming pathogens and destroys the majority of
	spoilage organisms. Usually involves a HTST method, heating milk to
	/2°C for 15 seconds or 63° for 30 minutes. Other equivalent
	offect. Pastourised milk must show a pagative result to the
	nhosnhatase test
Pests	Unwelcome animal life in food premises especially mice rats insects
	birds or other animals capable of contaminating food directly of
	indirectly
рН	A measure of acidity. The scale runs from 1 (stong acid) to 14 (strong
	alkali). pH7 is neutral. Levels of pH below 4.5 will normally prevent the
	growth of pathogenic bacteria
Phosphatase	Presence of phosphatase in pasteurised milk indicates that the heat-
	treatment has not been effective. The limit for phosphatase is 350
	mU/L.
Phosphatase lest	I he reference method is ISO standard 11816-1. Alternative analytical
	methous can be used if they have been validated against the reference

	method.
Potable	Safe to drink, usually related to water supply
Production Holding	Dairy farm. Must be registered with Animal Health Dairy Hygiene
Proofing	Structure of premises, especially doors, windows and the entry point of
	service pipes to prevent the ingress of pests e.g. fly screens, brush
	strips on doors etc
Prophylactic Tests	Suite of tests used to test for bovine tuberculosis, include the tuberculin
	(skin) test and the gamma interferon (blood) test
Refrigerator / Chiller	Equipment to keep food cool, normally between 0°C and 8°C
Sterilise	Treatment with heat or chemicals to kill all micro-organisms and
	viruses. Sterilisation will kill spores.
Tamper Evident	Closures that are positioned mechanically and a seal needs to be
	broken in order to open them, which leaves an obvious visual indication
	that the bottle has been opened.
Toxin / Toxic	Poisonous substance, contamination may be caused by growth of
	micro-organisms, chemical spoilage or inherent toxins such as in
	certain plants
UHT	Ultra High Temperature heat-treatment, another commonly used HTST
	method involving a time/temperature ration of 135°C for 1 second
Wholesome	Fit to eat
Ultra violet technology	Used to train food handlers on how to clean hands a surfaces
	effectively by applying a gel (to hands) or powder (to surfaces) and
	using LED light to show the residue of germs left following a normal
	cleaning routine.

### Annex 1

# NON-EXHAUSTIVE LIST OF ESTABLISHMENTS SUBJECT TO APPROVAL

### Meat

- Slaughterhouses
- Cutting plants
- Slaughter on farm (except in the case of the direct supply by the producer of small quantities of meat from poultry-lagomorphs slaughtered on the farm to the final consumer and to retail establishments)
- Game handling establishment
- Establishments producing minced meat, meat preparations and MSM
- Establishment manufacturing meat products

### Live bivalve molluscs

- Dispatch centres
- Purification centres
- Fishery products
- freezer vessels and factory vessels
- Establishments on land

### Milk and dairy products

- Establishments processing raw milk into heat treated milk and into dairy products made from raw milk
- Establishments making dairy products from already processed dairy products (e.g. butter from pasteurised cream, cheese from pasteurised milk of milk powder)
- Milk collection centres

### Egg products

• Establishments processing eggs

### Frogs' legs and snails

• Establishments preparing and/or processing frogs' legs and snails

### Rendered animal fats and greaves

• Establishments collecting, storing or processing raw materials

### Stomachs and bladders

• Establishments treating bladders, stomachs and intestines

### Gelatine

• Establishments processing raw materials

### Collagen

• Establishments processing raw materials

# Establishments proceeding to the re-wrapping of the above products whether of not associated with other operations such as slicing, cutting.

Cold stores insofar as they are used in relation to activities for which Annex III of Regulation 853/2004 lays down requirements.

Wholesale markets insofar products of animal origin are manufactured.