European Guide
for Good Hygiene Practices

in the production of artisanal cheese and dairy products

Target:

Farmhouse and Artisan producers

Farmhouse and
Artisan
Cheese & Dairy Producers
European Network

Revised version of 20th December 2016

INTRODUCTION

Framework

FACEnetwork is a European association which aims to represent and defend the interests of farmhouse and artisan cheese and dairy producers on a European level.

FACEnetwork has been mandated to prepare the present document, in the framework of a specific project financially supported by European Commission, through the contract referenced: SANCO/2015/G4/SI2.701585, signed on 12th March 2015. This contract requested the development of an endorsed community guide for good hygiene practices, dedicated to farmhouse and artisan dairies and cheese houses.

The legal basis used is the **article 9 of Regulation (EC) N°852/2004 on the hygiene foodstuffs,** which states that: *"Community Guides for good hygiene practices and for the application of HACCP principles" (…) should help food business operators to implement good hygiene practices and permanent procedures based on the principles of HACCP. They should be drafted by producers in the relevant sector and assessed and endorsed by the public authorities at European level, under European Commission's supervision."*

In this context, FACEnetwork has written this guide between March 2015 and March 2016. After an assessment period coordinated by DG SANTE within the EU MS, the official endorsement by EUMS at the Standing Committee on Plants, Animals, Food and Feed took place **on 13th December 2016.**

Working team

The team who prepared this guide was composed of [names/organisations, country]:

A group of 5 technical-experts from the sector responsible for writing the document:
- Marc Albrecht-Seidel / VHM - Verband für handwerkliche Milchverarbeitung im ökologischen Landbau e.V, Germany
- Remedios Carrasco / QueRed - Red Española de Queserias de Campo y Artesanas, Spain
- Cécile Laithier / Idele – Institut de l'Elevage, France
- Miroslaw Sienkiewicz / Agrovis & Stowarzyszenia serowarow rodzinnych, Poland
- Paul Thomas / SCA - Specialist Cheesemakers Association, United Kingdom

A group of 4 producers and 1 local veterinary inspector who working closely with the technical-experts:
- Frédéric Blanchard / FNEC – Fédération Nationale des Eleveurs de Chèvres, France
- Kerstin Jurss / Sveriges gardsmejerister, Sweden
- Jane Murphy / CAIS - Irish Farmhouse Cheesemakers Association, Ireland
- Angel Nepomuceno / QueRed - Red Española de Queserias de Campo y Artesanas, Spain
- Irene Van de Voort / BBZ - Bond van Boerderij-Zuivelbereiders, Netherlands

A group of 11 others technicians and producers to proof read the draft chapters all along the program and contribute to corrections, precisions about products or practices:
- Brigitte Cordier / MRE - Maison Régionale de l'Elevage, France
- Sophie Espinosa / FNEC - Fédération Nationale des Eleveurs de Chèvres, France
- Maria Jesus Jimenez / QueRed - Red Española de Queserias de Campo y Artesanas, Spain
- George Keen / SCA - Specialist Cheesemakers Association, United Kingdom
- Marc Lesty / FNEC - Fédération Nationale des Eleveurs de Chèvres, France
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- Bertram Stecher / Sennereiverband Südtirol, Italy

- Katia Stradiotto / ARAL - Associazione Regionale Allevatori della Lombardia, Italy
- Guido Tallone / Casare Casari - Associazione delle Casare e dei Casari di Azienda Agricola, Italy
- Angel Valeriano / QueRed - Red Española de Queserias de Campo y Artesanas, Spain
- Erkki Vasara & Risto Siren / Suomen Pienjuustolayhdistys ry, Finland

General coordination of the project was carried out by: Yolande Moulem, Co-secretary of FACEnetwork

Involvement of stakeholders

During the preparation of this document, structures identified as stakeholders, in different European countries as well as at European level, have been informed and/or consulted.

Around 400 stakeholders have been identified among the following types of representative organizations:

- producers associations,
- small dairies,
- consumers associations,
- competent authorities,
- technical centers.

The information of these 400 stakeholders has been organized in 2 steps:

- the sending of a first information letter in June 2015.
- the sending of a second information letter, and for some relevant European stakeholders, the sending of the complete draft guide itself, in April 2016.

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Section I – THE PURPOSE AND APPLICATION OF THE GUIDE

What type of guide is this?

This guide is a voluntary tool intended for application to the specific practices of the sector of farmhouse and artisan cheese and dairy production.

This Guide contains details of good hygiene practices; as practical and preventive recommendations, to help producers to be confident that their products are safe. These specifications comply with the general hygiene requirements (Regulation (EC) N°852/2004), as well as with the conditions for milk production (section IX of annex III of Regulation (EC) N°853/2004). The Guide also applies the principles of HACCP, following a specific and adapted method, and presents a collective analysis of the hazards concerning the sector.

In addition, as the Guide benefits from the experiences of several EU countries, it provides examples of derogations for small businesses and/or for operators using traditional methods.

Who is this guide designed for?

This voluntary guide aims to be applicable to farmhouse and artisan dairy processors. This sector is generally composed of:

- **"Farmhouse" cheese and dairy producers**, who process milk for the major part, produced by their own livestock, according to traditional methods
- **"Artisan" cheese and dairy producers**, who collect milk from local producers, and process it using small-scale equipment, according to traditional methods.

Thus, in this sector, each food business operator combines at least two or three activities, as he/she is at the same time:

1- (often) farmer / milk producer (concerned by annexe III of Regulation (EC) N°853/2004 and annexe I of Regulation (EC) N°852/2004) – (primary production)

2- (always) processor transforming milk into a final product ready to be eaten by the consumer (concerned by annex II of Regulation (EC) 852/2004 and by annexe III of Regulation (EC) N°853/2004) – (beyond primary production)"

3- (often) seller of all or part of his production to final consumer or to retailer (concerned by annexe II of Regultion (EC) 852/2004) – (beyond primary production)

In the following pages of this guide, the expression "food business operator" will be replaced by the word **"producer"**, which is more used in the field and which generally designates the operators in their several "dimensions" (farmer, processor, seller).

Regarding production methods, the milk can come from cows, sheep, goats, buffalos or domestic solipeds and may be pasteurised or unpasteurised. The main characteristic of the sector is that the milk is typically processed in the farm of origin or in a manufacturing site in the locality- a feature that can contribute to the high standards of hygienic quality necessary for traditional processes, and to a very close relationship between the milk producer and the dairy operator (when they are separate).

To trade their products, farmhouse and artisanal producers often prefer direct or short supply chains, but, they also use longer and indirect routes ("*affineurs"*, wholesalers or supermarkets), in accordance with increasing consumer demand.

Section I – THE PURPOSE AND APPLICATION OF THE GUIDE

Giving these characteristics of the sector, **the scope of this guide is to cover hygienic recommendations for producer's activity, which goes until the point when products leave the cheese plant. It comprises milk production, milk processing and the sales by the producer himself.**

Apart from the producers who are intended to be the principal users of this document, it will also be of interest to other stakeholders, including:

- **Technical experts** of the sector who are in regular contact with the producers and can effectively disseminate the Guide and ensure producers' training adapted to it.

- **Competent authorities**: in line with Regulation (CE) 882/2004 (article 10), this Guide, once endorsed by EU MS, might be taken into consideration during official controls. This guide provides for examples of derogations and adaptations specifically related to this sector as well

What does the Guide contain?

The guide describes a complete **Food Safety Management System (FSMS)** composed of the 3 following parts:

1- "Good Hygiene Practices" (GHP - section II) and "Good Manufacturing Practices" (GMP - section III). In the production of farmhouse and artisan cheese and other dairy products, the management of these good practices is essential to control risk posed by the relevant hazards, providing a foundation for the effective implementation of the HACCP-based plans. To set their own procedures, producers can refer directly to the GHP and GMP procedures of the Guide.

2- HACCP-based procedure, including:

- "Hazard analysis", presented in appendix in order not to weigh on the operational part of the document. This section details the main chemical, physical and microbiological hazards that concern dairy products, and lists the more relevant ones that are referred to in the other sections of the document. For each hazard, the section details its nature, its characteristics and provides concise advice for prevention or control.

- "HACCP-based Plans" (section V) At the level of each type of process flow (milk and products processing), a specific analysis is made, presented as a table (see below), and detailing:
- the hazards to focus on for each step concerned,
- the preventive means adapted to each of these specific hazards. Some of these preventive means are to be considered as Operational Prerequisites, when they are known as crucial for the hazard management at the step concerned. These Operational Prerequisites appear within the key steps pointed out in the guide (see below).
- the checking procedures that prove that this prevention has been made
- the corrective actions corresponding to the hazards and measures described.

3- **Other management policies**, **including: "Risk analysis at milk production's level (section IV), "Traceability" (section VI), "Self-Monitoring Plans" (section VII) and "Non-conformity Management" (section VIII)**

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Focus on the HACCP-based plans

- ***How to use them?***

Each HACCP-based Plan is presented as a separate "sheet" to make it easy for the user to select only the sheets that are related to his products and practices. The sheets are presented in standard tabular format for easy reading. Their expected use is described below:

	Process steps to monitor	**Why do we have to be careful?**	**Preventive actions**	**Checking /monitoring**	**Corrective actions**
Content of the column	Each row of this column corresponds to a process step or an operation. Some rows may be optional and some steps may not apply to a specific product.	This column gives information on the nature and cause of the hazards at each step. (M: microbiological contamination or growth, C: chemical, P: physical).	This column proposes actions to prevent or control the risk at the step concerned. Actions are based on good hygiene practices or other technical advice.	This column describes the means of checking that the preventive actions were carried out efficiently. **In most cases, <u>several options</u> are proposed.** **The checks can be <u>measurements or more subjective actions, based on the producer's experience</u>, for example: "visual inspection", "organoleptic inspection**	This column describes the appropriate action following failure of the preventive measures in order to restore a satisfactory situation. The corrective actions may be: - immediate to be made while production continues, and/or - Longer-term,: to be made before the next production batch
How to use the column?	The producer must review each step **<u>keeping only the steps corresponding to their practice deleting steps which are not applicable.</u>**		The producer has to take into account the preventive actions.	When several options are proposed, **<u>producers must select at least one of them</u>** The legal requirements described must be followed	The producer has to take into account the corrective actions indicated.

In summary, when using these tables, the producer has the responsibility for keeping the <u>steps applicable</u> to their products and practices and the <u>checks appropriate</u> to them.

Despite the efforts put into this Guide, there may be regional and national variations in styles of processing and some products or practices may not have been specifically mentioned in the document. Where a producer adds specific solutions adapted to their system, they should be able to explain and justify them.

In these HACCP-based Plans, some steps are highlighted, colored in grey, because they are more important actions for the management of a hazard. Within these "key steps", information of major importance is written in bold letters. Although advice given at the key steps, based on the experience of experts of the sector, is important to consider, it remains principally technical advice and not a regulatory obligation.

It is important to note that the notion of a key step is different from the HACCP notion of Critical Control Point (CCP). Indeed, a CCP is a specific point, procedure, or step in food manufacturing at which control can be exercised to *"reduce, eliminate, or prevent the possibility of a food safety hazard"*. If it is not fulfilled, a CCP may require that the process is to be stopped – with possible destruction of the batch. When CCPs are defined, they are required to be monitored and recorded for each batch.

Section I – THE PURPOSE AND APPLICATION OF THE GUIDE

In accordance with DG SANTE's guidelines: *"guidance document on the implementation of food safety management systems covering prerequisites programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain businesses"* our system is based on the correct implementation of good hygiene and good manufacturing practices, and also on preventive and corrective measures towards some specific hazards identified at some specific steps.

Thus, it is based in an adapted way of HACCP principles without the necessity of identification of CCPs in raw milk dairy products.

- ***Records***

In farmhouse and artisan cheese dairies, as only one or a few people control all the processes, it may be sufficient to record only non-conformities and the measures taken to correct them. In large food production businesses, the high number of employees makes it necessary to keep comprehensive records, in order to assure effective food safety management.

Non-conformities identified during routine checks carried out during processing (for example - temperature; pH; cleaning procedure; organoleptic quality...) may be recorded only when atypical results are indicated, along with any corrective actions taken. However, the results of the verification tests intended to check the effectiveness of the HACCP-based plan (such as results of microbiological analysis) should be kept in every case. These constitute "historical data", which demonstrate effective food safety management or allows upward trends to be identified.

The Guide does not propose models or templates for records; producers should instead adopt records appropriate to their business. It may be possible for producers to meet their obligation using simplified documentation.

- ***Verification of the efficiency of the Food Safety Management System (FSMS)***

Self-monitoring procedures - based on both microbiological analysis and on other checks (pH, taste, flavor …) throughout the production process – allow the producer to verify the general effectiveness of the plan prepared following this Guide. Examples are given in the section "Self-monitoring plans" for illustration

In the event that sanitary problems are encountered during the process or identified at end-product level, the plan should be updated. Evolution of the production processes must be followed by review and, if required, update of the plan.

Which are the hazards taken into consideration?

In the APPENDIX 1 of this guide is presented the hazard analysis made by the team who wrote this guide, and on which is built the rest of the document. This analysis is based on the experience of the producers, technicians, and experts involved in previous guide's preparation and implementation (at national levels). It leads to the identification of several significant hazards, evaluated in terms of either the ubiquitous nature of the hazard or the severity of its effects, and listed on page 97.

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How the Guide takes “flexibility” criteria into account?

Flexibility can be defined as the possibility to exempt/derogate or adapt some of the content of the hygiene package, particularly in relation to buildings, layout, equipment and operational practices, in some circumstances.

Member States are given the possibility to authorise food business operators not to apply specified requirements of the Hygiene Package. Specific derogations can be granted for foods with traditional characteristics. It is interesting to note that, in some countries, all farmhouse and artisan dairy products are recognised as businesses producing food with traditional characteristics.

Member States can also adapt the requirements laid down in the Annexes of the Hygiene Package in specified circumstances, for example, to enable the continued use of traditional methods of production, or to accommodate the needs of food businesses situated in regions that are subject to special geographic constraints.

Exceptions and adaptations are highlighted within the Guide. The guide provides examples on how they can be implemented in practice in farmhouse and artisan dairies, but before that, the producers should know if they are allowed by national rules. If it is not the case, they can request it, individually or collectively making contact with their competent authority.

Nevertheless, where the annexes of the regulation use terminology as "where necessary", "where appropriate", “sufficient”, etc., it is up to the food business operator in first instance to decide. In this case producers don’t need special flexibility provisions from national authorities; it is a matter of interpreting the requirements in an appropriate way.

This is very important for artisan producers because their methods are generally less well understood than those of industry and there are sometimes barriers to applying measures introduced by this terminology. It is the intention of the Guide to disseminate information to producers on this kind of measures, that are mainly documented in the “Premises and Equipment” chapter.

Section I – THE PURPOSE AND APPLICATION OF THE GUIDE

RESUME- HOW TO USE THIS GUIDE?

1. **Read all of the Good Hygiene Practices and Good Manufacturing Practices (GHP – section II and GMP – section III)**

These are suggestions for best practices and procedures which could be adopted. GHP and GMP are the foundation on which safe food production is based. The producer should select and adopt the recommendations which are appropriate to the products made by their dairy.

2. **Choose from Risk analysis for "milk production and storage on the farm" or HACCP-based Plan "milk collection, storage in the dairy and treatment" for the recommendations about milk as raw material**

Risk analysis for "milk production and storage on the farm" (section IV) is relevant to those with their own milking animals while those buying-in milk may benefit from showing it to their supplier.

HACCP-based Plan "milk collection, storage in the dairy and treatment" (in section V) applies to those buying-in milk or any producer who is heat-treating the milk.
The producer should read the appropriate sheet and adopt the preventive actions adapted to their situation. The producer should follow their adapted plan and carry out the necessary checks and corrective actions. Records should be kept for non-conformities.

3. **Choose from the HACCP-based Plans for products (section V)**

The producer should read the appropriate sheet and adopt the preventive actions adapted to their situation. The producer should follow their adapted plan and carry out the necessary checks and corrective actions.

4. **Explain information to the inspecting authorities**

The producer should be able to explain his FSMS and to prove that he applies it, for example by showing his records (non- conformities and corrective measures related; results of testings…)".

5. **Validate the food safety system and ongoing verification**

Microbiological and chemical analysis can be used to validate (prove the effectiveness of) the plan. Where testing is intended to specifically assess the acceptability of a certain batch of foodstuffs or of a process, the number of sample units set out in Annex I shall be respected as a minimum. The frequency of tests is not set by Regulation but by each producer and this should be based on factors such as historical data or the microbiological sensitivity of the product. It is recommended that new producers carry out tests more frequently on products until sufficient historic data is available to prove the built up effectiveness.

STAFF: GENERAL HYGIENE, TRAINING, HEALTH

Hazards posed by food handlers are easily controlled through simple good hygiene practices and the limited risk posed by the small number of personnel typically working in a small dairy/food production business may allow for some flexibility in the interpretation of regulatory requirements.
These hygiene requirements apply to all food handlers – either working alone or with others.

General Hygiene for any Food Handler

Effective handwashing with soap and water is the principal means of infection control in a food production business. Fingernails should be clean and unvarnished and false fingernails should not be worn. Care should be taken to wash the thumbs and between the fingers. Arms should also be washed where they will come into contact with food. In the case of outdoor milking where water is not available, hand-gel or wipes can be used. However, hands should be sanitised by washing with soap and water at the next opportunity.

Staff should wash their hands:

- Before milking animals.
- Upon entering the food production area.
- Before handling food or ingredients or starter cultures.
- After going to the toilet.
- After using the phone.
- After handling potentially contaminated material.
- Whenever they are dirty.

Staff should, through their behaviour and practices, seek to avoid contamination and cross-contamination of products. In particular:

- Cuts and abrasions should be covered with a waterproof dressing or glove.
- Food handlers should refrain from smoking, spitting, chewing or eating.
- Food handlers should avoid sneezing or coughing over food products.
- Jewellery should not be permitted in production areas though sometimes exceptions are made e.g. for a plain wedding band or small earrings.
- Where accidental release may pose a risk of contamination, allergens (including cereals containing gluten, crustaceans, molluscs, eggs, fish, peanuts, nuts, soybeans, celery, mustard, sesame, lupin and sulphur dioxide) should not be brought into the food-handling area unless as a declared ingredient.

Clothing

Staff should wear designated clothing for milking and clean clothes for food production; clothes worn in the dairy should not be the same ones worn for working on the farm. A change of outer clothing (overcoats or aprons) should be provided when entering the food production area and should be removed before leaving the premises or going to the toilet. Clothing should be in good condition - free from rips, fraying and loose buttons.

A change of footwear (or a footbath) should be provided when required to prevent dirt being brought into the dairy. Where a disinfectant footbath is used, the contents should be refreshed regularly to ensure their effectiveness.

Training

All food handlers and milking staff should be trained; this may be by obtaining a formal food hygiene qualification or through direct instruction by a more experienced colleague. Training should address the food safety hazards encountered in dairy production and promote understanding of good hygienic practice.

STAFF: GENERAL HYGIENE, TRAINING, HEALTH

Health

To reduce the presence of infectious disease on the premises, staff should be in a good state of health. In many member states, formal certification of fitness-to-work in the form of a pre-employment health check is not available; in this case, staff may confirm fitness-to-work by their attendance and should exclude themselves either under a doctor's instruction or in the case of:

- Diarrhoea and/or vomiting within the previous 48 hours.
- Infectious disease likely to be transmitted through food handling – such as *Salmonella*.

Staff may exclude themselves if infected skin or discharge from the ear, eyes or nose cannot be adequately covered and poses a risk of food contamination.

Visitors

Where their clothing poses a contamination risk to products, visitors to the food production area should be provided with a protective overcoat, hairnet (where used) and footwear and should be accompanied by a member of staff to ensure compliance with the general hygiene requirements. Visitors who are suffering from vomiting, diarrhoea or infectious disease should be excluded from the food production area.

Requirements for Equipment and Premises Used for the Production of Dairy Products

The location, design, dimensions and construction of buildings and adjacent areas intended for the production, storage and sale of dairy products, should allow these activities to be carried out in hygienic conditions by preventing direct contact with or proximity to waste materials, dirt, foreign bodies and pests including insects and rodents. The area adjacent to the premises should be kept clear of elements that could attract pests.

The cheese dairy should be as close as possible to the point of milking so as to minimise risks during the milk transport. Where possible, factors such as the direction of prevailing winds and the relative position of the sun (to maintain desired temperatures) will be taken into account when choosing a location for the dairy.

- **General layout and process-flow**. The premises should be suitable for the activities taking place at the dairy, taking into consideration factors such as production volume, cheese varieties produced and the number of operators.

The design of rooms should, where possible, follow the principle of process-flow from raw materials to dispatch of goods, avoiding counter flow; however this principle is not always essential in dairy production because high hygienic standards are required for the milk and the processed products.

It is possible for the dairy to use:

- a single entry and exit door for personnel, raw materials and finished products,
- the same room for different purposes (eg. production, packing, labelling, cleaning)
- separate buildings for some operations (eg. storage of packaging materials, maturation of cheese, sales etc.)

The producer instead takes measures to avoid cross contamination such as washing hands and materials between different steps, separating processes by time or carrying them out simultaneously with sufficient space between them, or protecting (eg. covering) products during processing and/or during moving them (or packaging materials) into the premises...

- **Storage and transport of milk**. While milk is commonly stored in a bulk tank, it is possible to use other containers such as hermetically sealed buckets or churns which may be refrigerated by alternative means (eg.: use of an in-can cooler, depositing cans in cold running water, etc.). Milk may be transported by churn, can, jar, tanker, pallecon or by any other container suitable for food contact. Transport may be made by foot, car, bike, trailer, pipe or other means so long as milk transport conditions are respected.

- **Changing area and toilets**. A designated area should be provided for changing into protective clothing before handling foods, however this does not need to be a separate room. Protective clothing should be stored so as to prevent contamination (eg hooks, lockers, etc.). A footbath is not compulsory but outdoor footwear should be replaced or sanitised before entering food production areas. An adequate number of flush toilets will be provided though these may be in an annexed building (eg. cheesemaker house).

- **Food handling areas: production, drying, maturation, refrigeration, packing and sales**. The premises will be maintained in such a way so as to ensure ease of cleaning and to reduce the risk of contamination. Premises and equipment that are poorly maintained can be a source of physical contamination and provide an environment where pathogens can colonise.

- **Walls and floors** should be smooth, impervious and easy to clean. Suitable materials may include tile or plastic panels though smooth painted surfaces (as long as the paint is non-toxic) may also be acceptable. Surfaces should be free from damage such as chips, cracks, holes or flaking paint. Where possible, the floor in the production area may be inclined to facilitate drainage. In areas without a drainage gully, precautions should be taken to avoid the formation of standing water except in maturation rooms when it is poured on to the floor for technological reasons. To avoid condensation, it is desirable to avoid cladding the ceiling with metal.

PREMISES AND EQUIPMENT

- **Windows and doors** should have smooth surfaces, which are easy to clean, and should be maintained in good condition, especially if they are made with materials such as wood. Windows which can be opened must be protected with an anti-insect mesh. Outside doors and windows will close correctly to avoid the ingress of dirt.

- **Ventilation** should be provided to avoid condensate and allow air exchange. Whether achieved naturally or artificially, air intake should be located away from potential sources of contamination such as stables or barns.

- **Lighting** could be natural or artificial but has to be adequate. while not compulsory, bulb shields can help to prevent breakage.

- **Machinery and tools** should be easy to clean. Food contact surfaces should be made with food-grade materials such as stainless steel or approved plastics. Tools will be stored off the floor.

- **Area or receptacle for storage of ingredients and packaging.** Adequate provision should be provided for the storage of ingredients, in a clean, dry and, if appropriate, temperature controlled area. This may be within the production area, in an adjacent or in a building annexed to the dairy as long as the stated conditions of storage are fulfilled and ingredients and packaging (including bottles and glasses) are protected from contamination. The use of sealed containers permits the storage of ingredients and packaging in the same area.

- **Cleaning area:** An adequate number of easily-accessible sinks should be provided with hot and cold water supplied. One sink may be used for cleaning instruments, cheeses and hand-washing provided that cross-contamination is avoided. Cleaning products may be kept in a separate room or a cupboard within the production area. Chemicals will be clearly marked. Tools and clean equipment can be stored in the processing room on open shelves.

- **Packing and labelling area**. This may be carried out in the processing room provided that cross-contamination is avoided.

- **Sales area (optional)**. The floor, walls and ceiling must be in good conditions but do not require the same standards as the processing room. If needed the sink of adjacent room can be used for washing hands and tools.

- **Waste handling**. Food waste, non-edible by-products and other refuse should be removed from the production areas as quickly as possible, deposited in containers and disposed of in a hygienic way according to national legislation.

ADAPTATIONS

FLEXIBILITY MEASURE

European regulation gives the opportunity to cheese dairies with traditional characteristics to have:

- **Walls, floors, ceilings, windows and doors** made with materials, which are not smooth, resistant to corrosion or impermeable (ripening natural caves, stone walls and floors, etc.).

- **Equipment** used for the production and/or packing made of materials that are not smooth, easy-to-clean and resistant to corrosion such as wooden equipment (shelves, tools, etc.), plant material (shelves of bamboo, raffia, coating plant leaves, reed etc.), stones for pressing, equipment made of copper and brass (moulds, cutters, presses etc.), cloths for draining and for packaging, aluminium foil, etc.

'Cheeses with traditional characteristics' means those that, in the Member State in which they are traditionally manufactured, are

- Recognised historically as traditional products.
- Or protected as traditional food products by a Community, national, regional or local law. Eg: PDO, GPI, PAT, etc.
- **Or manufactured according to codified or registered technical references to the traditional process, or according to traditional production methods.** In some countries, farmhouse and artisan cheeses are recognised as traditional.

Dairies making products with traditional characteristics, who want to take advantage of these adaptations must be sure that their competent authority has notified the European Commission of their use. If it is not the case dairies can request it, individually or collectively making contact with their competent authority.

Maintenance of Equipment and Installations

The condition of premises and equipment should be periodically inspected by the producer and maintenance work, undertaken in case of deficiency. Maintenance should preferably take place outside of production time. This may include:

- Refurbishment of items in disrepair (due to wear and tear): repainting of walls, floors, ceilings or doors, replacement of broken or missing tiles in walls and floors, replacement of air-conditioning or refrigeration equipment filters, condition of insect screens, cleaning and maintaining of water deposits, tools (knives, tables….) doors and windows, slat curtains, revision and cleaning of drainage systems (sinks, traps/syphons), electric panels, lights, etc.
- Checking the performance of machinery according to the manufacturers recommendations or own rules. Some recommendations:
  - Milking machine:
    - Teat cups: check regularly
    - Final Unit: to check if it is clean after each cleaning.

- Where disposable change after every milking'
- Vacuum Guage: check before milking. In case of problem check oil level, belt tension, control valve and vacuum line.
- Pulsators: clean air admission valve (tires).
- A general inspection once per year. If necessary, call a technician.

- Pasteurizer: check the diverter valve, the flow and the temperature sensor.

- Thermographs and thermometers may be checked:
  - Using a reference thermometer or checking with multiple thermometers.
  - Using iced-water (0°C) and steam/boiling water (100°C).

- pH meter: calibration with two buffer solutions.

The equipment or machinery that deteriorate or show anomalies in their operation and could affect the products' security must be replaced or repaired immediately.

The frequency of routine maintenance will depend on the intensity of use, the recommendations made by manufacturers or technical staff, the condition of installations and equipment. The routine maintenance and calibration of devices for monitoring of CCP or for parameters defined in regulation will be done according to manufactures instructions with the following recommended frequency:

- Pasteurizer: annually
- Thermographs or thermometers: annually.

The producer can carry out the verification and calibration, seeking external advice in case of non-compliance.

CLEANING

The principles of cleaning

Cleaning means to eliminate visible dirt deposits of which there are two types:

- Organic deposits such as fat, protein, lactose as far as milk deposits are concerned
- Mineral deposits such as limescale or milk stone which is a mixture of milk fats, protein, lactose and limescale)

In cheese production, thorough cleaning without disinfection is better than systematic disinfection of equipment and materials in order to preserve the natural flora and the balance of the microbial ecosystem. The use of disinfection is a decision for the professional cheesemaker.

Choice of detergents (cleaning products)

A detergent used in an aqueous solution helps to remove deposits (soiling) from surfaces and trap them as a suspension in the cleaning fluid. Several types of detergent exist:

- **Alkaline detergents** which remove organic materials
- **Neutral detergents** which are products for manual cleaning and must not be harmful to the skin.
- **Acid detergents** which remove mineral deposits such as limescale and milk stone.
- **Enzymatic detergents** which contain enzymes that are designed to remove a specific substrate and which constitute a possible alternative to alkaline detergents.

Other additives may be present in the product, to help in the detachment of different types of soiling which may depend on the surfaces to be treated. Examples include:

- **Wetting agents (surfactants)** neutralize surface tension and enable better contact with the deposits,
- **Chelating agents** limit the formation of limescale,
- **Foaming agents** enable the cleaning solution to be applied as a foam which can increase the contact time
- **Disinfectants** such as chlorinated alkali or peracetic acid can be combined with a detergent.

Do not mix an alkaline cleaning product with an acidic product because this neutralizes their effectiveness.

In cases where preservation of the natural microflora in the environment is desirable and the products manufactured comply with EU legislation, it may be possible to clean production equipment by rinsing only with water at a defined frequency.

All cleaning chemicals must be suitable for use in the food industry and compliant with current EU legislation. When choosing cleaning products, it is important to consider:

- The type of soiling or deposit: an alkaline detergent should be selected for organic deposits or acidic detergents for mineral deposits.
- The type of surface: chemicals should not corrode the surface to which they are applied. Equipment constructed from stainless steel or food-safe plastic has the highest resistance to cleaning products and disinfectants whereas cookware category aluminium and aluminium alloy (*almasilium*) do not tolerate alkaline chemicals well. Avoid using cracked, scratched or pitted equipment as it is hard to clean. Cleaning products that contain hypochlorite (bleach) are not recommended for aluminium surfaces and should be used only with cold water to avoid inactivation of the disinfectant. It is not recommended to soak stainless steel in hypochlorite.

- Hardness of water: the efficacy of detergents depends on the hardness of the water used for cleaning. Very hard water can reduce the efficacy of the detergent which can necessitate the addition of chelating agents. The frequency of acidic cleaning must take into account the hardness of the water, the condition of the surface and the process for which the equipment is used. More acid must be used with older equipment which is harder to clean while equipment that becomes hot in use is more prone to milkstone deposits than equipment that is used when cold.

- The cleaning method (eg. automatic or manual) - being careful to achieve a scrubbing action on the equipment surfaces.

Clean with "TACT"

When a detergent is used, it is necessary to define and apply the following parameters:

Time	**T**he chemical should be in contact with the surface for sufficient time.
Action	The mechanical effects of turbulence, scraping or scrubbing actions must be sufficiently vigorous to detach the deposits from the surface,
Concentration	Chemical dose must be sufficient to ensure its efficacy,
Temperature	Cleaning solution must be used at an appropriate temperature and in accordance with the manufacturer's instructions.

For all these factors, follow the recommendations on the cleaning product labels. Ensure to respect temperature recommendation according to the equipment and practices used.

It is recommended, particularly when establishing procedures, to fully check the parameters used for cleaning such as temperature, dose, time and quantity of rinse water.

Cleaning equipment to be used:

- To avoid damaging equipment during cleaning and to avoid encouraging the development of undesirable germs: abrasive scouring pads that scratch the material should not be used. Sponges and cloths can remain damp or wet after use and thereby encourage the development of germs. Rather, use scrubbing brushes or scrapers with a plastic handle and edges or bristles made of nylon for small equipment in cheese production areas or the external parts of milking equipment.

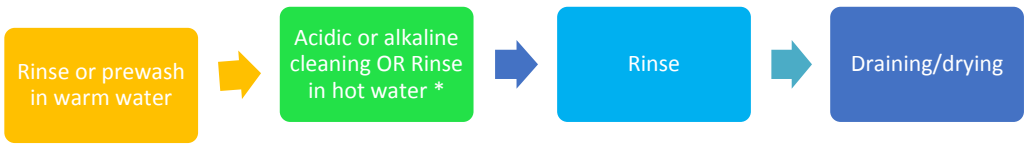
- In order to avoid spraying dirty water on the products or the equipment during cleaning, avoid the use of high-pressure sprays in premises where dairy products are present and rinse preferably with cold water to avoid condensation.

Water quality:

Refer to the recommendations of chapter GHP Water quality.

Protocol for cleaning

Cleaning includes the following stages:



* In case where preservation of the natural microflora in the environment is desirable and the products manufactured comply with EU legislation. Particular care must be taken to provide sufficiently hot water and ensure sufficient mechanical action and contact time.

CLEANING

During the prewash, where there are high levels of soiling on equipment, it may sometimes be necessary to pre-soak or apply mechanical action to remove them. It is essential to rinse equipment well, using sufficient quantities of water to avoid leaving behind residues of cleaning products.

The draining and drying stage should ensure an absence of standing water, which can encourage undesirable bacteria to multiply. Equipment must be arranged (by suspending it or placing it on a shelf, table, or draining board) so as to allow for easy draining. Avoid pooling of water on the ground.

Recommendations for cleaning traditional materials

Traditional materials must be cleaned using traditional methods - which have been (empirically) proven as being effective.

Cleaning production equipment made of wood:
The wood must be cleaned by brushing with water of drinking-quality (some machines exist for maturation boards with the use of water at ambient temperature) or by using soda crystals or by soaking in an alkaline product. Effective drying is important to the cleaning process.

Cleaning of copper vats:
A small quantity of water or whey (0.5-1.0L) should be left in the vat and an abrasive kaolin powder applied to the surface. Brush, rinse thoroughly and drain completely before heating the vat to drive off remaining moisture. A very dilute acid may be used in place of the powder though concentrated acids should be avoided as they can oxidise the copper.

Recommended Frequencies for Cleaning Surfaces and Equipment

Surfaces and equipment	**Recommended frequency**
Milking equipment	
Milking machine	clean after every milking session and with acid detergent at least once a week
Milk tank	Clean after draining
Individual wipes	Clean after every milking
Cheese-making equipment and premises	
Equipment (moulds, trays, tables, cheese harps, tubs, ladles...)	Clean after each use
Floor of the production premises	Clean at least once for every day of production Remove and clean regularly the wastewater drains and/or the syphons (traps).
Walls of the premises and the maturation room (*)	Clean when necessary Cleaning of the maturation room must be carried out when it is empty of cheese
Floor of maturation room	Clean when necessary
Small maturing equipment	Clean when necessary Clean cloths, wipes, buckets, brushes, gloves each day of use
Wood in maturation room	Clean the maturation boards after each maturation cycle Clean shelf-frame when necessary
Equipment for air conditioning, ventilation, insect traps	Regularly dust the grille and filters Clean them at least once a year Check regularly that the condensation waters of evaporators are correctly evacuated and are not dripping onto dairy products
Storage equipment (refrigeration chambers, shelves)	Clean regularly
Reusable packaging material	Clean after each use
Transport material (transport bins, containers, coolers...)	Clean after each use
Vacuum packaging machine	Follow the supplier's recommendations Clean when necessary

(*) Correct cheese maturation can only occur with the right atmospheric conditions (temperature, humidity & presence of air-borne mould propagules). Cleaning and disinfecting this room too frequently can upset this equilibrium and may lead to maturation defects.

Cleaning plans

The producers must have procedures to clean their premises and equipment (including milking equipment). It is not compulsory to document or display these procedures. However the producers must be able to explain them.

Should a written document be prepared, it may include the entire site (milking equipment included). It would be necessary to:

- Identify the premises, equipment and material to clean.
- Define the protocols for cleaning suitable for the premises, equipment and material taking into consideration the recommendations shown below.
- Ensure the personnel responsible for the cleaning operations are trained for the task – though training can be provided internally.

Examples of tables

Plan for cleaning the premises:

Rooms in the workplace (Specifying floors, walls or ceiling).	Cleaning materials (scraper, brush, foam gun etc.)	Name and type of the cleaning products	Dosage, temperature (cold, warm or hot water) and contact time	Frequency of operations	Person responsible

Plan for cleaning equipment:

Equipment (specify the type of equipment)	Cleaning materials (brush, pot-washing machine etc.)	Products used where necessary (specify the type)	Dosage, temperature (cold, warm or hot water) and contact time	Frequency of cleaning	Frequency of disinfection (where necessary)	Person responsible

Where necessary, the specifications for the cleaning product can be added to this plan.

Non–regular cleaning operations (eg: following a non-conformity) may be recorded based on the following model:

Date	Type of action	Product name	Equipment or premises concerned (must be exact)	Name of the person carrying out the operation

DISINFECTION

The principles and frequency of disinfection

Disinfection means to eliminate or reduce to acceptable level microorganisms. In cheese production, and more for raw milk cheeses, thorough cleaning without disinfection is better than systematic disinfection of equipment and materials in order to preserve the natural flora and the microbial ecosystem balance.

The use of disinfection is a decision for the professional cheesemaker. Disinfection may be necessary in the short term to clear up accidents in production facilities or in case of sanitary problems. In such cases, the equipment and premises must not be disinfected all at the same time, but rather follow a progressive disinfection procedure, spread out over several days.

For dairy products other than cheese, and in particular for non-fermented products, regular disinfection is recommended.

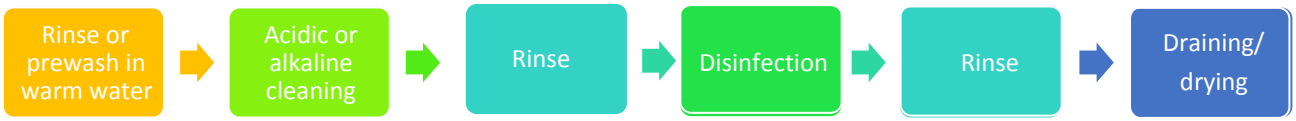
Choice of disinfectant

A disinfectant kills the microorganisms present on surfaces after the visible dirt deposits have been removed. The most frequently used products are sodium hypochlorite solution (bleach), chlorinated alkaline products (with the combined action of a detergent and a disinfectant), oxygenated water or hydrogen peroxide (that can be combined with acid as peracetic acid). Disinfectants must be suitable for use in the food industry and must comply with current European regulations. Disinfection can also be achieved by the heat treatment of equipment.

Safety notice: never mix chlorinated chemicals with acid products as this may release highly toxic chlorine gas.

Protocol for disinfection

Disinfection includes the following stages:



Where it is practiced, disinfection always follows cleaning because only clean surfaces can be disinfected effectively - however it is possible to use combined products such as chlorinated alkaline products that enable cleaning and disinfection in a single step.

Concerning the quality of water used for the disinfection of food contact surfaces, refer to the recommendations of chapter GHP Water quality.

Disinfection plans

Disinfection plans use the same principles as cleaning plans (see GHP cleaning).

Checking the disinfection plan

It is advisable, particularly when establishing procedures, to fully check that the parameters specified for cleaning are satisfied:

- Temperature of cleaning solutions,
- Dose of disinfectant and contact time,
- Quantity of rinse water.

It is possible to monitor the effectiveness of disinfection through the analysis of products rather than surface swabbing. In cases where maintenance of a positive microflora is desirable and where, consequently no disinfection is carried out, it is not necessary to monitor the efficacy of disinfection - as a large number of microorganisms would of course be found.

PEST CONTROL PLAN

Producers should prevent pests from gaining access to the plant and products. Cheese mites are not considered to be pests in this context. However, control of undesirable cheese mites must be included in the cleaning procedures.
Rodents, insects and birds, once inside the premises, can be a source of pathogenic microorganisms causing contamination of raw materials or products (both part-made and finished) or infectious disease among workers.

The hazards posed by pests outside the premises may be prevented by:

- Keeping the surroundings clean and dry; harden and improve drainage of ground surfaces where necessary.
- Installing traps against rodents around production premises.
- Preventing wild birds from nesting in the roof space and around the farm.
- Visual inspection of traps and roof space and removal of dead pests when they are found.
- Carefully sealing the joins in the structure of the premises to prevent the entry of insects.
- Where traps are already installed, increasing the number of traps or calling a specialist pest control company.
- Spraying insecticide outside the plant where insects are present in high numbers.
- Using appropriate and approved pesticides within their shelf life.

The hazards posed by pests within the premises may be prevented by:

- Visual inspection of the premises.
- The use of UV insect killers or fly-papers in production areas, warehouses and auxiliary facilities. Fly-paper and UV insect killers should be located to ensure dead flies do not fall off into vats, into product or packaging.
- Cleaning UV lamps periodically and changing bulbs according to manufacturer's recommendation.
- The replacement of fly-papers when full.
- Installing dense insect-proof mesh in all opened windows, doors or inlets/outlets (e.g. extractor fan vents) and changing mesh when damaged.
- Keeping unprotected windows and doors closed during production.
- Placing adequate screens or gates on drains in order to prevent rodents' and pests' entry.
- Keeping packaging materials in dry places inaccessible to rodents, flies and other pests.
- Not leaving unpackaged products exposed for longer than necessary.
- Using exposure rodenticides in dark nooks and unused spaces like caves, lofts etc.
- Using only proper and approved rodenticides, within their shelf life.

Where pest activity is identified in the premises, products or packaging, it is recommended to:

- Remove of dead pests and scattered or partially eaten poison.
- Remove products with visible signs of pest activity from the premises - as well as pest-damaged packaging materials.
- Thoroughly clean and disinfect the premises, ripening rooms or stores (including shelves and racking).
- Review procedures.

Whether in order to prevent pests or when pest activity is identified, the producer can choose to commission a professional pest control contractor.

WATER QUALITY

Water used in farmhouse and artisan dairies can be a source of contamination. Measures taken to ensure that water meets the criteria of Directive 98/83/EC, depend on the source of the supply.

Clean water can also be used in primary production, if the competent authority so permits and its characteristics have been defined.

Public Network Supply

The water is supplied from the public mains, however the dairy may:

- Store water in external tanks or use containers to carry water from the public network to the dairy.
- Subject the water to simple treatments such as pH neutralization or 'softening' of hard water.

Sampling

When the water comes from the public network supply it may be considered that hazards are already controlled and sampling and analysis are not required to be carried out. Some Member States do not require the food business operator to carry out analysis of water where it is supplied from the public water network and the results of official water tests are available from the water supplier.
See: "DG(SANCO)/2010-6150 - MR FINAL", point 5.1.3: "*Flexibility with regard to the implementation of procedures based on the HACCP principles in four of the visited MS"*.

Transport, storage or simple treatments and maintenance of the water installation

- Equipment used in the transport, storage or treatment of water should be clean, should not contaminate the water with pathogenic microorganisms and should be made of materials which will not contaminate water either with chemical substances in quantities greater than those permitted or with prohibited substances.
- Storage or transportation vessels should be covered to avoid contamination and should be kept in good condition, free from cracks or fissures which can harbour microbiological contaminants.
- The internal water installation (pipes and taps), shall be kept in good conditions so as to avoid any source of contamination.
- Some Member States may ask for water analysis to prove that those eventual transport, storage or simple treatments do not change the characteristics of potable water. If this is the case, an annual analysis will be carried out.

Own supply

Other sources of water used in dairy production across European Union include wells and bore holes, surface water, rainwater, snow, etc., and may be with or without elements of storage, transport or treatment. The chemical and microbiological quality of the water should be ensured by protecting and maintaining the source of the water, if possible, and the distribution system. In any case, sampling and analyses will inform about the quality of the water.

Sampling

- Water analysis should be carried out to ensure chemical and microbiological quality before starting to use water from sources other than the public supply.

Annual analysis shall be carried out for both microbiological and chemical parameters determined in each Member State, however based on historical results of water analysis by the dairy or data supplied on national drinking water information systems, it may be possible for the producer, if permitted by the national competent authority**:**

- not to monitor those parameters that are unlikely to be present in the water in concentrations in excess of permitted levels.

- to reduce the frequency of analysis (eg. every two years instead of annually).

Some member states allow for the relaxation of frequency or requirement for testing for chemical parameters in geographical areas in which no particular environmental pollution has been identified.
In cheese dairies which produce hard, firm/semi-hard cheese, it is considered that the non-conformity of water due to an excess of nitrate is unlikely to be relevant, given that the use of nitrate is permitted, according to Regulation (EC) No 1333/2008, in a maximum quantity of 150 mg/L of milk intended for processing, or in an equivalent dose where it is added after the elimination of the whey and the addition of water.

Microbiological hazards control

Microbiological quality may be guaranteed by:

- Disinfection. (Compulsory in some Member States). Where chemical disinfection is carried out, the efficiency of the treatment will be verified and the amount of disinfectant residues will be checked periodically to ensure compliance with any national limits. The concentration of disinfection by-products should be as low as possible.
- UV filtration, heat treatment, (including boiling the water) or other means.

Water intended to spin the mozzarella curd is treated at 80-90ºC for technological purposes. This heat is sufficient to inactivate the microbiological hazards of concern which may be present in the water

Corrective measures

The non-conformity of water tested for 'indicator' parameters (eg. Colony count 22º or sulphates), as defined in national legislation, should not be considered, in itself, to pose a safety concern to the dairy products, although the cause should be investigated and remedied on a case-by-case basis.
In the event of failure to meet a parameter which is not used as an 'indicator' and which may present a risk to food safety of the dairy products, use of the water should be suspended until the issue has been corrected. In the meantime, water should be obtained from an alternative source (eg. bottled water, transported water, etc.).

CULTURES

The use of acidifying cultures is not compulsory but where they are employed for technological or hygiene purposes, the following good practices are recommended.

Because they must be efficient in managing acidification some technical recommendations are detailed here, providing information necessary to complete the HACCP-based plans

Cultures that enable the acidification of a product may be: indigenous cultures such as those obtained from whey, made up from the milk microflora; commercially available direct-to-vat inoculation (DVI) cultures (in freeze-dried, liquid or frozen form); semi-direct (selected strains used as a preliminary inoculum in order to obtain a quantity of bulk starter) or the (liquid) bulk starter itself. Whilst frozen cultures should be stored at -45°C, this is rarely possible in a small dairy context. Indigenous cultures such as whey, contribute to product 'typicity' by bringing varied and specific flora which can make them less susceptible to bacteriophage than other cultures.

Where adjunct cultures (non-acidifying cultures) are used the good hygiene practices and hygiene recommendations outlined should also be followed.

Origin and Supply of Cultures

The culture used should be suited to the technology being employed in order to enable successful acidification. Do not use suspect cultures, those which are badly preserved or which have passed their expiry date. When ordering commercial cultures, ask to avoid dispatch over weekend. Check the condition of the culture upon arrival; especially when the delivery time exceeds 3 days. For frozen cultures, ensure that they are still frozen on arrival.
In lactic technology, whey used as a culture must come from good quality curd, being rated by its appearance, odour, colour, taste or pH, acidity of the supernatant whey and its storage temperature. Where curd is used as a culture it must meet the same criteria. Indigenous cultures can also be created directly from the milk of hand milked animals. This technique can be used in an environment in which pathogens and spoilage flora are controlled - but which is not sterile. The milk is taken from animals which do not present signs of mastitis and must be performed using clean equipment and after hand-washing.

The incubation takes up to 48 hours, preferably in a production room (~20°C) and a gel must form within that time.

It should be more or less firm with the characteristic odour, appearance and homogeneity of a well-made curd and sufficient acidity (>75°D, 32-34 °SH, or pH<4.5).

When preparing indigenous thermophilic cultures, producers must carefully follow the correct temperatures and ensure the development of sufficient acidity. This can involve, for example, "thermisation" up to 60° C for 2-3 minutes, cooling to 45 °C and incubation at that temperature until the acidity reaches eg 54-63 °D, 24 - 28 ° SH or pH 4.7-4.5, depending on the technology employed.

Storage of the culture

Commercial cultures should be stored them at the temperature recommended by the manufacturer. Cultures should be stored at cold temperatures, away from humidity and light and within their expiry date. In the case of DVI cultures, check for signs of clumping. For liquid cultures check odour, appearance, the appearance of the curd obtained or the acidification curve of the inoculated milk. The quality of liquid starter may also be evaluated by its acidity or pH before use. Close part-used sachets containing cultures correctly or store them in a container in a clean cold place using them as soon as possible after opening.

Whey used as a culture (back-slopping) must be stored in a clean place and in a clean container. In order to avoid a loss of acidifying capacity, it must not be stored for more than 3 days. Its use may be postponed by freezing but it should be using within 10 weeks following storage at -18°C. It is recommended to add powdered milk or previously-boiled milk before freezing. Whey should not be refrozen after defrosting.

Precautions whilst measuring-out cultures

It is recommended to wash hands beforehand measuring-out cultures and to perform the task in a clean place using clean equipment.

For commercial liquid cultures do not pipette directly from the culture; transfer a small quantity of the culture into a clean container before pipetting from it and discard the remainder. Replace the lid on the culture after decanting. Similarly, if using a sachet of freeze-dried culture more than once, measure-out in such a way that the container and the remainder of its contents are not contaminated (eg. clean/disinfect spoons where used).

Dose

Ensure that inoculation dose is respected, adjusting the quantity carefully according to the volume of milk. Pack-size is not always suited to the small volumes needed by small producers: where the volume of milk does not correspond to the dose in the sachet, cultures may be diluted in 1 litre of UHT milk and the required dose of the culture measured proportionally. Do not proceed to ripen the milk before cold storage. The preparation may be preserved before use at 4°C and must be used within 2 days after dilution at the latest, stored in a sealed container.

Cultures can also be weighed out using small sets of scales. Where DVI cultures are packed by activity without standardized pack weight, the quantity should be worked out as a proportion of the total pack weight for each sachet opened.

Preparation of the Culture

Some indigenous cultures, semi-direct commercial cultures and bulk starters require a preparation phase (incubation or sub-culturing). Clean equipment must be used and any milk is used during incubation/ sub-culturing, must either be Ultra-Heat Treated (UHT) or previously boiled.

In order to avoid the presence of inhibitors in milk, where milk is supplied directly from the farm it should comply with the appropriate withdrawal period after antibiotic treatment. Take milk from animals that show no signs of mastitis and do not use the milk of an animal within 7 days of it giving birth.

The incubation temperature must be suited to the culture used. Bulk starter preparation temperature should be appropriate to the type of culture eg. thermophiles incubated at thermophilic temperatures. The dose and incubation time must be established according to the supplier's recommendations and to the quality of culture obtained. The quality of cultures used after incubation can be evaluated by appearance, odour, acidity or pH. Where necessary, before sub-culturing, check the quality of the culture according to criteria defined under ‘Origin and Supply of Cultures’.

Inoculation of the Milk in the Vat

The temperature of the milk should be suited to the culture used; respect the dosage and the optimal conditions of use for the culture.

Section III – Good Manufacturing Practices
COAGULANTS: PRODUCTION, STORAGE, USE

This sheet covers the control of hazards in:

(i) The use and storage of commercial coagulants,

(ii) The production of coagulants by the dairy for their own use, including those of animal origin (generally kid and lamb) and vegetable origin (eg. *Cynara* spp). Regulation (EC) No 1332/2008 requires enzymes which are added to food to perform a technological function to be subject to a safety evaluation by the European Food Safety Authority (EFSA) prior to inclusion on a list of approved enzymes. The submission of proposals for all the different traditional methods for the extraction of enzymes is practically impossible and possibly unnecessary taking into account that the traditional production of coagulants in farmhouse cheese dairies have a long history of safe use. Among the applications submitted by March 2015, many for recombinant coagulants, a few concerned proteases from *Cynara* and rennet (from the abomasum of ruminants) and it is anticipated that these will appear on the approved list.

Controlling Hazards during the use of Commercial Coagulant

Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
M, C: Coagulants can contaminate milk with pathogenic bacteria or chemical residues.	Use only coagulants with a certificate of conformity, suitable for food-use. Respect manufacturer's recommendations (dose, dates, temperature). Maintain good hygiene when carrying out all operations and replace the lid on the bottle after decanting coagulants.	Visual and organoleptic inspection	Reject coagulants of suspect odour, colour or appearance. Amend handling and storage procedures. Change of supplier.

Controlling Hazards during the Production of Animal Rennet

In traditional practice, the abomasum (of a suckling ruminant) which may be dried, salted or frozen to preserve it prior to extraction of the chymosin enzyme, is chopped or prepared as a paste (including the stomach contents) and macerated in a brine (typically 10 -20% salt w/v and pH4.5-5.0). There are slightly different specific practices in different regions across Europe though the main hazards are summarized below.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
State of health and diet of suckler	C: The mother's milk may be contaminated and/or show presence of veterinary medicines	Follow specific guidance relating milk production (see "risk analysis for primary production")		
	M, P: Sucklers may swallow other substances which may contaminate coagulants (eg. soil)	Keep the animal housing and bedding clean and dry. Sucklers may be isolated from birth in a clean area or in the case of a free-range production system left with their mother so as to avoid stress.	Visual inspection of the housing and conditions of the animals	Reject contaminated abomasa.

COAGULANTS: PRODUCTION, STORAGE, USE

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
	M: If mothers or sucklers are not healthy, they can transmit infectious disease.	Ensure that the feeding mother and offspring are healthy, of good weight, without diarrhoea or behavioural signs of sickness.	Pre and post-mortem inspection	Reject abomasa of sick animals
Removal of abomasum	M: Contamination of abomasum with intestinal bacteria during slaughter and cutting.	Remove the abomasum so that it, or other viscera, are not damaged or contaminated.	Visual inspection (light brown colour with white fat, without gases)	Reject contaminated abomasa.
Dehydration by drying or smoking (optional)	M, P: During drying, contamination of the abomasum by insects or their larvae.	Dry the abomasum in areas free of pests.	See GHP “pest control”	Check abomasa and discard any contaminated ones. Find a more suitable place or fit mosquito netting
Conservation of dry abomasum	M, C, P: Contamination by moulds or development of mites.	Store in a dry container and if possible, covered with salt	Organoleptic inspection (visual and olfactory)	Reject abomasum with mites, moulds or bad odour.
Dehydration with brine (optional)	M, C, P: Contamination during dehydration caused by poor quality of salt, insufficient quantity of salt or unsafe handling.	Use a clean receptacle suitable for food use, maintain good hygiene, use suitable quality and quantity of salt. Avoid contamination of the receptacle. For technological reasons it is recommended to use abomasa within 1-2 years.	Organoleptic inspection (visual and olfactory)	Reject abomasa with do not have the expected colour and smell or where a gas is produced.
Salting(1)	M, C, P: Contamination caused by poor quality salt and or insufficient quantity of salt(1)	Use salt of known origin or certified as suitable for food-use.	Visual inspection	Reject salt which is visibly contaminated or not suitable for food use
Macerating and extraction of enzymes	M: Microbiological contamination through the water used, unhygienic handling or inappropriate salt concentration	Wash hands before preparation. Use clean instruments and potable water suitable for making coagulants. Follow the specified salt concentration and time.	See “water control” sheet	A producer should reject any coagulant they consider to be of doubtful hygienic quality.
Storage of rennet	M: Proliferation of possible bacteria present in the rennet or by contamination	Store in a cool place, with a quantity of salt appropriate to the recipe.	Organoleptic inspection: Acid smell. light gold colour (liquid extract) or light brown colour (rennet pastes)	Reject coagulants which do not have the expected colour and odour.

(1) Salting can be carried out during and/or after dehydration and for conservation.

COAGULANTS: PRODUCTION, STORAGE, USE

Controlling Hazards during the Production of Vegetable Coagulants

There are approximately 20 different species of plants identified as milk coagulants. This section focuses on the most common, (*Cynara* spp). The process consists of collecting and drying the flower, maceration of the pistil in water (4-8 hours following recipe) before filtration and immediate use or cold storage for up to 7 days.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Foraging (country-side gathering)	M, C: Plants may be contaminated by pesticides and other chemical pollutants.	Gather plants in areas known to be free of contamination. Do not gather plants caked in earth or mud, broken or in along the edges of busy roads.	Visual inspection. Careful selection of location and quality of foraged plants.	Reject broken or dirty plants or those from areas where hygiene is in doubt.
	M, C: Growth of moulds or development of mycotoxins if not gathered when dry.	Gather on dry days.	Visual inspection and aroma.	Reject plants which are not dry
Storage of plants	M, C: Development of mycotoxins if not stored in a dry place.	Store in dry place.	Organoleptic inspection: colour and aroma.	Reject plants which are not dry or those of doubtful appearance and smell.
	M, P: Contamination by rodents or other pests.	Store away from pests.	Visual inspection	Reject plants where presence of pests is suspected.
Maceration to extract the enzyme	M: Microbiological contamination through the water used, poor hygiene during handling or excessive maceration	Wash hands before preparation. Use clean instruments and potable water suitable for making coagulants. Recommended time: 4-8 hours	See “water control” sheet	A producer should reject any coagulant they consider to be of doubtful hygienic quality.
Storage	M: As well as being enzymatically unstable the extract can allow the growth of pathogenic bacteria	Use the enzyme immediately after preparation or for up to 7 days if stored in a cool place.	Visual inspection: brown colour. Measurement of temperature.	Reject solutions if more than 7 days old or those that have not been stored in cool conditions

Section III – Good Manufacturing Practices
ADDITIONS TO THE MILK AND CURD

This Section relates to additions made to the milk in the form of food improvement agents which includes additives, flavourings and enzymes as well as other ingredients such as herbs or spices, nuts and fruit. The addition of salt, cultures and coagulants are covered separately.

'Additives' are substances which are not normally consumed as food in itself but which may be added to food to perform a technological function such as preservation; the term should not be confused with other ingredients which are added to the milk or curd such as nuts, fruit, herbs or spices.

Food enzymes contain one or more substances capable of catalysing a biochemical reaction which are added to food to perform a technological function such as coagulation of the milk, inhibition of microbial growth (eg. Lysozyme used to prevent 'late blowing defect' which will be regulated as an additive until the community list of food enzymes is established) and accelerated maturation or flavour development (eg. Lipase). Though they are a source of enzymes, microbial cultures which are added to dairy products are outside the scope of EU regulation.
Foods should not be placed on the market if made using:

i) Food additives which do not comply with Regulation (EC) 1333/2008, as amended;
ii) Enzymes which do not comply with Regulation (EC) 1332/2008; or
iii) Flavourings which do not comply with Regulation (EC) 1334/2008 and smoke flavourings which do not comply with Regulation (EU) 1321/2013 implementing Regulation (EC) 2063/2003

The labelling of products made with food improvement agents should not mislead the consumer (eg. by implying a product flavoured with liquid smoke has been naturally smoked).

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Addition of Ingredients and Food Improvement Agents	C: Use of additives, enzymes and processing aids that are not suitable for food processing or where their application does not comply with stated conditions of use.	Check that food improvement agents are suitable for food use and permitted for the type of dairy product. Observe the stated conditions of use and dosage, particularly where legal limits exit for food products.	Visual inspection. Careful measurement of the quantity of additive. Check storage conditions and review expiry date (if applicable).	Recall and reprocess if the additive exceeds permitted levels (where defined). If reprocessing cannot remove the hazard or if the additive is not permitted, dispose of products as “not fit for human consumption”.

	M, C, P: Contamination of the milk or products through contaminated ingredients (including food improvement agents and charcoal used in or on some cheeses). Ingredients such as bought in herbs may come from a variety of different sources, produced using different methods with varying standards of hygienic practice and microbiological quality. *E. coli* and *Salmonella* spp. have been reported in dried herbs.	**Use only ingredients obtained from a reputable supplier or known source and checked upon delivery and before use. Heat-treat herb mixes or fruit where the source and harvesting conditions are not known**. Cover and store in accordance with the supplier's instructions. Reject ingredients which have deteriorated or have exceeded their expiry date, are mouldy or show signs of pest infestation. (1)	Manufacturer's product specification and Certificate of Conformity. Food improvement agents should conform to specifications listed in Regulation (EC) 231/2012 Visual inspection. It is possible for verification to be carried out through product testing as part of the self-monitoring plan rather than by testing the ingredients.	Reject the ingredient or the dairy product made with it if contamination is suspected Reject the ingredient or food improvement agent if physical contamination is suspected and report to supplier Consider change of supplier.
	C. Ingredients that may contain allergens, (such as dried fruits containing Sulphur Dioxide or Lysozyme derived from egg white) may pose a risk to susceptible consumers.	Allergenic ingredients listed in Regulation (EC) 1169/2011 Annex II should be declared to the consumer either in the ingredients list or by using the words "contains (name of allergenic ingredient)" where the product does not have to display an ingredients list.	Supplier's product specification or use ingredients of known origin (e.g. herbs grown and harvested by the producer)	Products which contain undeclared allergens must be removed from sale and relabelled.

(1) See also GHP Pest Control.

SALTING

Although salt is a very safe product it is necessary to safeguard the following risks:

- Chemical contamination by pollutants such as copper, lead, mercury or cadmium.
- Physical contamination by visible impurities.
- Microbiological contamination in the case of brines used to salt cheese.

With regard to microbiological contamination, it is important to note that brine is not sterile and should not be expected to be; a complex microflora can be desirable for technological purposes and may contribute to the safety of the brine.

How can contamination be avoided?

The salt should always be of good quality, suitable for food-use. The following measures should also be taken, depending on the type of risk and the technology of the dairy:

- Physical hazards can be avoided by visual inspection of the salt throughout the salting and by removing possible abnormal particles. If glass or metal contamination is suspected the salt should not be used.
- Microbiological hazards (in brine) may be avoided by:
    - Use of potable water.(1)
    - Storing the brine in a clean container. Where it is not possible to locate the tank within the production or ripening areas and where contamination is deemed to be possible (eg. outside the premises) it is possible to cover the tank with a lid.
    - Maintaining an acceptable temperature appropriate to the technology employed.
    - Addition of salt and stirring after each use.
    - Regular removal of suspended particles. Diatomaceous earth filters may be useful for reducing the frequency of renewal of brine.
    - Complete or partial renewal of the brine as frequently as it is used, the concentration of salt and the temperature demand.

It is not recommended to pasteurise brine as this can remove important ripening organisms which provide positive competition against the contamination of the rind by pathogenic bacteria as well as inhibiting contamination of the brine itself by salt-tolerant pathogens. Furthermore, brine can corrode HTST (High Temperature Short Time) pasteuriser plates.

In addition to the above measures, some producers may employ the following controls – though these may not be appropriate for all cheese technologies:

- Maintain a salt concentration ≥19.5° Baumé (equivalent to 21% w/v) to limit the growth of the most halotolerant pathogens (*Listeria* and Coagulase Positive Staphylococci).
- While the pH of most brines is higher than the level required (in the absence of other factors) to control the growth of pathogens, some producers monitor the brine to ensure that it conforms the expected values appropriate to the technology and recipe employed.

(1) See GHP Water quality

PRODUCT STORAGE AND TRANSPORT

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Storage in refrigerated displays, cabinets, cold rooms etc.	M: Contamination of unpackaged products with pathogenic microorganisms during handling.	Wear clean protective clothes, thoroughly wash hands.	Visual inspection.	If it is a recurrent issue review training of staff.
	M, P: Contamination of unpacked products (especially fresh) by microorganisms or foreign bodies from walls and/or shelves of cabinets or cold stores.	Keep all equipment and rooms in good hygienic condition. Maintain the equipment with appropriate frequency. Do not leave doors of cabinets or stores open longer than necessary.	Visual inspection.	Replace damaged or defective equipment. Refresh store rooms when they cannot be maintained in a satisfactory standard.
	M, P: Cross-contamination between stored products.	Do not allow contact of packed and unpackaged products. Remove spoiled or damaged products and all unnecessary items.	Visual inspection,	Adjust to obtain the correct storage temperature. Group and place stored products properly.
	M: Some fresh products are very sensitive to the development of harmful bacteria if the temperature is too high.	Immediately after production and ripening, place products in cold stores at the correct temperature.	Visual inspection, Temperature control.	Immediately adjust to obtain the correct temperature Remove damaged or spoiled products.
Loading	M, P: Physical and/or microbiological contamination by harmful microorganisms from:	Protect unpacked products against contamination (washable containers and other vessels).	Visual inspection.	Reject spoiled or damaged products and dirty, damaged or inadequate containers
	- Environment	Load products only into vehicles and containers appropriately designed, and which are maintained in good repair, clean and/or disinfected where necessary.	Visual inspection.	Repeat vehicle cleaning before loading
	- Other Foods	Avoid contact between packed or unpacked dairy products with other unpacked food products (meat products, fish, poultry, eggs,	Visual inspection.	Separate improperly placed products. If food has not been separated,

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
		vegetables.)		reject products where contamination (eg. with meat juices) has occurred and/or is suspected.
	- Handling	Keep high standards of personal hygiene. Wash hands thoroughly.	Visual inspection.	
Transport	M: Growth of pathogenic microorganisms in some fragile and sensitive products due to the temperature increase during transport.	Define the maximum acceptable temperature and ensure that it is always kept below this limit during transport. Use properly equipped roadworthy, refrigerated transport.	Temperature control.	Withdraw non-conforming or spoiled products Ensure efficient and appropriate cooling during transport
Unloading at the customer's premises	M: Growth of pathogenic microorganisms in some fragile and sensitive products due to the contamination during unloading.	Unload products quickly and place them at appropriate temperature. In case of deliveries common to several customers it is better to prepare a separate container to every customer.	Temperature control.	Withdraw non-conforming or spoiled products.

Section III - Good Manufacturing Practices
DIRECT SALE

The sheet GMP Direct Sale concerns a sale directly to the final consumer in farmer shops, on marketplaces, on exhibitions and fairs.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Display of products	M: Development of pathogenic microorganisms in products sensitive to temperature increase.	Maintain appropriate temperatures. In case of outdoor sales protect against sun, rain and dust.	Temperature control.	Withdraw products or find another application (change of intended use).
	M, C, P: Microbiological, chemical or physical contamination of unpacked products by environment (dust, insects, touching by people.)	Unpackaged fresh products should be displayed in conditions which prevent contamination.	Visual inspection.	Withdraw products or return them to the ripening room. Clean dirty equipment.
	M, C: Contamination of products by retail equipment: tables, pads, mats, price tags, decorative materials.	Use only clean materials Do not use the same tools and utensils for dairy products and other food products sold together (meats, eggs, vegetables etc.). Where contamination with allergens is possible, different tools for different dairy products can be used in order to avoid cross-contamination with allergens	Visual inspection	Clean dirty utensils and equipment and replace where they become unacceptably worn.
	M: Cross-contamination of products displayed next to each other on the counter.	Avoid contact between packed and unpackaged products Take care to avoid contamination between unpackaged dairy products and other food products (meats, eggs, fish poultry.)	Visual inspection	Withdraw non-conforming products. Reorganize counter displays.
Sale of products	M, P: In case of sales from the store, contamination by customers if they enter into the production area.	Customer may be permitted restricted access to production facilities only in protected clothes and overshoes.	Visual inspection	Restrict access of customers or visitors. Establish strict rules for visiting.

Section III - Good Manufacturing Practices
DIRECT SALE

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
	M, P: Microbiological or physical contamination by the seller.	Keep hygiene standards, wash hands. (1)	Visual inspection.	Retrain the staff.
	M, P: Contamination by retail utensils: knives, pliers, balances, calculators, pens etc.	Make sure all utensils are thoroughly cleaned (and/or disinfected if necessary) after use. Weigh products after packaging or weigh on a piece of the packaging material.	Visual inspection.	Improve cleaning procedures, retrain the staff.
	M, C, P: Microbiological, chemical or physical contamination by packaging materials and/or labels where they are a food-contact material.	Store packaging material in dry and clean place, protected against dust, humidity, pests and insects. Use only packaging material approved for dairy food.	Visual inspection.	Reject damaged or dirty packaging and/or labels.
End of sale on market place Return of unsold products to the production plant	M, P: Contamination of unsold products (especially fresh) during re-packing after sale. M: Growth of pathogenic microorganisms in some fragile and sensitive products returned unsold to the plant.	Repack the most vulnerable products first. Wrap pieces of cheeses (eg. with foil). Clean utensils after sale as soon as possible. Place products immediately in cold store or ripening room. Unpacked dairy products put out for sale should not be placed in contact with other dairy products in the store.	Olfactory and visual inspection.	Review procedures for storage of products. Withdraw non-conforming or spoiled products, return products to the store or ripening rooms, find another safe application. Reject product which has thawed and it should not be refrozen

See also: 1) GHP Staff General Hygiene, Training and Health

Section IV- Risk analysis for primary production
MILK PRODUCTION, STORAGE ON THE FARM

This section covers the hygiene relating to the production and storage on the farm of milk as raw material. It has been set up on basis of the specificities of cows, goats and sheep's milk.
*Some steps are particularly important relating milk intended for the production of raw milk dairy products: they are marked with an asterisk.

LR: Legal Requirement

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking	Corrective actions
Animal Husbandry	**M: Risk of milk contamination by bacteria which are pathogenic to humans. ***	**The farm must be brucellosis free or officially brucellosis free (for the three main dairy species).** **For cows, the farm must be officially tuberculosis free. For species that are sensitive to tuberculosis, the herd must be regularly tested within a surveillance plan framework approved by the competent authority.** **Where cows are also present, goats must be tested for tuberculosis.** **Ensure that animals introduced are disease free as well as other herds in contact**	**Farm register kept up to date.** **Results of compulsory prophylaxis analysis and on introduction of new animals if it is mandatory.**	**Withdraw the milk of sick or positive testing animals (for production and human consumption).**
	M: Lower resistance to disease in animals due to poor housing conditions or to unsuitable or insufficient feed or poor management/environement.	Provide sufficient ventilation. For bedding areas, ensure bedding surface is well adapted (to the breed, the farm building, the type of livestock management etc.) Store bedding materials in a dry area.	Visual and olfactory inspection of bedding and ambience in the building.	Future corrective actions: adjust ventilation.
		Feed animals in an appropriate and balanced way according to their needs.	Visual inspection of the physical state of animals.	Review rations distributed and seek professional advice.

Section IV- Risk analysis for primary production

MILK PRODUCTION, STORAGE ON THE FARM

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking	Corrective actions
	M: Milk contamination by substantial excretion of bacteria in the environment or by direct passage of bacteria into milk.*	Isolate sick animals Treat animals presenting symptoms of disease, particularly of: - the genital area - the digestive system (enteritis with diarrhoea and fever) - mammary secretion (inflammation of the teat due to injury or mastitis, abnormal appearance of milk) Treat animals presenting cracks, spots, wounds or other lesions visible on the teat.	Visual inspection of animals and/or control of temperature of animals, and/or palpation, and/or veterinary opinion and/or analysis.	Immediate corrective action: Withdraw the milk of sick animals.
	M: Contamination of teat skin when the animals are housed.*	Have suitable living areas, in particular sleeping areas, that are clean and dry, suitable for the size and number of the animals and the building type. Regularly maintain the bedding and exercise areas and particularly where straw is used : -Put sufficient quantities of straw down -Clean bedding out regularly Scrape cows yards on a regular basis Avoid excessive humidity around drinking areas located in sleeping areas Control the presence of poultry, birds and vermin in the housing and milking areas Do not put silage waste on bedding.	Visual inspection of cleanliness of the bedding and udders.	Immediate corrective action: Extra vigilance with hygiene during milking. Future corrective actions: for housing, clean out bedding and/or put down straw more abundantly. Repair defective pest control measures.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking	Corrective actions
		As far as possible, maintain access routes to the farm buildings, especially when animals are grazing.	Visual inspection of cleanliness of access routes.	Future corrective actions: maintain access routes if necessary and/or vigilance with hygiene during milking.
	C: Animals can accidentally absorb inappropriate products (disinfectants, insecticides, rat poison) by licking building surfaces or treated equipment or bait.	Use only authorised products at recommended doses according to instructions for use. Respect the time period recommended between the application of disinfectant and the reintroduction of animals into the building and/or in transportation vehicles.	Visual inspection.	Immediate corrective action: Identify animals concerned and seek veterinary advice. Future corrective action: Change placement of bait.
Feeding	M, C: Contamination of bought-in feed (forage) by pathogenic bacteria or mycotoxins.	Check quality of feed upon reception. Equipment used for transport must be cleaned.	Visual inspection.	Immediate corrective action: Do not accept the forage.
	M: Contamination of forage by pathogen bacteria before harvesting.*	Respect a sufficient time delay, if possible a minimum of 3 weeks, between spreading slurry and harvesting the forage. In the case of a history of Salmonellosis in the cow herd, avoid spreading this slurry, or spread this slurry on fields and plough it in immediately. It is recommended to employ a decontamination procedure before spreading onto fields, eg. store the slurry for two months without further additions, or another decontamination process. For poultry and pig slurry, wastewater treatment and plant sludge, avoid spreading directly onto fields and meadows.	Veterinary monitoring.	Immediate corrective action: Do not use potentially contaminated fields for forage or pasture during the time required for decontamination.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking	Corrective actions
	M: Contamination of animals due to use of contaminated feed.*	Sweep feed troughs, corridors and feed tables daily. Use clean equipment for distribution	Visual inspection.	Immediate corrective action: Do not distribute mouldy, sub-standard or suspect feed
Feeding Dry feed (hay and concentrates).	M: Contaminating hay during harvest or harvesting conditions which enable the development of pathogens or mycotoxins production during storage.*	Avoid incorporating soil during forage harvesting: appropriate cut-height, efforts to combat molehills. Harvest hay when dry.	Visual inspection.	Immediate corrective action: Do not distribute any altered or suspect feed. Future corrective action: readjust the height of the cut, review harvest conditions.
	M: Contamination of feed during storage.*	Preserve hay and concentrates where they are sheltered from bad weather (rain, run-off, infiltration). Keep animal feed storage areas away from the flow of farm waste effluents. Ensure that feed is sheltered from animal contamination: vermin, birds, poultry.	Visual inspection, absence of heat emission.	Immediate corrective action: Do not distribute contaminated feed. Future corrective action: Review storage conditions/ effluents storage.

Section IV- Risk analysis for primary production

MILK PRODUCTION, STORAGE ON THE FARM

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking	Corrective actions
Feeding Silage and baled silage	**M, C: Contamination of silage, baled silage during harvest or harvesting conditions which enable the growth of pathogens or mycotoxins production during storage.***	**Avoid incorporating soil during forage harvesting: appropriate cut-height, combat molehills (grass). Avoid incorporating soil during pit compacting. Complete each silage pit in less than two days. Compact pits sufficiently and close hermetically. Harvest forage at prescribed dry matter content levels depending on type of forage and the type of preservation: silage or wrapped bales. Harvest forage at sufficient sugar content in order to enable good fermentation: choice of forage species, harvest at suitable stage and time.**	**Visual inspection.**	**Immediate corrective action: do not use any altered or suspect feed. Future corrective action: readjust the height of the cut, review harvest conditions.**
	M: Contamination of feed (silage, baled silage etc.) whilst in storage.*	**Avoid incorporating soil when compacting the pit. Do not open pits immediately - if possible for at least 3 weeks. Avoid restarting silage fermentation by ensuring an adequate rate of consumption and a uniform silage pit face.**	**Appearance of silage Absence of heat emission.**	**Immediate corrective action: do not use contaminated feed. Future corrective action: Review silage production process.**
		Ensure that wrapped silage bales and silage cover are in good condition.	**Visual inspection.**	**Immediate corrective action: Repair damaged silage covers immediately.**
Feeding Grazing	M: Contamination of teats if conditions are inappropriate.*	Control the deterioration of areas where animals are grouped together (rest areas, drinking areas etc.)	Visual inspection.	Immediate corrective action: where possible, move grouping areas, move the animals to different pasture, use feed inside and/ or vigilance with hygiene during milking.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking	Corrective actions
	M: Contamination of pasture grass with pathogenic bacteria by spreading farm fertiliser, effluents, sludge from wastewater treatment plants.*	Respect time between spreading and grazing (three-week minimum). Beware of flow of effluent spreading towards grazing areas.		Immediate corrective action: move animals to different pasture.
	C: Residues of plant protection products on pasture grass where the product's conditions of use are not respected.	Strict observance of the manufacturers stated time between application of plant protection treatment and use of pasture.	Keep a register of plant protection treatments	Immediate corrective action: temporarily change the grazing pasture/ do not use the milk.
Calving	M: In the case of abortion, possibility of contaminating the other animals. *	Rapidly put foetuses and placentas out of reach of farm animals and seek veterinary advice. It can be a regulatory obligation to declare abortion depending on MS If possible, quarantine the animal.	Analysis of the foetus.	Immediate corrective action: Follow veterinary prescriptions.
	M: Possibility of mammary infection during calving.*	Ensure calving takes place on clean bedding.	Visual inspection.	Future corrective action: Improve hygiene in calving area
Milking	M: Contamination due to poor condition of teats.*	Regular inspection and maintenance of the milking machine by the farmer or by a qualified inspector Avoid aggressive milking techniques which increase the risk of damaging the natural defences of the teat. Limit air ingress at cup attachment and removal: – break the vacuum before removing the cups – limit dripping and over milking	Date and result of milking equipment inspection. Visual and auditory inspection. Visual inspection of teats before and after milking.	Immediate corrective action: treat and maintain the teats Future corrective action: have milking machine inspected by a qualified person. Organise assistance during milking.

Section IV- Risk analysis for primary production

MILK PRODUCTION, STORAGE ON THE FARM

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking	Corrective actions
	M: Contamination due to poor cleaning of milking machine*	Clean the milking machine after each milking. For robotic milking systems (cows) it is recommended (for raw milk) that they are cleaned three times per day.	Visual inspection, respect of cleaning and (when necessary) disinfection procedure.	Future corrective action: change cleaning procedure.
	M: Contamination due to unclean teats*	Milking must be carried out hygienically. Clean and disinfect cloths used to clean udders after each milking, or use disposable clothes. Limit contamination of the skin of teats by the hands of the milker by washing hands before milking. Sufficient lighting in milking parlour When squeezing the first milk from the teat (stripping the teat) collect into a specific container. In the case of cows, wash and wipe the teats dry before milking. In the milking parlour, ensure the waiting area is clean at the start of milking –Make sure the milking platform is clean during milking – Clean the cubicle after each milking For cows, milking in the cow shed: ensure faeces is cleared away before milking For outdoor milking: - Ensure milking animals have sufficiently clean and dry areas to lay down and that the teats are as clean as possible for milking - Keep the areas next to the milking zone as clean and clear of mud as possible by installing stone/concrete milking cubicles or by moving the milking machine frequently. For robotic milking (cows): the milking area	Visual inspection of teats	Immediate corrective action: wash teats again. Review cleaning procedures for milking areas and teats For robotic milking (cows): ensure that animals are clean. Review the teat-cleaning procedures.

Section IV- Risk analysis for primary production
MILK PRODUCTION, STORAGE ON THE FARM

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking	Corrective actions
		must be clean. Ensure that teat-cleaning system works correctly and check its efficacy.		
	M: Contamination of milk due to the cluster/cups dropping during milking*	Carry out milking in a calm atmosphere		Where necessary, clean before re –application
	M: In the case of clinical mastitis in the herd, cross contamination between animals and contamination of the milk.*	If in doubt, inspect the first quantity of milk stripped from the teats If possible, avoid treating sick animals during milking.	Visual inspection of animals, udders and milk	Immediate corrective action: Milk animals suffering from clinical mastitis separately Do not use this milk
	M: Contamination of milk caused by mammary infection.*	**See above: - Maintain teats in good condition: testing and maintenance of the milking machine. - Milking hygiene and cleanliness of the milking machine. - Avoid cross contamination between animals.**	**California Mastitis Test (CMT) Or individual cell count Or take into account clinical indicators, condition of the udder-conformation, teats and the level of inflammation. ***	**Immediate corrective action: Treat or cull the animals concerned.**
	C: Contamination of milk due to inadequate cleaning of milking machine or during disinfection.	**Observe the conditions of use of the product (authorised cleaning product, dosage, rinsing etc.)**	**Visual inspection**	**Future corrective action: change cleaning procedure or disinfection procedure**
	C: Contamination of milk by teat disinfectant.	**Observe the conditions of use of the disinfectant**	**Visual inspection**	**Immediate corrective action: Clean or wipe the teats Future corrective action: change disinfection procedure**

Section IV- Risk analysis for primary production

MILK PRODUCTION, STORAGE ON THE FARM

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking	Corrective actions
	C: Presence of residues of veterinary medicines in milk	**In the case of animal treatment with veterinary medicines, follow prescription/instructions and segregate the milk of the treated animal during the withdrawal period.** **Keep a record of treated animals and dates of end of treatments and withdrawal time.**	**Sanitary register Prescription of medicine**	
Drying period	M: Contamination of milk caused by mammary infections when lactation restarts.*		CMT Or individual cell count Or take into account clinical indicators, conditions of the udder – conformation, level of inflammation - and the teats	Immediate correction action: Treat animals suspected of infection during drying period/ cull the animals concerned
	C: Presence of antibiotic residues when lactation restarts.	**Follow veterinary prescriptions closely.**	**Interval between the date of treatment and date of calving and between first lactation and first use of the milk; sanitary register**	**Immediate corrective action: If the interval of time is too short, separate the milk or verify the absence of residues**
Water	M: Contamination of drinking water	Limit contamination of water by faeces. Clean regularly drinking troughs and vats used for water transportation.	Visual inspection	Discard dirty water, clean drinking troughs and vats, disinfect them when necessary. Change the drinking troughs or move them in another place. Treat the water.
	M: Contamination of equipment through cleaning water.*	**Refer to the recommendations of chapter GHP Water quality**		

Section IV- Risk analysis for primary production
MILK PRODUCTION, STORAGE ON THE FARM

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking	Corrective actions
	C: Contamination of drinking water and of equipment through contaminated rinse-water.	Follow regulations, prescriptions for use of water treatments (authorised product, dosage).		Future corrective action: review the system of water treatment
Transfer of milk to processing area.	**M, P: Contamination of milk by the equipment (milk line, churns etc.)**	**Use equipment that is clean, airtight and sealed. Where churns are used, they should be covered to prevent milk contamination.**	**Visual inspection.**	**Review cleaning procedure**
		Make sure equipment is in good condition: in particular any rubber parts eg. joint-seals.	**Visual and auditory inspection.**	**Replace any rubber parts or pipes in poor condition.**
Filtration	M, P: Contamination by the equipment.	Ensure filters are fitted correctly. The filtration equipment must be kept clean: cleaning of fixed filters or (where used) remove the disposable filter after each milking (before cleaning), replace it with a new filter before the next milking.	Visual inspection.	Change the filter.
	M : Presence of contaminants in the milk which contribute to the bacteria load	The milk should be filtered while milking or immediately afterwards for manual milking.	Visual inspection	Review practices
Cold storage	M, P, C: Contamination of milk whilst in storage.	Milk should be stored immediately after milking in a clean place (regularly cleaned) and in clean and covered vessels. Protect the area from insects and vermin. Do not store any inappropriate products or material in the storage area. In the case of outside milking and mountain dairies, storage and transport recipients should be covered as soon as possible to prevent physical contamination: insects, dust, light bulbs etc.	Visual inspection	Review cleaning procedure Review the pest control plan Review organization of the area

Section IV- Risk analysis for primary production
MILK PRODUCTION, STORAGE ON THE FARM

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking	Corrective actions
	M : Growth of pathogenic bacteria during storage	**In general (LR, for exception, see regulatory requirements), store milk in a refrigerated environment at : - 8°C maximum in the case of daily collection - OR 6°C maximum if collection is not daily The milk must be cooled to this temperature within 2 hours. In cases where milk is cooled in a refrigerated tank, remove dust regularly from the condenser**	**Thermometer**	**Adjust the temperature of the storage vessels. Where necessary, check the refrigeration unit is working correctly.**
	C, M: Contamination of milk by the equipment	Clean and/or disinfect after draining tank and rinse with appropriate quality of water the interior of the storage milk vat or milk transportation equipment Respect regulation and recommendations for use of treatment for water (authorized product, dose)	Visual inspection	Change cleaning and/or disinfection procedure Review the water treatment system.
	C: Contamination of milk due to inappropriate use of disinfectant and/or cleaning products	**Respect the conditions of use of the product (authorized product, dose, rinsing etc.)**	**Visual inspection**	**Change cleaning and/or disinfection procedure**

For more information, see the sheets: GHP Cleaning, GHP Disinfection, GHP Pest control, GHP Water quality

(LR) 853/2004 - The milk must be cooled immediately to
- 8°C maximum in the case of daily collection
- OR 6°C maximum if collection is not daily

Exceptions: the milk is processed within 2 hours of milking; derogation obtained for technological reasons. Also in these cases, the milk must comply with regulatory criteria (somatic cells and total plate count)"

FLEXIBILITY MEASURE

Section V- HACCP-based Plans

MILK COLLECTION, STORAGE IN THE DAIRY AND TREATMENT

This section covers the procurement, collection and storage of milk where it is bought-in and the heat-treatment of milk whether it is bought-in or processed on the holding of origin.

LR = Legal Requirement

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Procurement (Sourcing the milk supply for bought-in milk)	C, M, P: Where milk is not supplied from the processors own herd, control of the hygienic quality of the milk resides with the milk producer. The processor must put in place controls/checks to ensure that the milk supplied is of a satisfactory hygienic standard and that the milk is free from residues of veterinary medicines.	**Regular visual inspection of farm by the cheesemaker. Hygienic practice should be seen to comply with recommendations in "Risk analysis for primary production". (1)** **Inspection of records of veterinary medicines administered, routine monitoring of cell count and plate count and results of checks made for tuberculosis or brucellosis.** **Where bought-in milk is used for the production of dairy products associated with the greatest degree of technological sensitivity (eg. surface-ripened raw milk soft cheeses), checks on the hygienic standards practiced on the farm should be more frequent. This is particularly important for new dairy processing enterprises.**	Routine monitoring of milk on the farm for plate count and somatic cell count (for cow's milk) in line with (EC) 853/2004 Check farm records to ensure absence of antibiotic residues in the milk. This may be confirmed using a suitable antibiotic test. Check results of official monitoring for Tuberculosis or Brucellosis.	The food business operator should inform the competent authority and take steps to correct the situation, which may include: • Improvements to the hygienic quality of the raw milk by the producer. • Change of milk supplier • Pasteurisation • production of cheese with a maturation time of at least 60 days (eg. sheep and goats following the loss of Brucellosis-free status) • Reject the batch in the case of contamination with veterinary medicines or other substances for which a MRL is specified.
Transportation of the milk	C: Contamination with residues of cleaning chemicals or disinfectants poses a chemical hazard for the consumer and can inhibit starter cultures.	Transportation vessels designated for transportation of food products only and rinsed following cleaning or disinfection. (LR)	Organoleptic inspection prior to processing.	Reject the milk if contamination is suspected.
Transportation of the milk Storage	M: Ineffective cleaning of milk tankers or churns can allow pathogenic bacteria to survive and form biofilms which confer increased resistance to disinfection.	Tanker or churns cleaned effectively after use.	Visual inspection.	Review cleaning and/or disinfection procedure. If it is a recurrent issue review training of cheesemaker.

Section V- HACCP-based Plans

MILK COLLECTION, STORAGE IN THE DAIRY AND TREATMENT

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Transportation of the milk Storage	M. Growth of pathogenic bacteria	**The cold chain must be maintained and the milk must not exceed 10°C upon arrival at the processing site unless processed within two hours of the end of milking or the competent authority authorises a higher temperature for technological reasons. (LR)**	Check temperature upon arrival or time elapsed since milking.	If milk is transported following refrigeration, reject milk where it exceeds 10°C on arrival - unless with the prior approval of the competent authority.
	P: Physical contamination of the milk during transportation.	Cover vessels during transport. Where appropriate milk may be filtered after transportation.	Visual inspection.	Review cleaning procedure for churns or tanker and review staff training if appropriate
	Pathogenic bacteria may grow in milk if temperature control is lost or where not processed within four hours of reception at the processing site.	Milk cooled to <6°C if not processed within four hours unless the competent authority authorises a higher temperature for technological reasons. (LR)	Temperature or time elapsed since arrival at processing site.	Reject milk which has not been held in accordance with regulatory limits or authorised exemptions.

FLEXIBILITY MEASURE

Section V- HACCP-based Plans

MILK COLLECTION, STORAGE IN THE DAIRY AND TREATMENT

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Pasteurisation	Presence of pathogenic bacteria in raw milk or the use of: • Cow or buffaloes milk supplied from a herd which does not have Officially Tuberculosis Free (OTF) or Officially Brucellosis Free (OBF) status. • Sheep or goats milk from a herd which does not have OBF status and is used in the manufacture of a cheese matured for less than 60 days.	**(LR) Milk pasteurised according to one of the following processes then cooled rapidly to the technological temperature required:** **1) Low Temperature Long Time (LTLT) or 'Batch' Pasteurisation;** **2) High Temperature Short Time (HTST) Pasteurisation;** **3) Equivalent time and temperature combination such that products show a negative reaction to Alkaline Phosphatase (ALP) test.** **Ensure that vat is stirred effectively and covered during LTLT pasteurisation to ensure effective heat treatment of all parts of the milk**	Monitoring of holding time and temperature using a calibrated thermometer or thermograph. Where a calibrated thermometer is used to monitor temperature in the absence of a thermograph, appropriate records must be kept Critical Limits: 1) 63°C (30 minutes) 2) 72°C (15 seconds) 3) Equivalent combinations may be validated by demonstrating a negative reaction to the ALP in pasteurised milk and a decrease in ALP during the process. Examples include: 63.8°C (20 minutes) 65.1°C (10 minutes) 66.4°C (5 minutes)	Milk intended for pasteurisation but failing to meet the specified time and temperature combination or where verification suggests that pasteurisation has failed must not be used for human consumption without further treatment. For a batch process continue heating until the intended holding time and temperature have been achieved. For HTST, restart heating process until the intended holding time and temperature have been achieved. Where the corrective action fails, the milk should be disposed of accordingly.

MILK COLLECTION, STORAGE IN THE DAIRY AND TREATMENT

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Pasteurisation	• Milk from asymptomatic animals of other species from a herd in which TB or Brucellosis has been detected and which is not otherwise treated to ensure safety. NB. Sub-pasteurisation heat treatment (thermisation) may reduce bacterial load (especially coliforms, spoilage bacteria and Gram-negative pathogens) but does not guarantee the absence of Gram-positive pathogens (eg. Listeria monocytogenes)	**Pre-operation checks (eg. temperature & divert setting), effective cleaning and calibration are required for safe operation of HTST pasteurisers. The flow rate/holding time should be verified at appropriate intervals to ensure it is correct.**	Separated cream may require higher temperatures to achieve an equivalent lethality. Verification of effectiveness of critical limits is by testing for ALP with appropriate frequency. Due to the practical challenges of delivering samples for testing, it is possible that this test may be made monthly or less frequently rather than on every batch. Critical Control Points, such as pasteurisation time and temperature combinations, must be monitored and records kept of any corrective actions taken as well as the results of verification procedures.	Ensure that temperature control of samples submitted for ALP testing is adequate to prevent reactivation. Samples should be cooled rapidly to <8°C and remain at this temperature while in transit. Due to the low level of ALP in goat's milk, some member states do not test for ALP in this species while others look for evidence of decrease in ALP level after pasteurisation. Sheep's milk by comparison has a higher level to ALP compared to cow's milk. A negative reaction to the ALP test is defined as <350mU/L in cow's milk. It is good practice to investigate the causes where levels are acceptable but elevated above the typical value for the herd though this may be due to changes in lactation stage, breed or somatic cell count.
Pasteurisation	Milk may be contaminated **post-pasteurisation** by raw milk or as a result of inadequately cleaned equipment, such as contaminated tools or as a result of fouling of pasteuriser plates or holding tube. Fouling of plates may be detected through loss of thermostatic control of HTST pasteurisers.	Do not handle raw milk in the vicinity of pasteurised milk; where possible separate by time or distance and clean and disinfect tools used in the preparation of both raw and pasteurised products. Ensure that cleaning products are used at the manufacturer's specified concentration, temperature and for the appropriate contact time. (2)		Where contamination with raw milk is suspected, the milk must not be used for human consumption without further treatment. Review cleaning procedures and chemicals used. Use Milkstone remover according to the manufacturer's instructions.

1) Risk analysis for primary production 2) GHP Cleaning, GHP Disinfection






Fromages lactiques avec une couverture « bleue » (Penicillium), présentant un aspect sec

Fromages lactiques avec une couverture « ivoire » (Geotrichum), souvent dits « crémeux »

Fromages lactiques présentant du « bleu » (Penicillium) sur une couverture Geotrichum

section V- HACCP-based Plans

LACTIC COAGULATION CHEESES

Cheeses made with predominantly lactic coagulation rely on acidification to set the curd. The acidification/coagulation time may be very long, taking several hours, but the low pH reached prevents the growth of pathogenic bacteria in the curd. The pH at the end of drainage is often significantly lower than 4.60. This category includes both fresh or unripened soft cheeses and others which may be ripened. While the pH of ripened cheeses may increase, especially at the rind, they often lose moisture as they mature, becoming harder and they would be considered to be less technologically sensitive than some other surface-ripened cheeses.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Filling the Vat	M, C: Microbiological and Chemical contamination of the milk from equipment and utensils (vats, stirrers, buckets, scoops etc.) Dirty equipment can contaminate milk with pathogenic bacteria. Residues of cleaning agents can contaminate milk.	Ensure that equipment is always clean. Never put small items of equipment directly on the floor. (1)	Visual inspection	Repeat cleaning and/or disinfection. Rinse sufficiently with potable water. Amend cleaning procedure. If it is a recurrent issue review training of cheesemaker. (7)
Maturation without inoculation	M: Growth of pathogenic bacteria: Milk can contain undesirable bacteria. When the number of lactic acid bacteria (LAB) is low or conditions for their development are unfavourable, pathogenic bacteria can dominate	Where possible, promote the development of LAB through good animal husbandry (see sheet milk production). Use proper maturation temperature and time to promote sufficiently rapid growth of LAB. (2)	Experience of cheesemaker: organoleptic inspection, measurement of temperature, time and acidity development.	Add dose of acidifying culture. Reject suspect milk (taste, smell, appearance). Adjust production parameters (time, temperature). If it is a recurrent issue, improve milk production practices or change milk supplier.
Maturation with inoculation	M, C: Improper process parameters can allow growth of pathogenic bacteria	Maintain correct temperature, time and dose of cultures. Add cultures as soon as possible. (3)	Experience of cheesemaker: organoleptic inspection, measurement of temperature, time and acidity development.	Adjust production parameters: time, temperature, type and dose of cultures.
	M: Contamination of milk during inoculation due to poor quality of starter bacteria or inadequate handling by the cheesemaker	Use only starters of known origin (including homemade starters) or those with a certificate of conformity as suitable for food-use. Handle with care. Reject starters of suspect odour, colour or appearance. (3)	Visual and organoleptic inspection of direct or bulk starters	Reject inactive starters or those with suspect or damaged packaging. Adjust bulk starter preparation procedure.


Fromages lactiques avec une couverture « bleue » (Penicillium), présentant un aspect sec

Fromages lactiques avec une couverture « ivoire » (Geotrichum), souvent dits « crémeux »

Fromages lactiques présentant du « bleu » (Penicillium) sur une couverture Geotrichum

section V- HACCP-based Plans

LACTIC COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Addition of the coagulant* and incubation	M, C: A coagulant can be contaminated due to bad handling or storage. Coagulants can contaminate milk with pathogenic bacteria or chemical compounds	Use only coagulants of known origin (including homemade coagulant) or those with a certificate of conformity as suitable for food-use. Handle with care. Reject coagulants of suspect odour, colour or appearance. (4)	Visual and organoleptic inspection of coagulants.	Reject coagulants of suspect quality, abnormal appearance or smell, or those with suspect or damaged packaging. Amend handling and storage procedures. Change the supplier.
	M: Slow or insufficient acidification can allow growth of pathogenic bacteria.	Maintain appropriate time and temperature, according to the technology used	**Smooth gel of satisfactory appearance and with expected flavour, taste or acidity/pH.** **Recommended values: Final pH 4,5-4,7 achieved within 24 hours.**	Reject gels of doubtful appearance and flavour Adjust production parameters: time, temperature, type and dose of cultures
Curd treatment (Cutting, stirring, heating, whey draining)	M: Contamination of the curd by the hands and arms of the cheesemaker.	Ensure food handlers have clean hands/arms. Where necessary use protective gloves to cover skin lesions. (5)	Visual inspection	Wash hands/arms. Change torn gloves. If it is a recurrent issue review training of cheesemaker.
	M, C: Microbiological and chemical contamination of curd with badly cleaned equipment (harps, knives, stirrers etc.)	Ensure that equipment is always clean. Never put small items of equipment directly on the floor.	Visual inspection	Repeat cleaning and/or disinfection. Rinse with potable water of acceptable quality. Amend cleaning procedure. If it is a recurrent issue review training of cheesemaker.
	P: Contamination of curd with poorly maintained or damaged equipment.	Ensure equipment is maintained in good condition.	Visual inspection	Repair or replace damaged equipment. Reject the batch if metal contamination is suspected following visual inspection


Fromages lactiques avec une couverture « bleue » (Penicillium), présentant un aspect sec


Fromages lactiques avec une couverture « ivoire » (Geotrichum), souvent dits « crémeux »


Fromages lactiques présentant du « bleu » (Penicillium) sur une couverture Geotrichum

section V- HACCP-based Plans

LACTIC COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Curd Treatments: Forming, Salting (8) Mixing, Additives, (9) Draining	M, C : Microbiological, chemical or physical contamination of the curd by cheese cloths, draining bags and moulds	Ensure that cloths, bags and moulds are always clean. Never put small items of equipment directly on the floor. (1) (6)	Visual inspection.	Repeat cleaning and/or disinfection. Rinse with potable water of acceptable quality. Amend cleaning procedure. If it is a recurrent issue review training of cheesemaker. Repair dirty or worn cheesecloth or equipment.
	M, C, P: Contamination of the curd by tools, handling and ingredients.	Clean and/or disinfect regularly tools and equipment. Wear clean work-clothes. Use only food-grade ingredients (additives, salt, herbs, fruits, flavourings etc.) within their expiration date.	Visual inspection.	Change suppliers of additives if they do not fit to required standards
Rind Treatment	M: Contamination and cross-contamination may occur as a result of specific processes during ripening such as rind-washing.	Ensure equipment is always clean and maintained in good condition. (1) Ensure food handlers have clean hands. Where necessary use protective gloves to cover skin lesions.	Visual inspection.	Repeat cleaning and/or disinfection. Rinse with potable water of acceptable quality. Amend cleaning procedure. If it is a recurrent issue review training of cheesemaker.


Fromages lactiques avec une couverture « bleue » (Penicillium), présentant un aspect sec

Fromages lactiques avec une couverture « ivoire » (Geotrichum), souvent dits « crémeux »

Fromages lactiques présentant du « bleu » (Penicillium) sur une couverture Geotrichum

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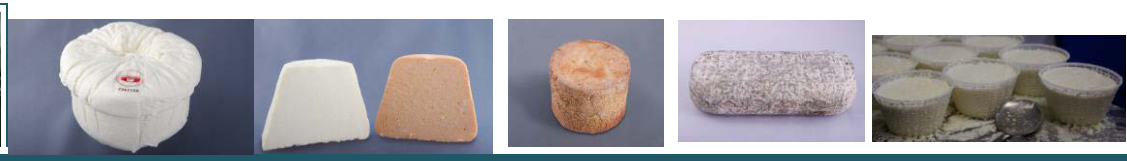
LACTIC COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
	M: Contamination and Cross-Contamination during Rind Washing (smearing). Poorly developed rinds may allow the growth of pathogenic bacteria while pH increases on the rind during ripening can permit growth of previously inactivated salt-tolerant pathogens such as Listeria monocytogenes.	Ensure high hygienic standards during milk production. (2) Ensure a good standard of hygiene during cheesemaking and ripening; in particular, maintaining an adequate standards of hygiene in hard-to-clean areas (eg. Wheels of vat or tables, hydraulic or pneumatic cylinders) as well as smearing equipment and ripening racks. Improve conditions necessary for the growth of ripening cultures. ”Old-young” smearing (where bacteria are transferred from mature to new cheeses) can promote rapid development of the correct rind microflora but may allow for cross-contamination.	Visual inspection of cheese surface	If it is a recurrent issue review procedures and training of milker and/or cheesemaker. Where smear solution cultures are not viable, consider adding a dose of smear-ripening bacterial or yeast cultures. It is possible to verify the safety of ”old-young” smearing processes by checking smear solution rather than products for presence of *Listeria monocytogenes*. If it is a recurrent issue stop use an alternative method to wash the rinds of the cheese.
Ripening**	M: Contamination of the cheese surface by pathogenic bacteria	Ensure food handlers have clean hands. Where necessary, use protective gloves to cover skin lesions. Ensure that the material is clean and maintained in good condition.	Visual inspection	Repeat cleaning and/or disinfection. Amend cleaning procedure. If it is a recurrent issue review training of staff.


Fromages lactiques avec une couverture « bleue » (Penicillium), présentant un aspect sec

Fromages lactiques avec une couverture « ivoire » (Geotrichum), souvent dits « crémeux »

Fromages lactiques présentant du « bleu » (Penicillium) sur une couverture Geotrichum



section V- HACCP-based Plans

LACTIC COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Optional step: concerns mostly fresh/unripened cheeses Refrigeration***	M: Contamination of **fresh/unripened cheeses** in the cold store by harmful microorganisms due to poor condition of the room and cooling equipment.	Keep cold store clean. Regularly clean air conditioning or cooling equipment. Protect the product against dripping condensate. Control pests	Refrigeration temperature Recommended temp <8^{o}C	Maintenance or replacement cooling equipment When necessary, disinfect and/or repaint the room
Cutting, Packing and Dispatch	M, C, P: Contamination of the cheese due to contaminated packaging materials, cutting, weighing and packing equipment or poor staff hygiene. (1) (5)	Use packaging materials (including traditional materials) suitable for food use and stored in clean, dry conditions. Ensure that equipment is clean before use and between cutting different products. Fresh products should be returned to chilled storage immediately after packing.	Visual inspection	Reject contaminated, damaged or suspect packaging. If necessary change supplier of packaging materials or improve storage conditions. Repeat cleaning and/or disinfection of cutting and weighing equipment. If it is a recurrent issue review training of staff.

Alternative operations: *Some producers use a small quantity of rennet while others do not. ** Some products are ripened while others are not.
*** Depending on the product, cooling can be followed by portioning and packaging or vice versa.

See also: 1) GHP Cleaning, GHP Disinfection. 2) Risk analysis Primary Production. 3) GMP Cultures. 4) GMP Coagulants. 5) GHP Staff General Hygiene, Training & Health 6) GHP Premises & Maintenance of Equipment. 7) GHP Water quality. 8) GMP Salting. 9) GMP Additions to the Milk & Curd.










section V- HACCP-based Plans

ENZYMATIC AND MIXED COAGULATION CHEESES

Predominantly enzymatic coagulation cheeses are a group comprising both hard and soft cheeses, both fresh and ripened. The group is quite diverse and may include products without inoculation or with minimal acidification. The coagulation time is quite fast – typically less than one hour.
“Mixed Coagulation cheeses” comprises surface-ripened cheese which includes mould-ripened cheeses, washed-rind cheeses, mixed-rind cheeses and internally mould-ripened (blue) cheese. Coagulation time may be typically between one and two hours.

The slow, or absent, acidification typical of some soft mixed coagulation and unripened, unacidified predominantly enzymatic cheeses may not control the growth of harmful bacteria; many are higher-risk products requiring high standards of dairy hygiene and strict control of the hygienic quality of the milk.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Filling the Vat	M, C: Contamination of the milk from equipment and utensils (vats, stirrers, buckets, scoops etc.) Dirty equipment can contaminate milk with pathogenic bacteria. Residues of cleaning agents can get into milk.	Ensure that equipment is always clean. Never put small items of equipment directly on the floor. (1)	Visual inspection.	Repeat cleaning and/or disinfection. Rinse sufficiently with potable water. Amend cleaning procedure. If it is a recurrent issue review training of cheesemaker.
Maturation without inoculation	M: Growth of pathogenic bacteria: Milk can contain undesirable bacteria. When the number of lactic acid bacteria (LAB) is low or conditions for their development are unfavourable, pathogenic bacteria can dominate.	Where possible, promote the development of LAB through good animal husbandry (see sheet milk production). Use proper maturation temperature and time to promote sufficiently rapid growth of LAB (2).	Experience of cheesemaker: organoleptic inspection, measurement of temperature, time and acidity development.	Add dose of acidifying culture. Reject suspect milk (taste, smell, appearance). Adjust production parameters (time, temperature). If it is a recurrent issue, improve milk production practices or change milk supplier.









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ENZYMATIC AND MIXED COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Maturation with inoculation	M, C: Improper process parameters can allow growth of pathogenic bacteria.	Maintain correct temperature, time and dose of cultures. Add cultures as soon as possible. (3)	Experience of cheesemaker: organoleptic inspection, measurement of temperature, time and acidity development.	Adjust production parameters: time, temperature, type and dose of cultures.
	M: Contamination of milk during inoculation due to poor quality of starter bacteria or inadequate handling by the cheesemaker.	Use only starters of known origin (including homemade starters) or those with a certificate of conformity as suitable for food-use. Handle with care. Reject starters of suspect odour, colour or appearance. (3)	Visual and organoleptic inspection of direct or bulk starters	Reject inactive starters or those with suspect or damaged packaging. Adjust bulk starter preparation procedure.
Addition of the coagulant	M, C: A coagulant can be contaminated due to bad handling or storage. Coagulants can contaminate milk with pathogenic bacteria or chemical compounds	Use only coagulants of known origin (including homemade coagulant) or those with a certificate of conformity as suitable for food-use. Handle with care. Reject coagulants of suspect odour, colour or appearance. (4)	Visual and organoleptic inspection of coagulants.	Reject coagulants of suspect quality, abnormal appearance or smell, or those with suspect or damaged packaging. Amend handling and storage procedures. Change the supplier.
Curd Treatments (cutting, ladling, stirring, washing, draining, moulding, pressing).	M: Contamination of the curd by the hands and arms of the cheesemaker.	Ensure food handlers have clean hands/arms. Where necessary use protective gloves to cover skin lesions. (5)	Visual inspection.	Wash hands/arms. Change torn gloves. If it is a recurrent issue review training of cheesemaker.










section V- HACCP-based Plans

ENZYMATIC AND MIXED COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
	M, C: Contamination of curd with badly cleaned equipment or cheeses cloths.	Ensure that equipment is always clean. Never put small items of equipment directly on the floor. (1)	Visual inspection.	Repeat cleaning and/or disinfection. Rinse with potable water of acceptable quality. Amend cleaning procedure. If it is a recurrent issue review training of cheesemaker. Repair dirty or worn cheesecloth or equipment.
	P: Contamination of curd with poorly maintained or damaged equipment.	Ensure equipment is maintained in good condition. (6)	Visual inspection.	Repair or replace damaged equipment. Reject the batch if metal contamination is suspected following visual inspection
	M, C, P: Contamination of curd washed with non-potable water.	Use only potable water with normal odour, taste and colour. (7)	Visual inspection. Use of water from public water supply. Potability certificate for private water supplies.	Reject water if unsuitable or batch if contaminated. Use another source of potable water.










section V- HACCP-based Plans

ENZYMATIC AND MIXED COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
	M: Growth of pathogenic bacteria during acidification and drainage. Many enzymatic and mixed coagulation cheeses involve slow acidification and low doses of starter cultures.	**Ensure high standards in milk production.** (2) Satisfactory acidification appropriate to the cheese variety.	Experience of cheesemaker: organoleptic inspection, measurement of temperature, time and acidity development.	Continue cheesemaking and quarantine batch pending further decision by cheesemaker. Suspect batches may be selected for testing under routine self-monitoring plan. Consider pasteurisation or change of supplier where self-monitoring plan suggests that microbiological quality is unsatisfactory or variable. Adjust production parameters for future batches: time, temperature, type and dose of cultures.
Milling	M, C, P: Contamination of milled curd due to dirty milling equipment or poor staff hygiene, residues of cleaning chemicals or as a result of poor maintenance (eg. metal shards or nuts, plastics, lubricants).	Clean equipment and utensils after use and rinse thoroughly. Check milling equipment for signs of damage.	Visual inspection before and after milling.	Wash and rinse again before production. In case of missing parts or visible damage inspect the product carefully. Reject the product in the case of contamination with metal or hard plastic.
Additives	C: Use of additives, enzymes and processing aids that are not suitable for food processing or where their application does not comply with stated conditions of use.	Check that additives, processing aids and enzymes are suitable for food use and permitted for the type of cheese. Observe the stated dose, particularly where legal limits exit for food products. Observe the stated condition of use. (9)	Visual inspection. Careful measurement of quantity of additive.	Recall and reprocess or, if reprocessing cannot remove the hazard, dispose of products as “nor fit for human consumption”.










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ENZYMATIC AND MIXED COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Salting	M, C, P: Contamination of the curd due to poor quality salt (8)	Use only salt of known origin or with a certificate of conformity as suitable for food-use. Cover and store in clean, dry conditions.	Visual inspection.	Reject salt of suspect quality.
	M: Contamination of the cheese with pathogenic bacteria present in brine used for salting or storing cheese. (8)	Use potable water and salt of acceptable quality. Where appropriate, control temperature, salt concentration or acidity. Sieve the brine to remove small curd particles. Keep the area around brine tanks clean or cover the brine to prevent contamination.	Visual inspection. Where necessary, measurement and control of temperature, salt concentration and acidity.	Add salt and lower the temperature if appropriate to the cheese technology; otherwise renew the brine; improve storage conditions and general hygiene. Reject brine of suspect quality.
Piercing	M, C, P: Contamination of cheeses by pathogenic microorganisms due to dirty or poorly cleaned or maintained equipment or as a result of poor handling.	When using a piercing machine, clean it after use and check it for signs of damage. Maintain the equipment in good condition and repair or replace worn parts when identified.	Visual inspection.	Wash and/or rinse again before production. Replace damaged elements immediately.









section V- HACCP-based Plans

ENZYMATIC AND MIXED COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Rind Treatment (eg. Smoking, Oiling, Waxing, Larding, Cloth-binding, Plastic-Coating, Rind-washing/smearing)	M, P: Microbiological contamination and cross-contamination may occur during rind-treatment. Physical contamination may arise as a result of damaged equipment or shelving.	Ensure equipment is always clean and maintained in good condition. (1) Ensure food handlers have clean hands. Where necessary use protective gloves to cover skin lesions.	Visual inspection.	Repeat cleaning and/or disinfection. Rinse with potable water of acceptable quality. Amend cleaning procedure. If it is a recurrent issue review training of cheesemaker.
	M: Contamination and Cross-Contamination during **Rind Washing (smearing)**. Poorly developed rinds may allow the growth of pathogenic bacteria while pH increases on the rind during ripening can permit growth of previously inactivated salt-tolerant pathogens such as *Listeria monocytogenes*.	Ensure high hygienic standards during milk production. (2) Ensure a good standard of hygiene during cheesemaking and ripening; in particular, maintaining an adequate standards of hygiene in hard-to-clean areas (eg. Wheels of vat or tables, hydraulic or pneumatic cylinders) as well as smearing equipment and ripening racks. Improve conditions necessary for the growth of ripening cultures. ” Old-young” smearing (where bacteria are transferred from mature to new cheeses) can promote rapid development of the correct rind microflora but may allow for cross-contamination.	Visual inspection of cheese surface	If it is a recurrent issue review procedures and training of milker and/or cheesemaker. Where smear solution cultures are not viable, consider adding a dose of smear-ripening bacterial or yeast cultures. It is possible to verify the safety of” old-young” smearing processes by checking smear solution rather than products for presence of *Listeria monocytogenes*.









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ENZYMATIC AND MIXED COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
	C: Use of rind additives which are not suitable for human consumption	Verify that the treatment is suitable for human consumption and if not inform the consumer that the rind must not be eaten. Follow the conditions of use for additives and ensure that they are suitable for the type of cheese.	Visual inspection	Inform the consumer that the rind must not be eaten. Recall the batch.
	C: Chemical contamination during smoking if combustion material is contaminated with varnish, plastics, pesticides, etc.	Use wood or other combustion material sold as suitable for smoking food product or obtained from a known source. Don't use wood from coniferous trees.	Visual inspection. Supplier specification when the combustion material is originated from an unknown source	Change combustion material or supplier.
	P. Physical contamination during rind treatment.	Ensure that equipment is maintained in good condition.	Visual inspection.	
Ripening	M, P: Contamination of the cheese surface by pathogenic bacteria.	Ensure food handlers have clean hands. Where necessary use protective gloves to cover skin lesions. Ensure that equipment is clean and maintained in good condition.	Visual inspection.	Repeat cleaning and/or disinfection. Amend cleaning procedure. If it is a recurrent issue review training of staff.
	M: Survival of *Brucella* in sheep and goats raw milk cheeses with less than 60 days of ripening time, when herd is not brucellosis free. (2)	Check that the batch is older than 60 days before release.	Production records or batch date of production	Recall batches ripened for less than 60 days and extend the ripening period to more than 60 days.







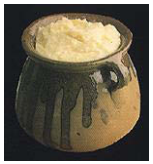


section V- HACCP-based Plans

ENZYMATIC AND MIXED COAGULATION CHEESES

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Refrigeration	M: Growth of harmful bacteria in **very soft, surface-ripened,** mixed coagulation cheeses. The acidity of the freshly made cheese may be low enough to control the growth of harmful bacteria but the pH rises during the ripening of surface-ripened cheeses.	**Store soft cheeses <8ºC upon completion of ripening**	Refrigeration temperature.	Reduce temperature or transfer stock to alternative store. Repair or replace refrigeration equipment if problem persists.
	M: Growth of harmful bacteria in **unripened, unacidified** enzymatic cheeses.	**Store cheeses at < 8ºC immediately after processing**		
Cutting, Packing and Dispatch	M, C, P: Contamination of the cheese due to contaminated packaging materials, cutting, weighing and packing equipment or poor staff hygiene. (1) (5)	Use packaging materials (including traditional materials) suitable for food use and stored in clean, dry conditions. Ensure that equipment is clean before use and between cutting different products. Fresh products should be returned to chilled storage immediately after packing.	Visual inspection	Reject contaminated, damaged or suspect packaging. If necessary, change supplier of packaging materials or improve storage conditions. Repeat cleaning and/or disinfection of cutting and weighing equipment. If it is a recurrent issue review training of staff.

See also: 1) GHP Cleaning, GHP Disinfection. 2) Risk analysis Primary Production. 3) GMP Cultures. 4) GMP Coagulants 5) GHP Staff General Hygiene, Training & Health 6) GHP Premises & Maintenance of Equipment. 7) GHP Water quality. 8) GMP Salting. 9) GMP Additions to the Milk & Curd.

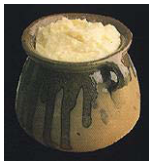




section V- HACCP-based Plans

CHEESES AND MILK PRODUCTS MADE BY EVAPORATION AND PRECIPITATION

This section covers cheeses which are produced from whey, milk or cream either by the precipitation of whey protein by heating, sometimes with added acid (eg. lactic or citric) or salt; or by the evaporation of the moisture content of the whey to leave behind caramelised the milk solids. Some whey cheeses are very high in moisture, requiring cold storage or short shelf-life to ensure their safety while others may be pressed, dried, smoked or ripened. The heat treatment employed in the production of many of these cheeses is likely to inactivate many of the microbiological hazards of concern and the safety of these products may be easily managed through the maintenance of good standards of hygiene.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Filling the vat	M: Presence or formation of staphylococcal enterotoxin produced by coagulase-positive staphylococci present in whey.	Process whey as soon as possible after it is obtained or store refrigerated so as to prevent the growth of coagulase-positive staphylococci.	Time of Processing Where necessary, measurement of temperature.	Adjust the temperature of the storage vessels. Where necessary, check the refrigeration unit is working correctly.
		Where toxigenic levels of coagulase-positive staphylococci are identified in the product from which the whey was obtained, the whey cheese should not be sold without testing for staphylococcal enterotoxin.	Test whey cheese of suspect quality for coagulase-positive staphylococci.	Reject the batch if tested positive for staphylococcal enterotoxin
	M, C: Contamination by equipment and utensils (vats, stirrers, buckets, scoops etc.) Residues of cleaning agents can get into ingredients used to prepare dairy products.	Ensure that equipment is always clean. Never put small items of equipment directly on the floor. (1) (2)	Visual inspection.	Repeat cleaning and/or disinfection. Rinse sufficiently with potable water. Amend cleaning procedure. If it is a recurrent issue review training of cheesemaker.
Addition of ingredients (eg. Acid, additional milk, cream, salt) before or after precipitation / evaporation	M, C, P: Contamination arising from the use of ingredients not suitable for food manufacture.	Check that milk (3), salt (9) and other ingredients are suitable for food use and used in the correct quantity.	Visual inspection. Manufacturer's Product Specification.	Reject ingredients of suspect quality.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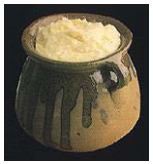
CHEESES AND MILK PRODUCTS MADE BY EVAPORATION AND PRECIPITATION

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Precipitation, heating, evaporation of moisture moulding and draining curd. .	M: Growth of pathogenic bacteria during heating.	Ensure fast and uniform heating of the ingredients.	Measurement of temperature and time.	Adjust production parameters for future batches: time, temperature.
	M: Contamination of the curd by the hands and arms of the cheesemaker.	Ensure food handlers have clean hands/arms. Where necessary use protective gloves to cover skin lesions. (6)	Visual inspection.	Wash hands/arms. Change torn gloves. If it is a recurrent issue review training of cheesemaker.
	M, C: Contamination of curd with badly cleaned equipment.	Ensure that equipment is always clean. Never put small items of equipment directly on the floor. (2) (6)	Visual inspection.	Repeat cleaning and/or disinfection. Rinse with potable water of acceptable quality. Amend cleaning procedure. If it is a recurrent issue review training of cheesemaker.
	P: Contamination of curd with poorly maintained or damaged equipment or small items (eg. jewellery) carried or worn by cheesemakers.	Ensure equipment is maintained in good condition. (7) Cheesemakers should follow guidance on small items outlined in GHP Staff (6)	Visual inspection.	Repair or replace equipment. Reject the batch if metal contamination is suspected following visual inspection.
Ripening	M: Contamination of the cheese surface by pathogenic bacteria.	Ensure food handlers have clean hands. Where necessary use protective gloves to cover skin lesions.	Visual inspection.	Adjust ripening parameters. Wash hands. Change torn gloves. If it is a recurrent issue review training of staff.
		Ensure fast drying and sufficient salting of the surface.	Organoleptic inspection. Where necessary, measurement and control of salt concentration and air humidity.	Add salt and lower air humidity if appropriate to the cheese technology.
Refrigeration	M: Growth of harmful bacteria in high-moisture cheeses.	Store high-moisture cheeses at <8ºC.	Refrigeration temperature.	Reduce temperature or transfer stock to alternative store. Repair or replace refrigeration equipment if problem persists.


section V- HACCP-based Plans

CHEESES AND MILK PRODUCTS MADE BY EVAPORATION AND PRECIPITATION

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Packing and Dispatch	M, C, P: Contamination of the cheese due to contaminated packaging materials or poor staff hygiene.	Use packaging materials (including traditional materials) suitable for food use. Cover and store in clean, dry conditions. Ensure that weighing and packing equipment is always clean and maintained in good condition. Fresh products should be returned to chilled storage immediately after packing.	Visual inspection.	Reject contaminated, damaged or suspect packaging. If necessary change supplier of packaging materials or improve storage conditions. If it is a recurrent issue review training of staff.

See also: (1) GHP Cleaning ; (2) GHP Disinfection ; (3) Risk analysis Primary Production ; (4) GMP Cultures ; (5) GMP Coagulants ; (6) GHP Staff: general hygiene, training and health ; (7) GHP Premises and Equipment ; (8) GHP Water quality ; (9) GMP Salting ; (10) GMP Additions to the Milk & Curd.

PASTEURIZED MILK FOR CONSUMPTION

LR = Legal Requirement

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking / Monitoring procedure	Corrective actions
Raw milk storage (1)	M: High storage temperature will result in bacterial spoilage of the milk.	Maintain refrigeration.	Storage temperature (LR: ≤8°C or ≤6°C (2) (3)	Reject product that has not been stored in compliance with EU temperature regulations.
Heat treatment (5)	M: Harmful bacteria may remain in the milk if the minimum intended pasteurisation time and temperature combination is not achieved.	**Maintain time and temperature of pasteurisation. (5)**	Pasteurisation holding time and temperature. LR: 63°C for 30 minutes (LTLT) or 72°C for 15 seconds (HTST) (6)	For a batch process, continue heating until the intended holding time and temperature have been achieved. For a continuous flow process, restart heating process until the intended holding time and temperature have been achieved.
	M: Poor cooling can result in bacterial spoilage of the milk.	Ensure immediate, rapid and effective cooling and maintain refrigeration.	**Cooling to an acceptable temperature: time and rate of cooling specific to the cooling method.** **Storage temperature ≤8°C in pasteurised milk tank**	Reject product that has not cooled to an acceptable temperature within an acceptable time

PASTEURIZED MILK FOR CONSUMPTION

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking / Monitoring procedure	Corrective actions
Bottling / Filling (Glass bottles, plastic bottles, cans, cartons, sachets, bag in box)	P: Foreign bodies (glass breakage, spiders and flies, small items, packaging materials etc.) can contaminate milk and cause choking or injury when the milk is consumed.	**Store all packaging securely (inverted) and use unbroken and intact packaging. (7)**	**Visual inspection of packaging.** **Packaging should be unbroken, clean and intact.**	Reject contaminated, damaged or suspect packaging. If necessary, change supplier of packaging materials or improve storage conditions.
	M: Unclean packaging and caps and poor filling technique or vending machines can result in contamination with pathogenic bacteria.	Use clean packaging and caps. Ensure clean filling technique. Regular cleaning of vending machines	Visual inspection of packaging and filling technique.	Reject unclean packaging.
	M: Poor cap application or poor closing of packaging can allow contamination with pathogenic bacteria.	Use unbroken bottles and caps or intact packaging. Seal caps carefully to ensure package integrity.	Visual inspection of packaging. (NB. Should not leak.)	Reject leaking packages.
Storage before despatch	M: Incorrect storage temperature or inappropriate shelf life can result in milk spoilage.	**Maintain refrigeration and ensure shelf life is appropriate to the product. (8)**	Storage temperature ≤8°C.	Reject product that has not been stored in compliance with member states temperature regulations.
Sale	M: Organoleptic non-compliance of products can indicate potential contamination.	Ensure wholesome product of expected organoleptic standard.	Taste test finished products. (Taste as expected for the product).	Reject non-compliant product.

(1) See also Risk analysis for Primary Production
(2) Immediately after milking, milk must be cooled to ≤8°C in the case of daily collection or ≤6°C if collection is not daily.
(3) When milk is not produced on the farm, food business operators must ensure that milking is quickly cooled to ≤6°C until processing.
(4) See also HACCP-based Plan Milk Collection, Storage in the dairy and Treatment
(5) In compliance with EU legislation
(6) Any other time and temperature combination which has equivalent or greater lethality is permitted.
(7) In the event of glass breakage, see “Hazard analysis – physical hazards”
(8) Taste test finished products at the end of shelf life. Change shelf life date if organoleptic standard has not been achieved.

section V- HACCP-based Plans

RAW MILK FOR CONSUMPTION

This section covers the sale of raw drinking milk – where it is not prohibited or restricted under national law.

LR = Legal Requirement

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking / Monitoring procedure	Corrective actions
Milk storage (1)	M: Poor cooling will result in bacterial spoilage of the milk.	**Ensure immediate and rapid cooling. (2)**	**Cooling time/temperature** **≤4 °C within 2 hours.**	Reject product that has not cooled to an acceptable temperature within an acceptable time or pasteurize the milk
	M: High storage temperature will result in bacterial spoilage of the milk.	**Maintain refrigeration temperature. (2)**	**Storage temperature** **≤ 4 °C.**	Reject product that has not been stored in compliance with EU temperature regulations
Bottling / Filling (Glass bottles, plastic bottles, cans, cartons, sachets, bag in box)	P: Foreign bodies (glass breakage, spiders and flies, small items, packaging materials etc.) can contaminate milk and cause choking or injury when the milk is consumed.	Store all packaging securely (inverted) and use unbroken and intact packaging. (3)	Visual inspection of packaging. Packaging should be unbroken, clean and intact.	Reject contaminated, damaged or suspect packaging. If necessary, change supplier of packaging materials or improve storage conditions.
	M: Unclean packaging and caps and poor filling technique or vending machines can result in contamination with pathogenic bacteria.	**Use clean packaging and caps and ensure clean filling technique. Regular cleaning of vending machines.**	Visual inspection of packaging and filling technique	Reject unclean packaging
	M: Poor cap application or poor closing of packaging can allow contamination with pathogenic bacteria.	Use unbroken bottles and caps or intact packaging. Seal caps carefully to ensure package integrity.	Visual inspection of packaging. (NB. Should not leak.)	Reject leaking packages.

section V- HACCP-based Plans

RAW MILK FOR CONSUMPTION

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking / Monitoring procedure	Corrective actions
Storage	M: Incorrect storage temperature or inappropriate shelf life can result in milk spoilage	Maintain refrigeration (2) and ensure shelf life date (2) is appropriate to the product (4)	Storage temperature ≤4°C	Reject product that has not been stored in compliance with Member State temperature regulations
Sale	M: Organoleptic non-compliance of products can indicate potential contamination.	Ensure wholesome product, organoleptic standard achieved	Taste test finished products. (Taste as expected for the product).	Reject non-compliant product

(1) See also Risk analysis for Primary Production
(2) In compliance with national legislation
(3) In the event of glass breakage, see “Hazard analysis – physical hazards.”
(4) Taste test finished products at the end of shelf life. Change shelf life date if organoleptic standard has not been achieved

BUTTER, CREAM

The cream used to make butter can be pasteurised; some member states require it to be pasteurised though a full account of national legislation is outside the scope of this guide.

Process step to monitor	Why do we need to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Cream separation	M: Growth of pathogenic bacteria between milking and the completion of cream separation.	In case of mechanical separation, separate the cream as quickly as possible after each milking For pan-based separation, maintain appropriate temperature: * In case of pre-maturation, maintain at a temperature which can allow the development of and acidification by lactic acid bacteria * Otherwise, hold the milk at < 8°C (LR)	Thermometer, Length of time	Review cream separation system
	M, C: Contamination of the cream by pathogenic bacteria via the separator or the collecting containers or by residues of cleaning products.	After use, take apart and clean the milk supply system, the cream separator and the collecting containers. Rinse equipment thoroughly.	Visual inspection	Repeat cleaning process. Review procedures where necessary as well as staff training (if it is a recurrent issue)
	M: If the cream separator does not have sufficient capacity, creaming sludge can be pulled along into the cream.	Do not separate beyond the capacity of the cream separator.	Visual inspection	If needed, use a cream separator with an adjustable flow rate according to the volume of milk to be treated, or use a buffer tank
Inoculation*	M: Contamination of milk during inoculation due to poor quality of starter bacteria or inadequate handling by the cheesemaker.	Use only starters of known origin or those with a certificate of conformity, suitable for food-use. Handle hygienically. Reject starters (including homemade starters) of abnormal odour, colour or appearance.	Visual and organoleptic inspection of direct or bulk starters.	Reject inactive starters or those with abnormal or damaged packaging. Adjust bulk starter preparation procedure.

section V- HACCP-based Plans
BUTTER, CREAM

Process step to monitor	Why do we need to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Cream maturation (a very important step in the case of fermentative maturation)	For fermentative maturation: M: Acidification which is insufficient or too slow can lead to the development of pathogenic bacteria.	Cover the containers. Adjust the temperature of the cream in order to allow the development of lactic bacteria until the desired acidity is obtained.	Thermometer, Length of time. Organoleptic inspection of the cream or pH /titratable acidity.	Readjust the temperature or maturation time.
	M: Growth of bacteria when the cream is being ripened.	Cool the cream as quickly as possible. Cover containers.	Thermometer	Adjust storage temperature
Packaging of cream**	M, P, C: Contamination of cream by the equipment, the packaging or the handler.	Clean and disinfect any reusable packaging. Use clean equipment that is maintained in good condition. Store packaging away from potential contaminants. Maintain personal and clothing hygiene.	Visual and olfactory inspection	Repeat cleaning process. Review procedures where necessary as well as staff training (if it is a recurrent issue)
Storage of cream**	M: Growth of bacteria during storage.	Cool the cream as quickly as possible. Cover containers.	Thermometer	Adjust storage temperature
	M, C: Contamination by pathogenic bacteria of cream via storage containers or by cleaning product residues	After each use, clean and disinfect the storage containers. Rinse equipment thoroughly. .	Visual and olfactory inspection.	Repeat cleaning process. Review procedures where necessary.
Churning***	M, C, P: Contamination of cream via the churn by pathogenic bacteria, foreign bodies or by cleaning product residues.	Use clean equipment that is maintained in good condition. After each use, clean the churn and rinse thoroughly.	Visual and olfactory inspection.	Repeat cleaning process. Review cleaning procedures where necessary. Minimise sources of physical contamination in food handling areas.
	M: Presence and growth of pathogenic bacteria in butter.	Maintain a suitable temperature for churning. **Stop churning at the grain stage and extract the maximum amount of buttermilk**	Visual inspection Thermometer.	Readjust temperature and length of churning time.

section V- HACCP-based Plans
BUTTER, CREAM

Process step to monitor	Why do we need to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Washing the Butter***	M: Growth of pathogenic bacteria if the washing process does not remove the buttermilk sufficiently	Perform washing with adequate quantities of water and for a sufficient number of washes	Visual inspection	Adjust the quantity of washing water
	M, C: Contamination of butter by the water used for washing	Use potable water	Use of water from public water supply. Potability certificate for private water supplies.	Review water treatment where necessary
	M: Growth of pathogenic bacteria where the water is too warm.	Adjust washing water temperature to the temperature of the butter.	Thermometer	Cool the water used for washing butter.
Blending***	M: Growth of pathogenic bacteria due to a poor distribution of moisture droplet or large droplet size	Evacuate the maximum of washing water. Blend sufficiently in order to obtain a good distribution of moisture and droplet size.	Visual inspection And/or Water test paper	Readjust length of blending time
Salting***/*	M, C: Contamination of butter by the salt	Use food quality salt within the expiry date	Visual inspection	Change supplier
Moulding/ Packaging***	M, P, C: Contamination of butter by the moulding equipment, the packaging or the handler.	Use clean equipment that is maintained in good condition. Store packaging away from possible contamination. Monitor personal hygiene. Store quickly at cold temperatures.	Visual inspection.	Repeat cleaning process. Review procedures where necessary as well as staff training (if it is a recurrent issue).

Steps concerning cream production only/ * Steps concerning butter production only/ * Optional steps
See also: 1) GHP Cleaning. 2) GHP Disinfection 3) GMP Cultures. 4) GHP Staff General Hygiene Training and Health. 5) GHP Pest Control 6) GHP Water quality 7) GMP Additions to the Milk and Curd

(LR) 853/2004 - The milk must be cooled immediately to
- 8°C maximum if it is transformed or collected the same day
- OR 6°C maximum if it is not transformed or collected the same day

section V- HACCP-based Plans

FERMENTED MILK PRODUCTS

This family of fermented milk products includes kefir, yoghurt, buttermilk, ymer, filmjölk, **rjażenka** and others - whose common feature is their acidification by lactic acid bacteria. There are two ways of making fermented milk products:
1. **Set type method**. Milk is mixed with ingredients (sugar, fruits, flavours, colourings etc.) then inoculated with starter cultures, filled into its final packaging before incubation and, finally, cooling.

2. **Stirred type method**. Milk is inoculated with starter cultures and incubated in a fermentation vessel. When a required pH has been reached, the coagulum is cooled and mixed with ingredients before filling and packing.

Depending on the technology used, the producer should determine the exact sequence of steps appropriate to their product.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Filling the vat	C, M: Contamination of milk by processing equipment and utensils (vats, stirrers, buckets, scoops etc.) Dirty equipment can cause contamination of milk with pathogenic bacteria. Residues of cleaning agents can contaminate milk.	Ensure that equipment is always clean. Never put small pieces of equipment directly on the floor. (1) (2)	Organoleptic inspection.	Repeat cleaning and/or disinfection. Rinse thoroughly with potable water. Adjust cleaning procedure. If it is a recurrent issue review training of staff.
Pasteurisation** (3)	M: Fermented milk products are very sensitive to the development of pathogenic bacteria. Some bacteria can survive inadequate pasteurisation.	Provide adequate facilities for pasteurisation.	Measurement of temperature and time.	Re-pasteurise the milk if the required temperature drops below the limit. Change or improve pasteurisation equipment.
Cooling to incubation temperature	M: Possibility of recontamination due to too long cooling time or unsuitable cooling equipment.	Ensure quick cooling time using effective cooling equipment.	Measurement of temperature and time.	Change or improve cooling equipment
Addition of starter cultures (4)	M: Contamination of milk during inoculation due to poor quality of starter bacteria or inadequate handling by the production staff.	Use only active starters of known origin or those with a certificate of conformity and suitable for food-use. Store and handle hygienically.	Visual inspection: check appearance and expiry date.	Reject packs of poor quality, abnormal appearance and smell. Adjust handling and storage procedures, change the supplier.

FERMENTED MILK PRODUCTS

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Addition of* fruit, colourings, flavourings etc. (5)	M, C, P: Possibility of contamination during additions of ingredients.	Use only tools cleaned and/or disinfected after each dosing. Use only ingredients obtained from a reputable supplier or known source and checked upon delivery and before use. Heat-treat herb mixes or fruit where the source and harvesting conditions are not known.	Visual and organoleptic inspection.	Reject ingredients and packaging of suspect quality, abnormal appearance and smell. Adjust handling and storage procedures, change the supplier
Incubation*	M: Acidification if slower than expected according to the recipe can allow development of harmful microorganisms.	**Ensure good technical condition of process facilities: (incubation vessels or chambers) Maintain appropriate time and temperature, according to the given technology**	**Visual and organoleptic inspection** **Monitoring of acidification or pH measurement** **Generally recommended value: final acidity pH ≤ 4,5**	Reject products with unusual smell and/or taste Adjust incubation parameters
Cooling of the product	M: Possibility of development of harmful microorganisms because of long and slow cooling.	Ensure rapid cooling of the products	Measurement of temperature and time.	Maintain and/or replace cooling equipment
Packaging	M, C, P: Possibility of contamination by packaging machines, packaging material, production staff or the packing environment e.g. by airborne fungi.	Clean and/or disinfect filling and packaging lines after each use. Keep packages in dry and clean place, protected against pests. Carefully clean reusable packaging. Minimise air circulation; close doors and windows and turn off fans if not required.	Visual inspection.	Reject packages if damaged or of poor quality, Maintain packaging equipment in a good state of repair. If it is a recurrent issue review training of staff.

* According to a specific technology, these steps may occur in different order.
** This step is strongly recommended but not compulsory
See Also: 1) GHP cleaning. 2) GHP Disinfection 3) HACCP-based Plan Milk Collection, Storage and Treatment. 4) GMP Cultures. 5) GMP Additions to the milk and curd

section V- HACCP-based Plans

NON FERMENTED DAIRY PRODUCTS

This category covers a wide range of products. Some are made with raw milk while others may be subjected to heat treatment during production that is equivalent to, or greater than, pasteurisation (e.g. Custard, Clotted Cream). Heat-processing of some raw milk products may negate the need to pasteurise the milk prior to processing where the time and temperature combination are at least equivalent.

Where national regulations exist regarding heat treatment of specific product types these must be respected.

Without the presence of a competitive microflora, and in the absence of other factors such as low pH which could reduce or inhibit the growth of pathogens, the safety of many non-fermented dairy products is ensured by using raw materials of good microbiological quality, maintenance of a high level of hygiene during production and either low water activity or refrigeration during storage. Products assigned a shelf life of five days or less are considered not to support the growth of *Listeria monocytogenes* (Regulation (EC) 2073/2005). Freezing, (eg. ice cream) may halt bacterial growth but is not guaranteed to reduce bacterial load.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Procurement of Ingredients or Food Improvement Agents	C, M, P: Contamination of the milk or products through the use of contaminated ingredients or following the use of undeclared allergens.	Use only ingredients obtained from a reputable supplier or known source. (1) Declare allergenic ingredients to the consumer in line with regulation (EU) 1169/2011 (L)	Visual and olfactory inspection of ingredients.	Reject the ingredient or the dairy product made with it if contamination is suspected Products which contain undeclared allergens must be removed from sale and relabelled.
Cooking / Heat Treatment of non-dairy ingredients.	M: Where non-Ready to Eat (non-RTE) ingredients (e.g. egg that may contain *Salmonella*) are used in the preparation of dairy products they may be a potential source of microbiological contamination in the product or processing room.	**Where appropriate, consider using non-RTE ingredients that have been heat-processed.** **Time and temperature combinations should be capable of inactivating the pathogens of concern.**	Temperature (and if appropriate time) of heat treatment.	Products intended for heat-treatment but which fail to meet the specified time and temperature combination must not be used for human consumption without further treatment. Where appropriate review training and procedures.

Process step to monitor	Why do we have to be careful?	Preventive actions	Checking/Monitoring procedure	Corrective actions
Refrigeration (including refrigerated 'ageing' of ice cream bases) or Freezing.	M: Growth of vegetative and spore-forming pathogenic bacteria and toxin production during prolonged cooling of heat-treated products or during refrigerated storage at too high a temperature.	**Where slow cooling is not a technological requirement and pathogens are not controlled by low water activity, refrigerate products below 8°C and maintain the chill chain. Cool rapidly to storage temperature (typically ≤8°C within four hours).** Growth of pathogens may be controlled by limiting the shelf life of the product. Frozen dairy products should be cooled and frozen rapidly to a recommended temperature of -18°C and not refrozen after thawing (eg. at market) (2) (3)	Temperature of products during cooling and refrigerated store during storage.	Reject milk where the temperature exceeds the specified storage conditions or the chill chain has not been maintained. Adjust or service refrigeration equipment. Large volumes cool less quickly; review pack size and distribution to ensure adequate cooling. Where appropriate review training and procedures.

1) GMP Additions to the Milk and Curd. 2) GMP Product Storage & Transport. 3) GMP Direct Sale.

Section VI – TRACEABILITY

Traceability is defined by Regulation (EC) 178/2002 – article 18, as 'the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;

The producer must be able to identify and to trace at any moment:

- One step back: The origin of all the ingredients used in processing: milk, coagulant, lactic cultures, salt, etc.
- One step forward: The recipient of products sold (except when they are sold to the final consumer). 'Products' includes ingredients intended for further processing foods for human consumption - such as whey and other by products which could be used as feed.

To be able to meet this requirement, the producer must have systems and procedures in place that allow for the information to be made available to the competent authorities upon their request.

What Information should be kept and provided?

Raw materials of animal origin (example: milk) and dairy products (except those which contain products of both vegetable origin and processed products of animal origin), which are received or supplied to other food companies (rather than the final consumer) should be accompanied by the following information regarding traceability:

- Description of the products (raw milk, cheese, etc.)
- The quantity of affected products
- The name and address of the dairy or business from which it has been dispatched
- The name and address of the food business operator to whom the products are dispatched
- A reference identifying the lot, batch or consignment
- Dispatch date

On receiving raw materials of non-animal origin (example: packaging materials such as cheese paper wax, coating, etc.), or dispatching dairy products containing products of both vegetable origin and processed products of animal origin, the producer shall be able to identify both the supplier and/or the name of the FBO to whom the product is dispatched.

How to provide the information?

A batch is defined ((Reg. (EC) No. 2073/2005) as *"a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period".*
According to this definition the producer shall define his batch, as long as the definition regarding "*practically identical circumstances"*, "*given place*" and *"defined production period*" is met.
Some dairies identify the batch using the date of production, a longer common period of production, the expiry date, etc. The producer takes the responsibility for choosing their own method; however in defining a batch size larger than one production day, the producer accepts the possible loss of more products in the event of non-conformity or of any food incidents.

The dairy should keep its own records of raw materials and products received and dispatched. Easy-to-implement systems are often the most effective:

- By keeping copies of invoices or dispatch notes, or,
- Through a goods-out log, a handwritten log recording the batch number, quantity, customer and dispatch date can adequately ensure ease of traceability.

Internal traceability

The Internal traceability between raw materials and ingredients received and cheeses or dairy products that are produced is voluntary, and can help to limit the extent of a withdrawal or recall in the event that contamination is identified in a specific batch of an ingredient.

Section VII-
SELF MONITORING

Self-monitoring measures play an essential role in the delivery of the **food safety management system** presented in this guide. The producer has the responsibility for ensuring that their product does not represent a health hazard for consumers and for this purpose, develops their own **food safety management system** to eliminate, prevent or reduce food safety hazards to acceptable level.

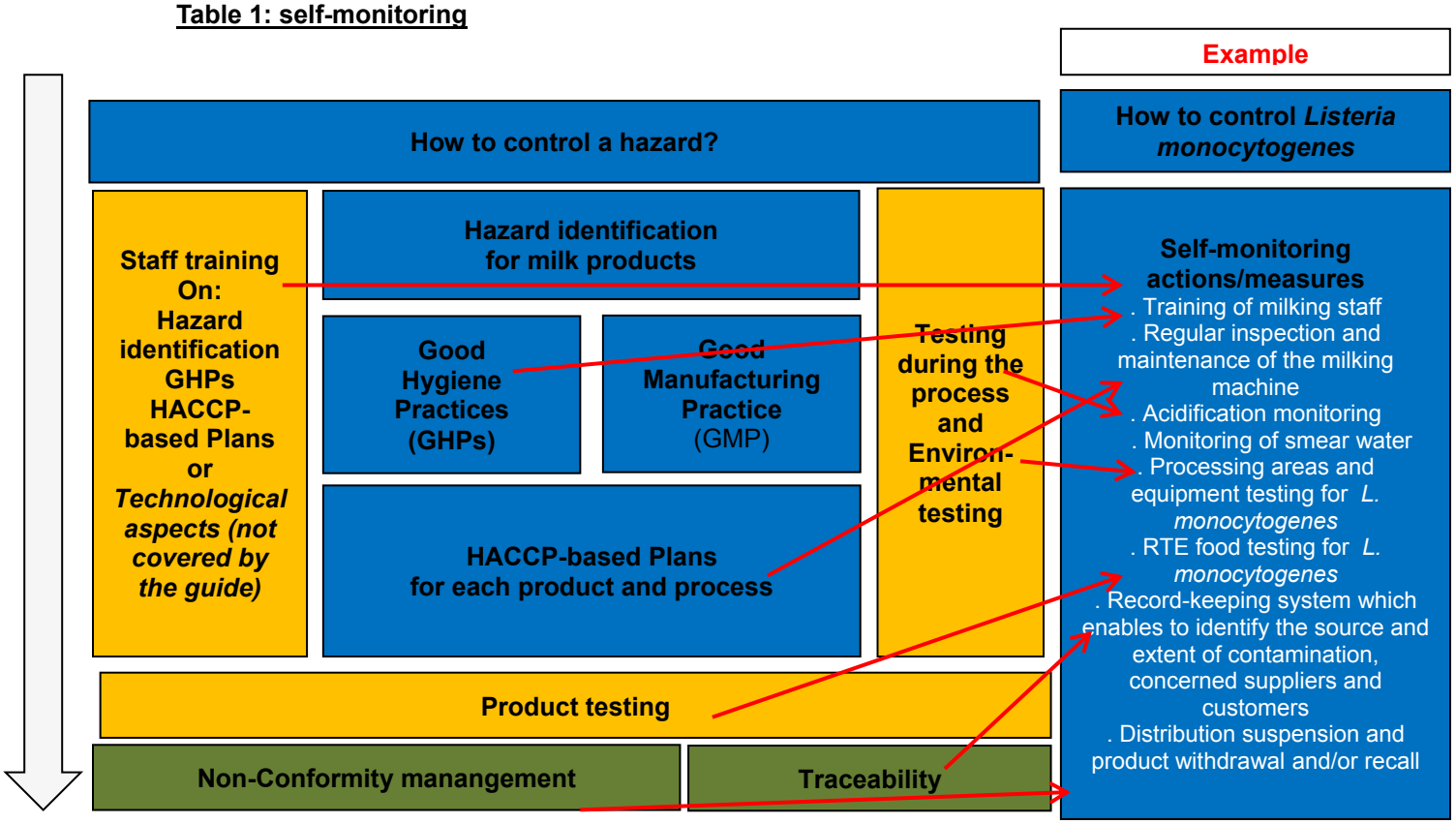
The **food safety management system** should set out self-monitoring measures appropriate to each stage of the production process. (see table 1):

- **Good hygiene practices (GHP)** are the basic foundation upon which the health control plans are based so their actual contribution to product safety is considerable. Often they cover routine measures such as checking the maintenance of machinery which are easy to carry-out and highly-effective.
- **Good manufacturing practice (GMP)** covers all aspects of manufacture including raw material, transportation, processing, storage, delivery and sale of the finished product. GMP ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.
- **HACCP-based plans** detail the preventive actions specific to the product or operations at a particular stage in its production.

The **food safety management system** is completed by five additional modules (shown in orange and grey):

- **Staff training** is essential to guarantee the correct application of food safety measures; mistakes may result from by poor communication (especially regarding changes in procedure), lack of training or lack of comprehension.
- **Analysis during the production process** can provide useful information to producers and identify issues before products reach the market.
- **Analysis of products** are used to verify the correct functioning of their food safety management system based on HACCP principles and good hygiene practice.
- **Non Conformity Management** plans provide information on procedures for dealing with non-conformities where they are identified.
- **Traceability** enables the rapid identification and segregation of Non-Conforming Products

Table 1: self-monitoring



Section VII-
SELF MONITORING

The Means of Analysis

Producers can only assure food safety by the use of a food safety management system. Reliance on end-product testing alone is not sufficient and ineffective. However testing can provide useful information to producers but it is important to distinguish clearly between sampling for validation and sampling to control the production process

1. Verification and validation of the food safety management system

Every food safety management system requires verification and validation procedures to demonstrate its efficiency and effectiveness. Therefore producers shall perform product testing as appropriate against the microbiological criteria set out in Annex I of Regulation 2073/2005.

There is no predefined frequency the producer has to follow. The frequency of sampling should rather be adapted to the nature (e.g. kind of products, size of production) and size of the food businesses, provided that the safety of foodstuffs will not be endangered.

Also the number of sample units of the sampling plans set out in Annex I may be reduced if the producer can demonstrate by historical documentation that he has effective HACCP-based procedures.

When carrying out sampling, it is highly recommended to:

- Use an aseptic technique to avoid cross-contamination between lots/batches (as defined by the producer) - particularly when sampling against a food safety criterion.
- Identify the correct sampling time. Pathogens tend to become inactivated in long-aged hard cheeses so analysis could take place during maturation rather than at curd stage while the short shelf life and moisture content of soft cheeses may justify targeting analysis on milk or curd instead.

However, where tests are carried out for the purpose of verifying the effectiveness of the Food Safety Managament System, the sampling must be carried out at the point specified in Regulation (EC) 2073 (see pages 83-85). Also, where testing is intended to specifically assess the acceptability of a certain batch of foodstuffs or of a process, the number of sample units set out in Annex I shall be respected as a minimum.

2. Analysis during the production process to control the production process

Besides validation of the food safety management system other forms of analysis may be appropriate. This could involve microbiological, physical or chemical analysis – such as monitoring of processing areas and equipment, milk, checking water activity or acidity or conducting shelf-life studies for RTE food.

Milk testing must be in accordance with regulation (EC) n°853/2004 (see section VIII). Producers manufacturing ready-to-eat foods, which may pose a *Listeria monocytogenes* risk for public health, shall sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme. For more details consult the EU 'Guidelines on sampling the food processing area and equipment for the detection of Listeria monocytogenes'. (1)

Shelf-life studies can be appropriate to determine if a RTE food can or cannot support the growth of pathogenic bacteria. For more details consult guidance documents for conducting shelf-life studies (2) (3)

All testing procedures should be based on the producer's assessment. Except for a few criteria, for which minimum frequencies of testings are fixed in the regulation (for eg. criteria for milk as primary material), the producer is responsible for setting the frequency of sampling.

Tests may be carried out during the whole production process. The choice of method depends on what the producer wants to check, for example:

- When modifying a disinfection process checking the total bacterial count may help to verify the effectiveness of the modification.
- When rind washing, analysis of smear water or swabbing cheese-ripening shelves for presence of Listeria monocytogenes can be more effective at detecting a sporadic, low-level of contamination of the curd than end-product testing.
- Demonstration of the suitability of a food or ingredient for its intended use or designated shelf life.
- When using pasteurisation the effectiveness of pasteurisation can be checked by the analysis of milk for Alkaline Phosphatase or Enterobacteriaceae (for more information, see pages 50-51 and 84).

Producers may use other sampling and testing procedures like pooling samples together, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. Those procedures may include use of alternative sampling sites and use of trend analyses.

It is important to:

- Show new employees how to take samples if this forms part of their duties.
- Ensure that the laboratory is accredited and has experience in the testing of milk products as food testing laboratories have different areas of expertise and the quality of work and consultancy can vary between them. The producer should have confidence in their choice of lab.
- Ensure that the lab receives clearly-labelled samples in an undamaged condition. The temperature during transportation to the lab is unlikely to affect the quality of samples sent for chemical analysis (eg. Enterotoxin) or microbiological analysis of firm/semi-hard or hard ripened cheeses or low-pH fermented products such as yoghurt but the chill chain should be maintained for products where refrigeration is required to ensure safety (eg milk samples or some non-fermented dairy products). The lab should be able to report the condition and temperature of samples upon arrival and offer interpretation of results in line with EC 2073/2005 as well as any specifications provided by the producer.
- Take a sufficient quantity of sample to enable the laboratory to perform the tests. Samples should be random but representative of the batch.
- If analysis is required at a particular point in time (eg. Coagulase Positive Staphylococci tested when they would be expected to be highest or raw milk samples tested for plate count) the lab should be made aware of this so as to avoid delays which could make the results hard to interpret correctly.

When carrying out sampling it is important to:

- Use a method which identifies organisms appropriate to the process or product (e.g. checking the total bacterial count to verify the effectiveness of the disinfection process).
- Use an aseptic technique to avoid cross-contamination between samples.
- Be aware of inhibitory effects of residual sanitisers or disinfectants. This is particularly important when swabbing surfaces.
- Standardise the surface area where swabs are taken to enumerate bacterial load to ensure accurate interpretation of the results.
- Follow any instructions supplied with commercial sampling kits.

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(1) *Guidelines on sampling the food processing area and equipment for the detection of Listeria monocytogenes Version 3 – 20/08/2012*
http://ec.europa.eu/food/safety/docs/biosafety_food-hygiene_microbio_criteria-guidelines_sampling_en.pdf

(2) *GUIDANCE DOCUMENT on Listeria monocytogenes shelf-life studies for ready-to-eat foods, under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs*
http://ec.europa.eu/food/safety/docs/biosafety_food-hygiene_microbio_criteria-translation_guidance_lm_en.pdf

(3) *http://ec.europa.eu/food/safety/biosafety/food_hygiene/microbiological_criteria/index_en.htm*

Summary of Regulation (EC) 2073/2005 applicable to dairy products covered by this guide

Table 1: Food Safety Criteria

The food business operator may reduce the number of sample units (n) if they can demonstrate by historical documentation that they have effective HACCP-based procedures. Sampling and testing frequency should be decided by the food business operator. Where testing is intended to specifically assess the acceptability of a certain batch of foodstuffs or of a process, the number of sample units given below shall be respected as a minimum. For food safety criteria, small m and big M are the same.

Organism	Food	Criterion	n	c	m	M	Definition
Listeria monocytogenes	**Ready to Eat (RTE) foods able to support the growth of *Listeria***	1.2	5	0	Absent in 25g		In five samples, none may exceed "absent in 25g" **before the food leaves the immediate control of the producer**, when the FBO is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed 100cfu/g throughout the shelf-life.
		1.2	5	0	100cfu/g		In five samples, none may exceed 100cfu/g **within the shelf life of a product placed on the market**, when the FBO is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed this limit throughout the shelf-life.
	RTE foods unable to support the growth of *Listeria* This category includes products with: • pH ≤4.40 or; • a_W ≤0.92 or; • pH ≤5.00 and a_W ≤0.94 or; • shelf life <5 days. • Other products subject to scientific justification.	1.3	5	0	100cfu/g		In five samples, none may exceed 100cfu/g **within the shelf life of a product placed on the market.**
Salmonella	**Cheese, butter or cream made from raw/unpasteurised milk** (Unless the producer can satisfy the competent authority that there is no Salmonella risk due to ripening time and a_W.)	1.11	5	0	Absent in 25g		In five samples, all must be "absent in 25g" **within the shelf life of a product placed on the market**.
	Ice Cream (except where the manufacturing process or the composition will eliminate the risk).	1.13	5	0	Absent in 25g		In five samples, all must be "absent in 25g" **within the shelf life of a product placed on the market.**
Staphylococcal Enterotoxin	**Cheese as referred to in the Process Hygiene Criteria relating to Coagulase Positive Staphylococci (CPS) (2.2.3, 2.2.4 & 2.2.5)**	1.21	5	0	Not Detected in 25g		In five samples, all must be "Not Detected in 25g" **within the shelf life of a product placed on the market.** This criterion applies where levels of CPS exceed 10^5/g at the point specified in the relevant process hygiene criterion.

Summary of Regulation (EC) 2073/2005 applicable to dairy products covered by this guide

Table 2: Process Hygiene Criteria

The food business operator may reduce the number of sample units (n) if they can demonstrate by historical documentation that they have effective HACCP-based procedures. Sampling and testing frequency should be decided by the food business operator. Where testing is intended to assess the acceptability of a process, particularly where it is new or has been modified, the number of sample units given below shall be respected as a minimum.
Results below m may be considered satisfactory. Results above M or results where more than c samples have values between m and M are unsatisfactory.
In the event of an "acceptable" result (where c (or fewer) results exceed m but none exceed M) the food business operator should review the production process to avoid a trend towards unsatisfactory results.
Explanatory notes are provided below the table.

Organism	Food	Criterion	n	c	m	M	Definition	Action in case of unsatisfactory results (see below)
E. coli	**Cheeses made from milk or whey which has undergone heat treatment**	2.2.2	5	2	100 cfu/g	1000 cfu/g	In five samples, two may exceed 100 cfu/g as long as none exceed 1000 cfu/g**, at the time during manufacture when the count is expected to be highest. ****	A & B
	Butter and Cream made from Raw Milk (or milk that has undergone a lower heat treatment than pasteurisation.)	2.2.6	5	2	10 cfu/g	100 cfu/g	In five samples, two may exceed 10 cfu/g as long as none exceed 100 cfu/g, **at the end of the manufacturing process.**	A, B & C
Coagulase Positive Staphylococci Where values **>10^5 cfu/g are detected, the cheese batch must be tested for staphylococcal enterotoxins** to verify compliance with food safety criterion 1.21.	**Cheese made from Raw Milk**	2.2.3	5	2	10 000 cfu/g	100 000 cfu/g	In five samples, two may exceed 10 000 cfu/g as long as none exceed 100 0000 cfu/g, **at the time during manufacture when the count is expected to be highest. ****	A, B & C
	Cheese made from Milk which has undergone a lower heat treatment than pasteurisation*	2.2.4	5	2	100 cfu/g	1000 cfu/g	In five samples, two may exceed 100 cfu/g as long as none exceed 1000 cfu/g, **at the time during manufacture when the count is expected to be highest. ****	A, B & C
	Ripened cheese made from milk or whey that has undergone pasteurisation or stronger heat treatment*							A, B & C
	Unripened soft (Fresh) Cheeses made from milk or whey that has undergone pasteurisation or stronger heat treatment*	2.2.5	5	2	10 cfu/g	100 cfu/g	In five samples, two may exceed 10 cfu/g as long as none exceed 100 cfu/g, **at the end of the manufacturing process.**	A & C
Enterobacteriaceae	**Pasteurised Milk or other Pasteurised Liquid Dairy Products**	2.2.1	5	0	10 cfu/ml		In five samples, none may exceed 10 cfu/ml, **at the end of the manufacturing process.**	D
	Ice Cream & Frozen Dairy Desserts	2.2.8	5	2	10 cfu/g	100 cfu/g	In five samples, two may exceed 10 cfu/g as long as none exceed 100 cfu/g, **at the end of the manufacturing process.**	A

* unless the food business operator can demonstrate to the satisfaction of the competent authority that the product does not pose a risk of Staphylococcal enterotoxins
**Coagulase-Positive Staphylococci is a weak competitor and for many ripened cheeses the level will be highest at around 24-72 hours, decreasing thereafter. This depends on multiple technological factors specific to each cheese variety including pH, moisture and rind-washing. The level of E. coli in many ripened cheese varieties (including hard, lactic) may be expected to peak during coagulation and decrease during ripening.

Indicators of Faecal Contamination in Raw Milk Products
As several pathogens associated with human disease are associated with faecal contamination of the milk, where process hygiene indicators such as E. coli are used for raw milk product and where atypical results or upward trends are observed during self-monitoring checks, milk production hygiene should be investigated by the food business operator and improvements made where they are identified as being appropriate.

Actions to be taken in the event of Unsatisfactory Results as identified in Regulation (EC) 2073/2005
A: Make improvements in production hygiene.
B: Make improvements in selection of raw materials.
C: If values >10^5 are detected, the cheese batch has to be tested for Staphylococcal Enterotoxins.
D: Check on efficiency of heat-treatment and prevention of recontamination as well as the quality of raw materials.

A note on Raw Milk intended for manufacture of products
Criteria applicable on raw milk internted for futher processing, according to requirements of Regulation (EC) 853/2004 annex III section IX chapter I (III)

	For raw cow's milk	For raw milk from other species	
		Intended for the manufacture of products by a process involving a heat treatment	Intended for manufacture of raw milk products
Plate count at 30 °C (per ml)	≤ 100 000*	≤ 1 500 000*	≤ 500 000*
Somatic cell count (per ml)	≤ 400 000**	-	-

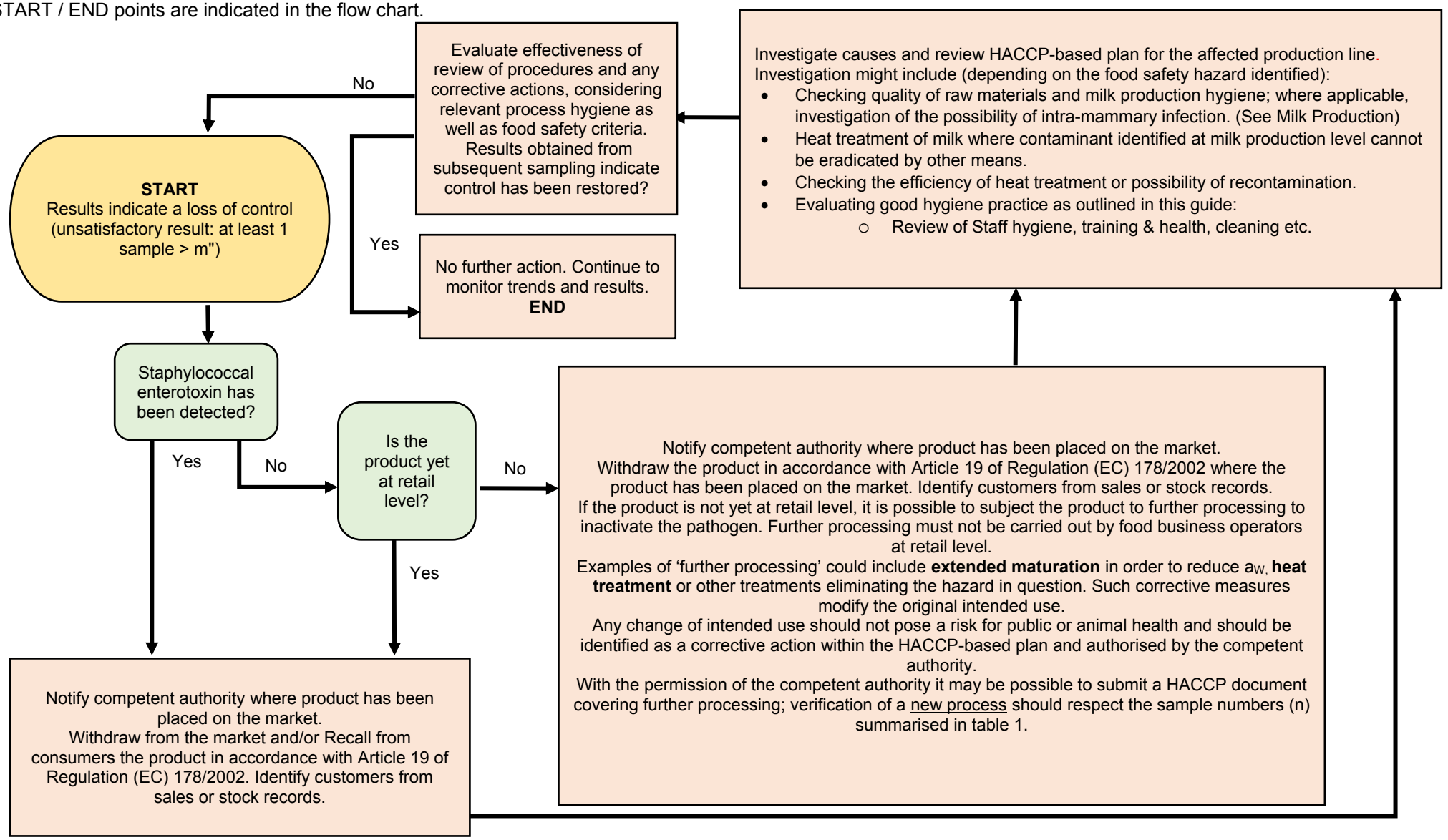
* Rolling geometric average over two months, two samples per month
** Rolling Geometric Average over a three-month period with at least one sample per month unless authorised by the competent authority

A note on Raw Milk & Raw Cream intended for direct Human Consumption
In addition to the requirements of Regulation (EC) 853/2004 annex III section IX chapter I (III), as regards raw milk or raw cream intended for direct human consumption, its placing on the market may be prohibited or subject to restrictions set at Member State level according to article 10(8) of the aforementioned regulation – which may include additional microbiological criteria.

Section VIII - NON CONFORMITY MANAGEMENT -

Non-Conformity Management: Food Safety Criteria

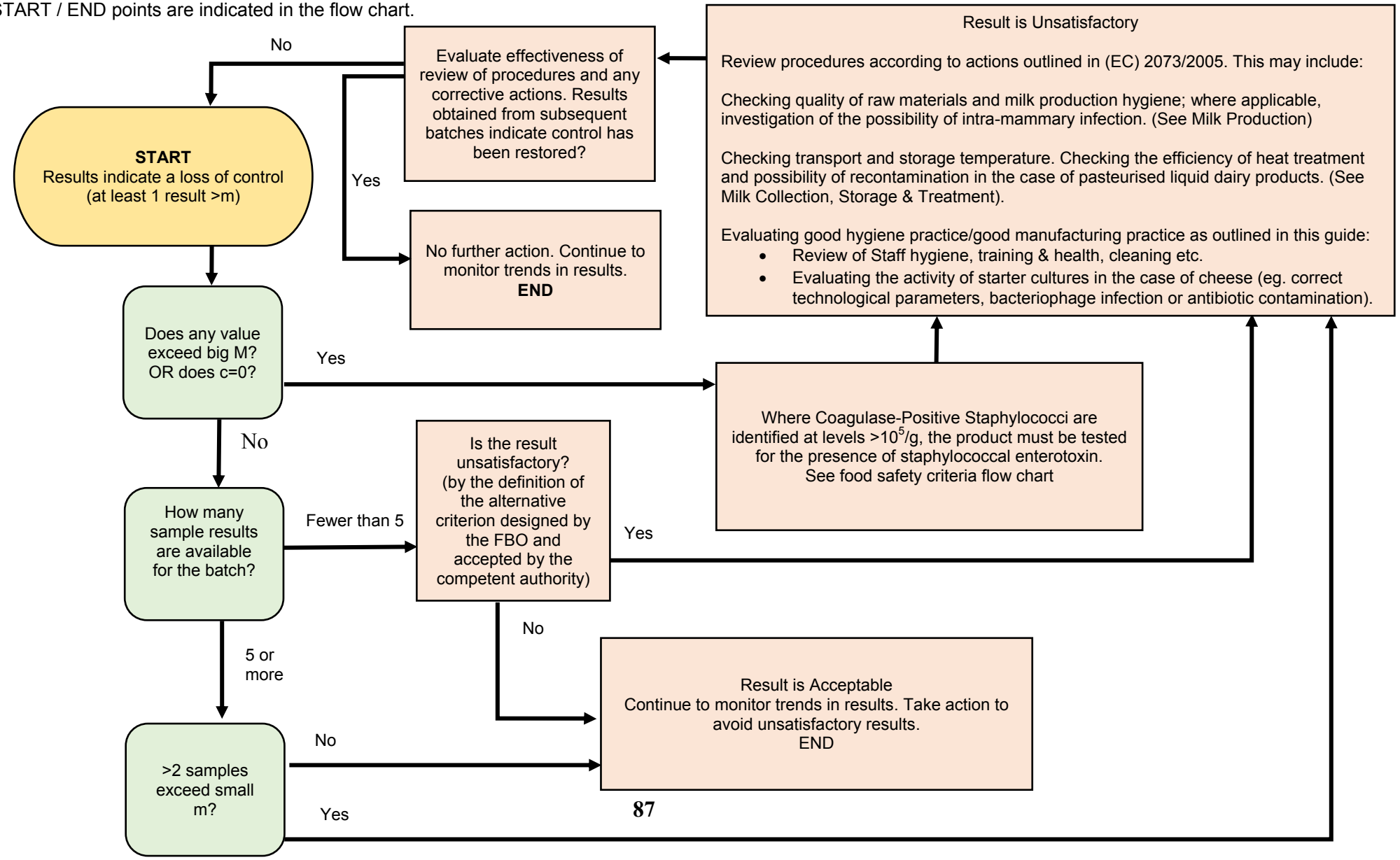
This flow chart is an example of a procedure which may be followed in the event that microbiological results obtained **when testing products against a food safety criterion <u>at the point specified in Regulation (EC) 2073/2005</u>** suggest a loss of control. Products are tested when *placed on the market during their shelf life* or, in the case of *Listeria monocytogenes* criterion 1.2, *before the food has left the immediate control of the food business operator who has produced it* (Summarised in table 1).
START / END points are indicated in the flow chart.



Section VIII - NON CONFORMITY MANAGEMENT -

Non-Conformity Management: Process Hygiene Criteria

This flow chart is an example of a procedure which may be followed in the event that microbiological results obtained **when testing against a process hygiene criterion <u>at the point during manufacture specified in Regulation (EC) 2073/2005</u>** (summarised in table 2) suggest a loss of control. START / END points are indicated in the flow chart.



Withdrawal, recall

'Withdrawal' is the process by which a product is removed from the supply chain, with the exception of product that is in the possession of consumers.

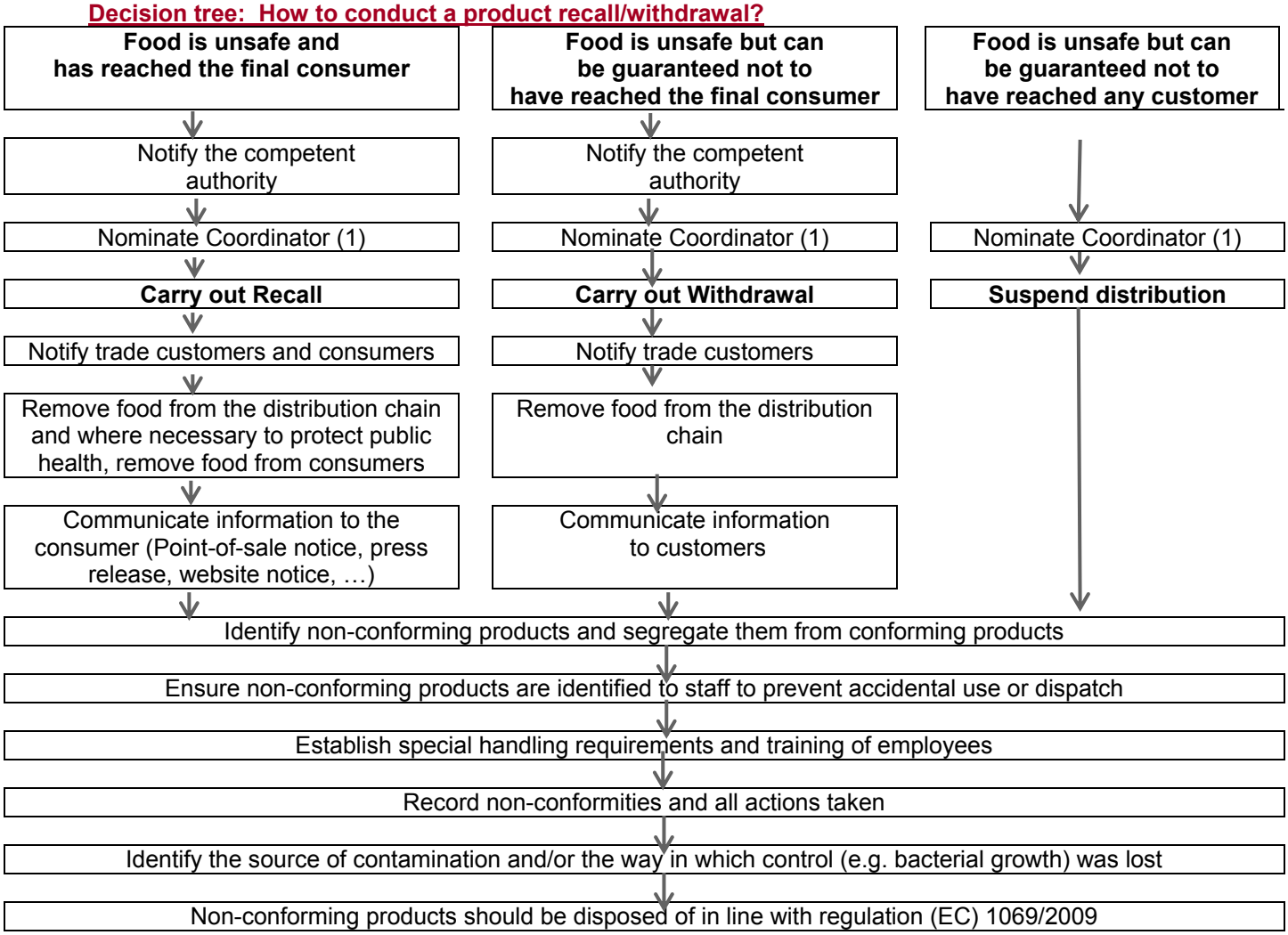
'Recall' means the process by which a product is removed from the supply chain and where consumers are advised to take appropriate action, for example to return or destroy food.

In case of suspicion of the safety of a dairy product that is no longer under the control of the cheese dairy, the traceability system should allow the producer to track the products for the purposes of facilitating withdrawal or recall. The producer must:

- Collect the following information on the affected food:
  - Food name and description
  - Batch codes involved
  - Quantity of food implicated
  - Distribution details
  - Whether the food may have reached consumers.
- Notify the competent authorities in order for them to supervise the action plan decided by the producer.
- Perform a withdrawal or (where the product poses a significant hazard to consumers) a recall.

In case of non-conformity and in addition to the above measures, follow the guidance of the Non Conformity Management.

Decision tree: How to conduct a product recall/withdrawal?



(1) To ensure efficiency, it is recommended to nominate a single person within the business to coordinate the recall/withdrawal or make contact with customers or the press.

APPENDIX 1
HAZARD ANALYSIS

CHEMICAL HAZARDS

Additives, Enzymes and other Ingredients (1)

Dairy products may become contaminated by the addition of additives and enzymes which are not authorised or by the use of inappropriate doses of authorised additives. Products may also be contaminated by the addition of ingredients which are chemically contaminated.

Preventive Measures: Use only additives and enzymes permitted for use in dairy products under EU legislation. Obtain additives, enzymes and ingredients from a reputable source and keep delivery documents as a record of batch numbers received. Follow the supplier's instructions for use and measure quantities accurately.

Allergens (2)

The presence of allergens may pose a significant risk to consumer health.

Preventive measures: Herbs, nuts & other ingredients should be evaluated for the presence of allergens including: gluten, crustaceans, molluscs, fish, peanuts, nuts, soybeans, celery, mustard, sesame, lupin, sulphur dioxide and eggs. The presence of allergenic ingredients, including milk, in dairy products must be declared to the consumer in line with Regulation (EU) 1169/2011. The presence of allergens in an ingredient may not be obvious, for example, lysozyme is often produced from egg white.

Antibiotics, other veterinary medicines and biocides

Residues from veterinary medicines, including antibiotics and parasite treatments such as anti-protozoal or anti-helminthic drugs that have been administered to milking animals, can pose a risk to consumer health if they contaminate the milk supply. Antibiotics may also inhibit the growth of starter cultures.

Preventive Measures: Teat dips and sprays should be authorised for use as veterinary products. Identify milking animals undergoing treatment, milk them separately and exclude the milk from supply into the food chain. Clean/rinse the milking equipment after such animals are milked**.** Veterinary medicines must be administered in accordance with the label instructions unless authorised for 'off-label' use by a veterinarian. Observe the correct withdrawal period following treatment of a milking animal and note that this may be extended by 'off-label' use. Suitable monitoring procedures may include i) inspection of farm records detailing veterinary medicines administered or ii) screening for the presence of antibiotics.
Maximum Residue Limits (MRLs) for permitted substances are stated (and prohibited substances listed) in Commission Regulation (EU) 37/2010 as amended. Further prohibited substances are listed in Council Directive 96/22/EC as amended.

Pesticides

Residues from pesticides contaminating feeds or grazing land may contaminate the milk supply.

Preventive Measures: Use pesticides according to the manufacturer's instructions, observing the specified period between application and harvesting or grazing.

APPENDIX 1
HAZARD ANALYSIS

Detergent and disinfectant residues

Chemicals used in the cleaning and disinfection of the milking equipment, bulk tank, churns, road tankers or pipelines and cheesemaking equipment should be considered as a possible source of contamination of the milk supply. Chemical residues may pose a direct risk to consumer health or, at lower levels, may inhibit starter activity which may compromise the safety of the product.

Preventive measures: When purchasing chemicals (eg. disinfectants) make sure they are licensed for this application. Follow the correct cleaning procedure and the correct dose of chemical. After cleaning and disinfection, rinse equipment with potable water according to manufacturer's instructions.

Dioxins and polychlorinated biphenyls (PCBs) (3)

Dioxins are a group of chlorinated organic compounds which may be present as environmental contaminants. They can be produced by uncontrolled incineration and industrial processes. Dioxins cause a number of health problems including immunological, neurological and reproductive disorders and cancer. They are persistent in the environment and are fat soluble, becoming concentrated by the cheesemaking process.

Preventive measures: Industrial releases are a more significant source of dioxins than agricultural activities and monitoring is carried out at national level rather than by farms. Farmers should however avoid the unauthorised incineration of waste materials which can increase the levels of dioxin present in the vicinity of the milking herd or flock. Contaminated land should not be used for grazing or growing of feed crops.

Heavy metals (3)

Lead and other heavy metals can accumulate in the body; chronic toxicity can cause a range of gastrointestinal and neurological symptoms in milking animals and humans, children being particularly at risk.
The principal sources of contamination are through environmental contamination or contaminated feed. Soils in some areas may contain high levels of lead and care should be taken to avoid over-grazing.

Preventive measures: Exclude milking animals from grazing areas that contain illegally-dumped waste, car batteries, burnt-out vehicles, old machinery, mine-workings and bonfire ash. Avoid the use of run-off water from land with high levels of lead. Seek veterinary advice in the event of suspected lead poisoning in a milking animal. Food contact surfaces and the water supply may also be possible sources of heavy metal contamination (see Good Hygiene Practices Water Supply).

Aflatoxin M1:

Some genera of moulds including species of *Aspergillus*, *Penicillium* and *Fusarium* are able to produce toxins such as Aflatoxin (B1, M1, B2, and M2), Ochratoxin and Citrinin which have carcinogenic (cancer-promoting) and nephrotoxic (kidney-damaging) properties in humans if consumed over a long period of time. Aflatoxin B1 may be found in animal fodder and is the most important of the aflatoxins. Following ingestion by milking animals, it is excreted in the milk as aflatoxin M1. Directive 2002/32/EC sets maximum levels for Aflatoxin B1 in feed.

Aflatoxins are thermostable. Regulation (EC) N°1881/2006 sets a maximum level for aflatoxin M1 in milk, heat-treated milk and milk destined for the processing of dairy products of 0.050 µg/kg. Concentration and dilution criteria must be applied in order to establish the maximum level that is acceptable in dairy products.

Chronic ingestion of mycotoxins by milking animals may manifest in symptoms such as loss of reproductive health, digestive disorders, skin lesions and abortion.

Animal feedstuffs can be contaminated in the field or during storage. Although Aflatoxins can be excreted in the milk, they are mostly excreted in faeces and urine.

During separating of the milk fat, most aflatoxins are eliminated in the skimmed milk and the aflatoxins always present in cream are eliminated during churning in the buttermilk and cleaning water. In cheese making, the distribution depends on the technology employed which determines the quantity of whey lost from the curd. For yoghurt, almost all of the aflatoxin remains in the product. The most harmful mycotoxins are not usually formed to a significant degree in low carbohydrate foods, such as cheese, under conditions typically encountered during ripening. Aflatoxin that is already present in milk due to contaminated feed may become concentrated in the curd during cheese production though its retention in the curd depends on the technology employed and prevention of contaminated feed remains the principal control.

Preventive measures: practical ways to reduce or to avoid mycotoxin production in fields are limited. Good practices for harvesting and storage of feeds can help to maintain low levels of mycotoxins in animal feed as low moisture, anaerobiosis and low pH are not favourable for their development. Where necessary remove moisture from feeds.

Miscellaneous Hazards:

Migration of chemicals from food contact materials can occur. This can be prevented by only using approved food contact materials.
For smoked cheese and other smoked products the smoking step must be considered in the hazard analysis.

1) At the time of writing, the list of authorised enzymes is still in preparation.

2) Histamine and other biogenic amines produced by lactic acid bacteria during the maturation of some long-aged hard and blue cheeses has been implicated as a cause of allergy-like symptoms in susceptible consumers. It is not considered to be a significant hazard in farmhouse and artisan cheese: there are no preventive measures which can be applied by producers to guarantee the absence of histamine and currently there are no criteria in EU legislation for acceptable levels in cheese.

3) Commission Regulation (EC) 1881/2006 lays down maximum levels for dioxins and dioxin-like PCB's in raw milk and dairy products including butterfat and for lead and Aflatoxin M1 in raw and heat-treated milk, including that intended for processing into dairy products.

APPENDIX 1
HAZARD ANALYSIS

PHYSICAL HAZARDS

Glass, wood, plastic and metal from equipment and premises

Splinters from damaged equipment pose a risk to consumer health. Fragments of glass from broken items and metal shards from damaged equipment pose significant risks to consumer health. Packaging from starter cultures and other ingredients may pose a choking hazard.

Preventive measures: Premises should be maintained in good condition. Equipment should be free from damage and checked to ensure that glass and metal components are intact before and after use. Glass items should not be present in the dairy unless their use is unavoidable. Glass breakage should be recorded and production suspended while the breakage is cleared up. Glass particles can travel up to ten metres from the point of breakage and potentially contaminated batches of milk, curd or cheese should be destroyed. Protective clothing, including shoes, should be changed after clearing up a glass breakage. Dispose of packaging from starter cultures and other ingredients immediately after use.

Miscellaneous Foreign Bodies

While posing a minor physical hazard, milk may be contaminated by grass and dirt from the teats which poses a risk of microbiological contamination. Physical contamination of dairy products arising from pest activity can be a source of microbiological contamination by pathogenic or spoilage bacteria. Damaged food contact materials surfaces can pose a risk of physical contamination while unsuitable materials may pose a risk of chemical contamination.

Cheesemaking personnel and visitors should be considered a significant source of possible physical contamination. Physical contaminants may pose a choking hazard to the consumer or can be a source of microbiological contamination. Examples include: buttons, jewellery, coins, pens, mobile phones, gloves, nail varnish, false fingernails and hair.

Preventive measures: Careful preparation of the teat for milking. Filter the milk before storage or processing. Protect the production space or the vat from pests including flying insects. Inspect ingredients and packaging upon receipt. Follow a documented Staff and Visitor Hygiene policy. (See GHP Staff Hygiene and Training). Ensure that clean protective clothing is provided by the dairy and is fit for purpose. Use appropriate food contact materials.

APPENDIX 1
HAZARD ANALYSIS

MICROBIOLOGICAL HAZARDS

Brucella spp (except *B. ovis* which is not pathogenic for humans)

Brucella is the agent responsible for brucellosis, an infectious disease which is contagious to both animals and humans and is present all over the world. The main animal reservoirs of *Brucella* are cattle (*B. abortus*), sheep and goats (*B. melitensis*) and domestic swine (*B. suis*).

Brucellosis is a zoonosis and human infection can occur by:

- consuming contaminated food (principally raw milk and raw milk products)
- contact with infected animals and particularly:
  - genital secretions, aborted foetuses and placentas
  - skin (even when apparently healthy)
  - digestive, conjunctival or nasopharyngeal mucosa
  - infected organs, particularly the liver, spleen and udder
  - contaminated manure or wool.

Regulation (EC) n°853/2004 sets specific hygiene rules applicable to foodstuffs of animal origin and indicates what action to take regarding brucellosis in relation to raw milk. National regulations set out technical and administrative measures regarding collective prophylaxis and sanitary surveillance of cattle, sheep and goats. The prevention of human brucellosis is based on programmes of prevention and eradication of infection among livestock. The aim of these programmes is to reduce the prevalence of infection in herds by implementing sanitary and/or medical controls (vaccination of animals) and, as far as possible, to achieve eradication of the infection, initially farm by farm, then at a wider regional or national level.

Preventive measures: In the cases of cow, goat and sheep herds, the control of Brucella contamination of milk production requires the use of raw milk solely from herds (in the case of cows) or from farms (in the case of goats and sheep) that are brucellosis-free or officially brucellosis-free. On-farm control of this risk requires the management of animal movements, monitoring and recording of aborted foetuses and the application of compulsory prophylaxis measures. In herds or farms that are not brucellosis-free or officially brucellosis free, milk from sick animals or from animals who show a positive reaction to tests for brucellosis must never be used. Milk from the rest of the herd must be treated to ensure its safety, in accordance with the regulation (EC) 853/2004 (section 9, chapter 1, art.3) and with approval from the competent authority.

Mycobacterium bovis and *M. tuberculosis*

Two main species are known to be pathogenic to man: *M. tuberculosis* causes human tuberculosis while *M. bovis* (bovine tuberculosis) causes infection in cattle. *Mycobacterium caprae* has also been recently involved in human infection.
The natural reservoirs of *M. tuberculosis* are humans and primates and, occasionally, other mammals. Transmission in humans most often occurs by prolonged exposure to sick people. The natural reservoirs of *M. bovis* are cattle, goats, pigs and, very rarely, sheep, humans and various wild mammals.

Animals that are sick or have latent infections can transmit the disease to humans through:

- Inhalation of contaminated aerosols (generated by coughing animals) or infected dust in the environment
- Infection of wounds while handling contaminated objects or tuberculous lesions in the abattoir
- Ingestion of raw milk or insufficiently heat-treated milk.

Regulation (EC) n°853/2004 sets specific hygiene rules applicable to foodstuffs of animal origin and indicates what action to take regarding tuberculosis in relation to raw milk. National regulation sets out technical and administrative measures regarding collective prophylaxis and sanitary surveillance of cattle, sheep and goats.

Preventive measures: The prevention of M. bovis in human is principally based on programmes of prevention and eradication of infection among livestock. Control of this risk requires the management of animal movements; sanitary controls on introductions to the herd, and the application of compulsory prophylaxis measures (i.e. herd screening and removal of infected animals). In herds not tuberculosis free, milk from animals who show a positive reaction to tests for tuberculosis, nor any symptoms of these diseases must never be used. Milk from the rest of the herd must be treated to ensure its safety, in accordance with the regulation (EC) 853/2004 (section 9, chapter 1, art.3) and with approval from the competent authority.

Shiga toxin-producing *Escherichia coli* (STEC)

Escherichia coli (*E. coli*) is a group of diverse bacteria normally present in the digestive microflora of humans and warm-blooded animals. Most *E. coli* strains are harmless but some of them are pathogenic because they have acquired virulence factors. These are, in particular, the Shiga toxin-producing *E. coli* (STEC, also known as VTEC), which have acquired the *stx* virulence gene and are therefore capable of producing Shiga toxins. Among these, some serogroups which carry additional virulence genes are considered highly pathogenic.

Infections caused by STEC constitute a major problem for public health, due to the severity of clinical symptoms that they can generate, in particular haemorrhagic colitis and haemolytic uremic syndrome (HUS). HUS affects primarily young children and elderly people. It constitutes the main cause of acute renal failure in children under 3 years old. The infectious dose is very low and a few bacteria can result in infection. Article 14.1 of Regulation (EC) n°178/2002 requires that no foodstuff may be placed on the market if it is hazardous. Shiga toxin-producing *E. coli* are on the list of agents to monitor by EU Member States (Directive 2003/99/EC).

STEC, like all *E. coli* are heat-labile bacteria. Vigilance is recommended in processing of raw milk. The contamination of products rarely occurs from the factory and the prime source of STEC is the milk itself.

While humans can carry STEC, domestic ruminants, and in particular cattle (sheep and goats), are the main carriers. They are asymptomatic carriers and contribute to the contamination of the environment by spreading the bacteria present in their faeces. Other wild animals, vermin and birds can also be carriers of these bacteria and thereby contribute to its circulation on farms. Animal feed (grass, forage) and drinking water can also become contaminated in this way. STEC can survive for several weeks or even several months in a farm environment, in drinking trough sediment, faeces or manure on the ground.
Intra-mammary contamination with STEC cannot be discounted.

Contamination of milk occurs during milking due to unclean teats or unclean milking areas. Contamination can also occur indirectly via contaminated water. STEC can also be present in the milking machine if this is poorly designed, poorly maintained and/or inadequately cleaned.

Preventive measures: As stated in point 14 of the preamble to Regulation (EC) 2073/2005, it was the opinion of the Standing Committee on Veterinary Measures relating to Public Health that *"microbiological guidelines aimed at reducing the faecal contamination along the food chain can contribute to a reduction in public health risks, including VTEC."* Risk of contamination of products with STEC may be reduced by control of faecal contamination during milk production. By following good hygienic practices at this stage, as described in the section IV of this guide, the producer is able to prevent faecal contamination and reduce the risk of contamination by STEC.

Listeria monocytogenes

The genus *Listeria* comprises several species of which the species *Listeria monocytogenes* is pathogenic to humans and animals while the species *L. ivanovii* is pathogenic to animals and, rarely, to humans. *L. monocytogenes* is responsible for a disease affecting humans and animals (a zoonosis) called listeriosis which can - in people more susceptible to Listeria infections - leave serious permanent damage and leads to death in 15 to 30 % of human cases. Infection mainly occurs by ingesting contaminated foodstuffs.

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Regulation (EC) n°2073/2005 requires *L. monocytogenes* to be absent in 25 g of dairy products or it permits it to be present at < 100/g where studies have shown that the organism will not exceed this level during the entire life of the product.

Regulation (EC) No 2073/2005 also requires, in its article 5, the monitoring for *L. monocytogenes* on contact surfaces and the production environment, as a part of the sampling scheme to be established by the producer (testing frequency decided by the producer in the context of their procedures based on HACCP principles and good hygiene practice – see article 4 point 2 of Regulation (EC) 2073/2005). *L. monocytogenes* is destroyed by pasteurisation and inhibited by good acidification. *Listeria* spp are soil-borne and salt-tolerant bacteria, ubiquitous in the external environment and able to grow at cold temperatures (<4°C).

Listeria species are found in forage, especially fermented forages (silage, wrapped bales) and can grow where these are poorly harvested, poorly made or poorly handled during distribution. They have the ability to form biofilms, which helps them to persist in processing environments.

Listeria spp are excreted in the faeces of some animals and the farm environment including bedding, water and milking machines can become contaminated. Milk contamination occurs during milking due to unclean skin on the teats or via the contaminated milking equipment. More rarely, milk may become contaminated from subclinical (not visible) intra-mammary infection.

As *Listeria* spp are soil-borne, the contamination of cheese-making premises can arise from the movement of people, equipment, milk or products. In cheese-making facilities, the most frequently contaminated areas are the floors particularly in wet areas such as standing water or drain pipes. During production, contamination of dairy products may occur either from the milk or from cross-contamination due to handling or equipment such as poorly-cleaned moulds.

Preventive measures: In order to prevent contamination, measures must be taken to control the quality of animal feed (from harvesting to distribution) and water, as well as cleaning of equipment, treatment of mastitis and the establishment of good general hygiene practices on farms, particularly at milking time and in processing areas.

***Salmonella* spp.**

Non-typhoidal serotypes of *Salmonella* cause salmonellosis which is one of the main bacterial gastroenteric diseases in industrialised countries. Other serotypes (*S. Typhi* and *S. Paratyphi* A, B and C) are the cause of typhoidal fevers. Transmission to humans occurs mainly through consumption of contaminated foods. There are food safety criteria for *Salmonella* in Regulation (EC) 2073/2005 which set out that it should be absent from cheese, butter and cream made from raw milk or from milk treated at a lower temperature than that of pasteurisation, and likewise for ice creams, excluding products where the manufacturing process or the composition of the product will eliminate the *Salmonella* risk.

Salmonella is destroyed by pasteurisation. The main reservoir is the gastrointestinal tract of mammals (swine, cattle) and birds (wild birds, domestic poultry), rodents and reptiles. The animal reservoir constitutes the main source of risk, particularly for raw milk products and *Salmonella* present in animal faeces can contaminate pastures, soils and water, surviving there for several months allowing the environment to become a source of risk. For *S. Typhi*, humans are the only reservoir.

Milk is contaminated primarily during milking by the presence of dirt on the skin of the teats or in the environment. On rare occasions, milk may be contaminated as a result of udder infection. Dairy products can become contaminated from the milk, from handling by asymptomatic carriers or through contaminated water.

Preventive measures: To prevent the contamination of milk and dairy products by *Salmonella* spp, it is recommended to completely isolate animals that are clinically ill, to have an adapted system to manage animal faeces to avoid spreading the bacteria, protect water and feed from faecal contamination and to control vermin and birds that can excrete salmonella. Finally good hygienic practices are necessary at the level of both milk production and processing.

Enterotoxins produced by Coagulase-Positive Staphylococci (including *Staphylococcus aureus*)

Food borne illness due to coagulase –positive staphylococci is an intoxication that follows the ingestion of Staphylococcal enterotoxins (SE) formed in food in which the pathogen has grown to high levels prior to consumption. The production of staphylococcal enterotoxins occurs when the population of enterotoxigenic staphylococci has reached at least 10^5-10^6 cfu/g. Staphylococcal enterotoxins are heat-resistant proteins that remain virulent after the organism has died and cannot be inactivated by normal food processing methods.

Regulation (EC) n°2073/2005 sets out a process hygiene criterion for the number of coagulase-positive staphylococci that must be applied at the point at which the number of this pathogen is expected to be at its highest. Regulation (EC) 2073/2005 also defines at the same point of the process a food safety criterion, for the presence of staphylococcal enterotoxins.
The food should be checked for the presence of enterotoxins when the number of coagulase-positive staphylococci exceeds 10^5 cfu/g.

Staphylococci are ubiquitous salt-tolerant bacteria resident on skin, in mucosa and the nasopharynx of warm-blooded animals (mammals, birds) and particularly in humans. Coagulase- producing staphylococci are one of the bacteria responsible for clinical and subclinical mastitis in ruminants. The main sources of milk contamination are through:

- infected animals (clinical or sub-clinical mastitis)
- the teats when they are chapped, cracked, wounded or infected
- the hands of the milker and, less frequently,
- the milking equipment.

Animals can become infected during milking in one of these ways. The cheesemaker's hands (in particular cuts, inflamed or cracked skin), as well as nose and throat infections can be vectors for staphylococci in finished products. Equipment used during processing, if contaminated, can also be a vector. Good control of acidification/coagulation and draining can limit the development of Coagulase positive staphylococci in cheese, depending on the technology.

Preventive measures: The measures for prevention must integrate:

- control and monitoring of veterinary hygiene (especially mastitis),
- good practices for handling, cleaning equipment and premises used for milk production and cheesemaking, as well as
- rigorous personal hygiene.

Viruses

Because viruses are only able to **replicate inside a host cell**, dairy products - especially fermented dairy products such as cheese - are considered to present a low risk for the transmission of viral disease to humans. Personal hygiene arrangements outlined on pages 16-17 are considered effective controls to prevent the transmission of Norovirus and other viruses capable of causing viral gastroenteritis.

Campylobacter

This bacterium can cause of foodborne diarrhoeal illness and is identified as a potential hazard in raw drinking milk in some member states. It is not normally able to multiply in foods under typical storage conditions and control of the hazard depends on prevention of faecal contamination during milk production. It is not considered to be a hazard in cheese where it does not remain viable for very long.

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A note on the risks posed by Chemical, Physical and Microbiological Hazards

It is not possible to perform a semi-quantitative hazard analysis within the scope of this guide as the frequency of occurrence of a hazard depends on factors at national, regional and business level. An indication of the most significant hazards, evaluated in terms of either the ubiquitous nature of the hazard or the severity of its effects is provided below.

The **most significant chemical hazards** are considered to be the presence of residues of veterinary medicines and biocides and the presence of allergenic ingredients based on the frequency of use.

The **most significant physical hazards** are considered to be the glass and metal contamination based on the severity of injury.

The **most significant microbiological hazards**, based on the criterion outlined in Regulation (EC) 2073/ 2005 are *Listeria monocytogenes*, enterotoxins produced by *Coagulase-Positive Staphylococci* (CPS) and *Salmonella* (in raw milk products).

In the case of emerging microbiological hazards not included in Regulation (EC) 2073/ 2005 which have been identified as significant in some member states, they should be controlled by the food safety management system, even though routine testing for such hazard (e.g. STEC) is not specified within this Regulation.

In addition to the microbiological hazards significant to milk processing Tuberculosis and Brucellosis are considered to be the most significant hazards significant during milk production.

APPENDIX 2
GLOSSARY

GLOSSARY of main SHORT CUTS used in this document

Short cuts mentioned in the Good Manufacturing Practices and in the HACCP-based Plans (sections III, IV, and V):
LR: Legal Requirement (obligations mentioned in the Regulation)
M: Microbiological Hazard
C: Chemical Hazard
P: Physical Hazard

Short cuts mentioned in the self-monitoring and the non-conformity management sections (VII and VIII):
m: minimum threshold (limit amount) settled by the Regulation for microbiological criteria
M: maximum threshold
n: number of samples of product to be tested (for microbiological testing)
c: maximum number of samples allowed to give a result between m and M
cfu: "Colonies Forming units": unit by which the number of bacteria in a sample is expressed

Overall GLOSSARY of terms specific to this document

Producers
In this document, the word **"producers"** is used to designate the operators of the sector of farmhouse and artisan cheese and dairy products. These operators can carry out several types of activities from milk production to sale of ready-to-eat products (farmer, processor, and seller).

It is another way to express the notion of "food business operators", notably used in the Regulation.

Flexibility
Flexibility can be defined as the possibility to adapt some of the content of the hygiene package, particularly in relation to buildings, layout, equipment and operational practices, in some circumstances (see details in the section 1 of the guide).
In this guide, when examples of flexibility measures are mentioned, they are high lightened this way: FLEXIBILITY MEASURE

FSMS – Food Safety Management System
FSMS is the combination of Good Hygiene Practices, Good Manufacturing Practices, HACCP-based plans, traceability, withdraw and recall plans, and other management policies, implemented in order to manage food safety and hygiene in a food business*.

HACCP-based plans
HACCP-based plans are part of the FSMS. They are procedures which identify, evaluate, and control significant hazards for food safety, in line with the HACCP principles (HACCP = Hazards Analysis and Critical Control Points).

Good Hygiene Practices (GHP), Good Manufacturing Practices (GMP)
GHP and GMP are preventives practices and conditions which are essential for food safety*.

Validation
It consists of providing evidence before the start (or change) of a process that the control measures planned will be effective when correctly followed. This may include documented proof of the efficiency of time/temperature combinations used in heat treatment or microbiological analysis, whether predictive or based upon results obtained experimentally.

Verification
It is the periodic evaluation of the effectiveness of the implemented HACCP-based procedures. (eg. by microbiological analysis of products)."

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* Ref: *"guidance document on the implementation of food safety management systems covering prerequisites programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain businesses" – DG SANTE - 2016*