



European Guide for the hygienic manufacture of Processed Cheese

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CONTENT

1. INTRODUCTION.....	3
2. SCOPE.....	3
3. DEFINITIONS	4
4. RESOURCE MANAGEMENT	5
4.1. SITE AND BUILDINGS	6
4.2. TRACEABILITY	11
4.3. EMERGENCY AND CRISIS	14
4.4. STAFF TRAINING AND DEVELOPMENT	14
5. PREREQUISITE PROGRAMMES (PRPS)	16
5.1. MAINTENANCE OF BUILDINGS, PREMISES AND EQUIPMENT	16
5.2. PEST CONTROL	17
5.3. SUPPORTING SERVICES AND SUPPLY UTILITIES	18
5.4. WASTE DISPOSAL AND CONTROL OF WASTE AND EFFLUENTS	21
5.5. PREVENTION OF FOREIGN MATTER	21
5.6. ALLERGEN CONTROL	22
5.7. CLEANING AND DISINFECTION	23
5.8. PERSONNEL HYGIENE	25
5.9. MANAGEMENT OF PURCHASED MATERIALS (RAW MATERIALS AND INGREDIENTS)	27
5.10. LABELLING	30
5.11. STORAGE & WAREHOUSING	30
5.12. RELEASE OF END PRODUCTS.....	31
6. HACCP SYSTEM.....	31
6.1. THE HACCP PRINCIPLES	31
6.2. DATA AND INFORMATION NEEDED TO CONDUCT THE HAZARD ANALYSIS	32
6.3. THE HAZARD ANALYSIS (PRINCIPLE 1).....	36
6.4. HACCP PLAN (PRINCIPLES 2-5).....	41
6.5. REVIEW.....	44
7. HANDLING OF NON CONFORMING PRODUCTS.....	44
7.1. HANDLING	44
7.2. DECISION OF FATE.....	44
7.3. RECALLS/WITHDRAWALS	45
7.4. DOCUMENTATION	46
8. VERIFICATION (PRINCIPLE 6)	46
8.1. GENERAL	46
8.2. INTERNAL AUDIT	47
8.3. ENVIRONMENTAL MONITORING	47
8.4. VERIFICATION OF THE HACCP PLAN	48
8.5. VERIFICATION OF FINISHED PRODUCT	48
8.6. CONTROL OF MONITORING AND MEASURING.....	48
9. REFERENCES.....	48
9.1 LEGISLATION.....	48
9.2 OTHER.....	49
ANNEX I: EXAMPLE LAYOUT OF A PROCESSED CHEESE PLANT.....	50
ANNEX II: DEVELOPING A MODEL HACCP PLAN	51
ANNEX III: DATA ON EFFECT OF HEAT TREATMENT OF PROCESSED CHEESE	61
ANNEX IV: EXAMPLES OF RECORD FORMS	65

1. INTRODUCTION

The processed cheese sector is a significant part of the dairy sector using dairy products as raw materials.

Processed cheese manufacturers shall ensure that at all stages of production, processing and distribution of food under their control they satisfy the relevant hygiene requirements laid down in Regulations 852/2004 and 853/2004.

Safe food is achieved through adequately designed and effective food safety management systems that include good hygienic practices and HACCP. Further, adequate traceability and recall procedures are important tools in case of loss of control which has gone undetected, or has been detected after the product has left the control of the food business operator.

ASSIFONTE has developed these Guidelines to provide practical information for national hygiene guides developed in accordance with Article 8 of Reg. 852/2004. The guidelines contained in this document serve as a reference for designing food safety control systems for processed cheese, from the planning and documentation to the implementation.

2. SCOPE

These “Guidelines” describe the responsibilities of processed cheese manufacturers and assist in proper implementation of the hygiene regulation.

These “Guidelines” are intended for high-quality processed cheese, processed cheese preparations and similar products and describe a practical way of obtaining safe products in accordance with the latest state of knowledge. Food business Operators (FBOs) following these guidelines commit themselves to manufacturing processed cheese and processed-cheese-preparations and similar products in compliance with the highest standards of food safety.

These “Guidelines” provide advice and guidance on the hygienic manufacture and on the conditions necessary to the production of processed cheese. They give guidance on the implementation of the requirements in EU hygiene regulations and take account of the principles contained in the Codex Alimentarius. It should be emphasised that legislation always prevails over the requirements laid down in this guide and that competent authorities’ interpretation of the EU hygiene regulations takes priority over the recommendations in these “Guidelines”.

These “Guidelines” are intended for all industrial processed cheese manufacturers. They provide a framework for quality managers when designing their food safety management systems adapted to their specific products, technology and production sites. The “Guidelines” aim at providing sufficient flexibility so that they can be applicable to all operators in the sector.

These “Guidelines” apply in conjunction with the EDA/EUCOLAIT Guidance on Cheese as Raw Material in the Manufacture of Food Products. They were drafted in compliance with:

- European Parliament and Council regulations (Reg. (EC) 178/2002 and Reg. (EC) 852 and 853/2004);
- Regulations (EC) 2073/2005 (amended by Reg. (EC) 1441/2007, (EU) 365/2010 and (EU) 1086/2011) and (EU) 931/2011;
- CODEX recommendations (General Principles of Food Hygiene CAC/RCP 1969 rev4, (2003). CAC-RCP 57-2004 (Code of hygienic practice for milk and milk products); and
- ISO 22000:2005 and ISO 22002-1:2009.

3. DEFINITIONS

Acceptable level:	The level of a particular hazard in the end product that is needed at the next step in the food chain to ensure food safety; it refers to the acceptable level in foods for direct consumption only when the next step is actual consumption.
Allergen:	Any substance that can cause an allergy.
Cleaning:	Elimination of soiling, food residues, dirt, grease or any other undesirable matter.
Contaminant:	Any biological or chemical or other substance, or any foreign matter, which was not purposely added to the food and which may compromise food safety and health.
Contamination:	Introduction or presence of a contaminant in the foodstuff or food environment.
Control measure:	Action or activity one may undertake in order to prevent or eliminate a hazard or to reduce it to an acceptable level.
Corrective action:	Action directed towards the process to eliminate the cause of a detected loss of control or other nonconformity or directed towards the product to control nonconforming product.
Critical control points (CCP):	Step at which one or more control measures can be applied and which is essential to prevent or eliminate a hazard or to reduce it to an acceptable level.
Critical limit:	Criterion used in monitoring of a CCP and which separates the acceptable from the non-acceptable.
Disinfection:	Reduction, by means of approved chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability.
Establishment business:	/ Any building or zone where foodstuffs (raw materials, ingredients, semi-finished and finished products) are handled including their surroundings under the same management.
Food safety:	The assurance that food will not cause harm to consumers when prepared or ingested according to its intended use.
Food hygiene:	The measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use (Reg 852/2004).
HACCP – Hazard Analysis Critical Control Point:	HACCP is a management tool to assess food safety hazards, identify Critical Control Points (CCPs) where control can be applied effectively and control the control measure(s) linked to the CCP.
HACCP - Plan:	A document resulting from the hazard analysis that specifies how identified CCPs are kept in control.
Hazard:	Biological, chemical or physical agents present in the food, or the condition of the food, with the potential to cause a harmful effect on health (e.g. Salmonella spp., allergens, glass fragments).
Hazard analysis:	Process to determine which hazards need to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required.

Hazard identification:	The step in the hazard analysis which identifies biological, chemical, or physical agents which may have a harmful effect on human health and which are likely to occur in the foodstuff in question.
Hazard assessment:	The step in the hazard analysis which qualitatively and/or quantitatively evaluates the possible severity of adverse health effects caused by the hazard and the likelihood of occurrence of that hazard and determines whether specific control is needed to enable acceptable levels to be met.
Microbiological criterion:	A criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch (Reg 2073/2005).
Minimise	Reduce the probability or the consequence of an unavoidable situation, such as microbial development or its impact.
Monitoring:	A procedure to detect any failures in the functioning of a control.
Pathogen:	An infectious or toxin-forming microbe or microorganism such as a virus, bacterium, prion, or fungus that causes disease in its host. A food borne pathogen is a micro-organism that may cause illness in humans as a consequence of consuming food with sufficient levels of the pathogen.
Potentially unsafe:	Products manufactured under conditions where critical limits have been exceeded or where there is a loss of control of Prerequisite Programmes (PRPs) that may put into question the food safety status of the end product.
Process criteria:	Process control parameters (e.g. holding time, temperature) applied at a processing step.
Processed cheese and processed cheese preparations:	Process(ed) cheese and processed cheese preparations are made by grinding, mixing, melting and emulsifying one or more varieties of cheese with or without the addition of other milk products and/or other foodstuffs with the aid of heat and with or without the aid of processing/emulsifying salts and/or emulsifying agents.
Risk:	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
Step:	Point, procedure, operation or phase in the food chain including raw materials, from primary production to final consumption.
Traceability:	EU REG. 178/2002 article 3, n°15: "Traceability" means 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.
Validation:	An assessment prior to operation, the role of which is to demonstrate that individual (or a combination of) control measures are capable of achieving the intended level of control.
Verification:	An assessment carried out during and after the operation, the role of which is to demonstrate that the intended level of control has actually been achieved.

4. RESOURCE MANAGEMENT

The processed cheese manufacturer shall provide and maintain the resources (buildings, equipment, staff, infrastructure and facilities) that are adequate to the operations involved.

The design and construction of the premises and the process flow shall take into account the relevant hygienic and safety standards. The local authorities should be consulted from the planning stage, in order to take into account any legal demands and thus avoid costly alterations later on.

4.1. SITE AND BUILDINGS

4.1.1. Selection of a suitable site

When selecting the location for a new production site, at least the following shall be taken into consideration:

- Availability of services, such as electricity, gas, potable water, drainage and waste collection; and
- Avoidance of areas that frequently flood and that are in the proximity of storage or processing of refuse, and areas where contamination from chemicals, dust, odours, pests, etc. is very likely.

The site boundaries shall be clearly identified.

4.1.2. Construction

Buildings shall be designed and constructed in a manner appropriate to the manufacture and storage of processed cheese as laid down in EU Regulation (EC) No 852/2004: Annex II, Chapter 1. Buildings shall be of durable construction and shall provide adequate space, with a hygienic* flow of materials, products and personnel, and physical separation of raw from processed areas.

*) Such as forward product flow, flow of materials towards cleaner areas, avoiding unnecessary personnel transit through hygienic areas

4.1.2.1. Ceilings

Ceilings must be designed in a way to minimise the accumulation of dust and condensation as well as the development of moulds.

Ceilings may be solid or suspended. The advantage of suspended systems is that horizontal pipe work can be concealed above the ceilings and thus eliminate a potential source of dust falling from pipes. If such suspended ceilings are used, these should either be properly sealed to prevent harbourage of pests or access points should be made available throughout.

4.1.2.2. Walls

Walls shall be protected as needed to avoid any damage from processing and internal transport. Pipes and ducting shall be bracketed away from walls so as to allow access for cleaning. Where piping passes through a wall, holes shall be sealed or otherwise made cleanable to avoid contamination by means of air being led through the holes.

External walls shall be constructed to prevent vermin gaining access to the indoor premises.

4.1.2.3. Doors and windows

Doors shall be self-closing, where necessary. External opening doors shall be closed or screened when not in use.

Preferably, windows and other openings shall be fitted and designed in a way to avoid the accumulation of dirt. Preferably, windows should not be able to open. However, where this is not the case, insect nets shall cover the opening of any windows that can be opened to outdoor areas. Internal window ledges, where present, shall be inclined. It is highly recommended to use safety glass or foil covered glass.

4.1.2.4. Floors

The floors in wet areas shall slope sufficiently allowing liquids to run towards drainage. Drains shall be trapped and covered to reduce the risk of cross contamination. Drain covers shall be removable to allow for proper cleaning and sanitising.

4.1.2.5. Outdoor areas

Outdoor yard surfaces to be used by staff while working (e.g. loading bays, refuse storage areas and courtyards connecting the different buildings on the site) must all be constructed with a suitable slope in order to allow for sufficient water drainage. Standing water shall be prevented.

Consideration shall be given as to how to avoid the outdoor premises becoming attractive to vermin.

The yard surfaces shall be constructed of material which is durable.

Access to the site shall be controlled. For instance,

- Fencing of areas in order to keep unauthorised persons out of the site;
- Securing the area by traffic arrangement.

Areas and pathways for personnel shall be marked, pedestrianized and separated from heavy traffic.

4.1.3. Layout and design of premises and processes

4.1.3.1. Design principles and layout

The purpose of a hygienic layout of the premises and the process flow is to facilitate good hygienic practices, to avoid contamination and to enable effective cleaning.

Zoning is a widely used principle in the hygienic lay-out of food businesses. Zoning of rooms and areas consists of visual and/or physical barriers that control traffic of staff, products, and utensils between the zones.

Comparison of zoning systems recommended by various organisations

IDF	EU GMP	ISO 14644-1	FS 209D	BR 525
	Grade A & B	ISO 5	100	Class E
		ISO 6	1.000	Class G
Red	Grade C	ISO 7	10.000	Class J
Yellow	Grade D	ISO 8	100.000	Class K
Green	-	ISO 9	-	-

Cross- contamination shall be prevented. An assessment of potential contamination sources shall be conducted, in particular to identify the susceptibility of the product and activities taking place along the processing line.

Areas where the potential for microbiological cross-contamination exists (airborne or from traffic patterns) shall be identified and a segregation (zoning) plan implemented, taking into account the need and feasibility of

- physical barriers, walls or separate buildings;
- access controls with requirements to change into required work clothes;
- restricted traffic patterns or equipment segregation;
- air pressure differentials;
- separating wet areas from dry areas;
- separating high risk areas from other areas, e.g. that the filling area is separated from the handling of raw materials and other food processing;
- forward moving flow of product (by pipes, conveyors, trucks etc.), from the reception of raw material to release of final product to reduce distances travelled by material and staff;
- separating operations or areas in which steam is used or aerosols are formed from areas where products are exposed;
- adequate and separate location of facilities for staff (cloak rooms, toilets, cafeterias, etc);

The premises and equipment shall be located and set up in a way that allows for efficient cleaning. Supply lines (steam, water, cleaning-in-place (CIP), etc.) and drains shall always flow towards areas of lower risk.

An example of a layout is shown in **Annex I**.

4.1.4. Buildings where foods are processed or handled

4.1.4.1. General

All surfaces in contact or close to the product shall be made with smooth, impermeable, corrosion resistant and non-toxic material. All such surfaces shall be designed so as to:

- be easily cleaned and disinfected;
- protect the product from external contamination;
- not present any 'dead space', that is space which is not easily accessible for cleaning;
- be resistant to the cleaning systems applied.

4.1.4.2. Ceilings

Ceilings shall be made of non-toxic materials, which do not flake, and which are impervious to water and steam.

4.1.4.3. Walls

Walls shall be covered with material which is impervious, non-absorbent, light coloured, washable and non-toxic. Their surfaces shall be smooth, without cracks or flakes and easy to clean and to sanitize.

Wall floor junctions and corners shall be designed to facilitate cleaning. In processing areas wall floor junctions shall be rounded.

4.1.4.4. Doors and windows

Doors shall be made from smooth and non-absorbent material, easy to clean.

4.1.4.5. Floors

The floors shall be made of impervious and non-absorbing material, washable, slip resistant and non-toxic, without cracks and shall be easy to clean and sanitize.

4.1.5. Suitability and design of processing equipment

4.1.5.1. Design

All machines and equipment used for manufacture shall be designed so as to:

- be easily cleaned and disinfected;
- not increase the likelihood of contaminating the product from external sources;
- minimise contact between the operator's hands and the products;
- not present any 'dead space', that is space which is not easily accessible for cleaning;
- use food grade lubricants;
- allow easy disassembling for inspection with tools normally used by the operating and the cleaning personnel if not designed specifically for CIP.

All elements including those within a CIP circuit shall be designed and dimensioned to ensure efficient cleaning.

All equipment surfaces in contact or close to the product shall be made with smooth, impermeable, corrosion resistant and non-toxic material. Contact surfaces shall not affect, or be affected by, the intended product or cleaning system.

They shall meet current EU regulations on materials in contact with food (see http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm).

Food contact equipment shall be constructed of durable materials able to resist repeated cleaning.

4.1.5.2. Installation

Machinery shall be placed in a way that allows adequate maintenance and cleaning to be carried out. The operation of machinery must correspond with its intended purpose and its location must allow it to work according to good operational practice. The location of machinery shall also allow its operation to be monitored, where needed.

If items of equipment are not sealed to the floor they shall be raised from the floor by a sufficient space to allow easy cleaning and inspection. Ingress of contaminants such as insects, dust and condensate shall be prevented by ensuring that all the equipment is fitted with appropriate lids. The openings shall also be protected by raised edges so as to prevent the entry of surface drainage.

All joints shall be smooth and finished close to the adjoining surfaces, be free from crevices and have smooth rounded corners. Where standing water cannot be removed and may result in contamination of food, the surfaces shall be sloped in order to allow self-drainage.

The fitting of shafts shall be such that leakage of lubricant into the product or leakage of product into the lubricant is prevented. It is recommended to use a seal for the shafts on the product side and another seal on the lubricant side. Any leakage on either side shall flow into an open area without pressure.

4.1.5.3. Vessels for mixing or processing

Drives and shafts of agitators shall be protected in order to protect the product from condensate and lubricant. Agitators shall be designed in such a way as to allow their cleaning with a CIP system wherever possible.

4.1.5.4. Pumps, pipelines, valves, sensors etc.

Pipelines shall be designed so as to be cleanable with CIP whenever possible. All product and cleaning pipelines shall be rigid, self-draining and fixed. Pipelines shall preferably be welded or equipped with hygienic joints. Use of plug-cocks shall be avoided if they must be manually disassembled, cleaned and disinfected.

The use of flexible pipelines shall be limited to a minimum, because of their unhygienic junctions. The internal surface shall be regularly inspected. Permanent junctions which are hygienic shall be used.

In order to prevent cross-contamination, there shall not be any piping which connects directly between areas where raw materials are stored and handled and areas where pasteurised products are processed, handled and packed. The same principle shall apply to C.I.P. circuits.

Pumps shall be of hygienic design and preferably cleanable in place.

All pipes shall be designed and equipped to avoid contamination by condensation.

Insulation used on the various pipelines shall have an outer which is of non-absorbent and cleanable material.

4.1.5.5. C.I.P. equipment

Equipment for C.I.P. (Cleaning-in-Place) shall be designed and installed with no empty spaces that may trap product and prevent cleaning effectiveness.

CIP systems shall be separated from active product lines.

The C.I.P. circulation pump shall have sufficient capacity to ensure a minimum cleaning solution flow rate of 1.5 m/s at every point of the pipe work.

4.1.5.6. Heat treatment equipment

Heat treatment equipment shall be designed and installed to ensure that all particles reach the required temperature within the required time. Heat treatment equipment which is linked to a Critical Control Point (CCP) must be equipped with time and temperature control and monitoring devices and with a system which prevents non-conforming product (i.e. not treated as intended) from moving forward in the process flow. Non-conforming product must be sent back to be heat treated again.

4.1.5.7. Homogenisers

Particular care is necessary in the cleaning of the plunger seals and the pulsation dampeners.

4.1.5.8. Filling equipment

Surfaces shall slope in order to avoid food stagnating. Pockets, crevices, etc. shall be avoided. Control panels and electrical boxes shall be cleanable and watertight. All equipment not designed to be cleaned in place must be easily disassembled for cleaning.

4.1.5.9. Cooling equipment

All parts in contact with the product shall be easily accessible for inspection.

The mechanical parts and the framework of the cooling equipment shall be designed so as to avoid inaccessible crevices.

4.1.5.10. Waste containers

Containers for waste and inedible or hazardous substances shall be:

- clearly identified for their intended purpose;
- constructed of impervious material which can be readily cleaned and disinfected;
- closed, when not in immediate use
- preferably fitted with a foot-operated lid or other suitable means to minimise contamination of hands.

This equipment shall be designed in such a way as to prevent rodents from having access and avoids any contamination of the food, the potable water, the equipment, the premises and the thoroughfares.

4.1.5.11. Drains and sewage system

The sewer system shall be constructed with a slope to enable wastewater to discharge and avoid stagnation.

Drains shall have sufficient capacity to remove expected flow loads. Drains shall not pass over processing lines.

The drainage direction shall not flow from a contaminated area to a clean area.

4.1.6. **Staff facilities**

Staff facilities shall be well lit, ventilated and kept clean.

Wherever protective clothing is required, cloakrooms shall be made available to any person liable to go into the processing, packaging and storage areas, including visitors. Personnel may only access a high-risk zone through a cloakroom specially fitted for the purpose, and must observe procedures for putting on working clothes which are clean and visually identifiable. Working clothes and normal clothes shall be stored separately.

Facilities to wash and disinfect hands and shoes shall be available at the entry to the processing areas. Alternatively, shoes must be changed to footwear dedicated for the processing area. Those washbasins situated close to the toilets must be located in a way that makes personnel pass in front of them before returning to the processing area. Washbasins shall be equipped with hands free operated taps dispensing warm water, with adequate soap dispensers and with hygienic hand drying equipment. When paper napkins are used the dispensers and waste bins shall be in

adequate numbers close to each washbasin. The drainage of the washbasins shall be linked directly to the general drainage network.

Toilets for female staff shall be equipped with waste bins.

Adequate eating facilities must be provided. Steps must be taken for the safe and sound storage of food brought in by employees for their personal consumption.

4.1.7. Laboratories

In-line and on-line test facilities shall be designed in a manner that during operation does not increase the risk of product contamination.

Microbiology laboratories shall be designed, located and operated so as to prevent contamination of people, plant and products. They shall not open directly on to a production area.

4.1.8. Storage facilities

Storage areas shall be designed or arranged to allow segregation of raw materials (cheese and other dairy ingredients), other ingredients (salt, additives, etc.), flavouring ingredients (vegetables, fruits, meat, etc), packaging, chemicals (e.g. cleaning materials), waste and processed cheese.

A separate area or other means of segregating materials identified as potentially unsafe shall be provided.

Dry storage facilities (e.g. used to store dry ingredients, packaging) shall provide protection from dust, condensation, drains, waste and other sources of contamination. They shall be kept dry and well ventilated.

The monitoring and control of temperature and humidity shall be applied as required by product or storage specifications.

All materials and products shall be stored off the floor and with sufficient space between the material and the walls to allow inspection and pest control activities to be carried out.

The storage area shall be designed to allow maintenance and cleaning, prevent contamination and minimise deterioration.

4.1.9. Documentation

Documentation related to Section 4.1 includes:

- Layout of premises;
- Plan of hygienic zones;
- Operating and maintenance manuals for all equipment and devices.

4.2. TRACEABILITY

4.2.1. Introduction, objective and scope

In accordance with Regulation (EC) 178/2002 (article 18) food business operators must be able to identify persons from whom they have been supplied with food and they must be able to identify businesses to which their products have been supplied. This information is required in case the source of a food safety issue needs to be identified and in case of product withdrawal/recall. When requested, the information shall be made available to the competent authorities.

4.2.2. Traceability in general

A planned traceability system shall be in place that is able, at all times, to trace backwards (one step upstream in the food chain) any raw materials, ingredients, additives and primary packing materials delivered and to trace forwards (one step downstream in the food chain) any finished

products that have left the manufacturer. To conduct effective tracing, relevant data needs to be registered and maintained for potential later use.

The identification can, for instance, be a production code and/or best before date and/or batch-number/code.

The identification is normally split up during various steps of the total process into:

- purchase and storage of raw materials;
- purchase and storage of packing material;
- grinding and mixing;
- melting and heat treatment;
- filling;
- packing;
- dispatching.

4.2.3. Responsibilities

Clear responsibilities shall be assigned within the food business. Responsibility allocation shall be documented.

4.2.4. Practical guidance

4.2.4.1. Purchase and storage of raw materials, ingredients and packaging materials

Producers shall be able to ensure that raw materials, ingredients and packaging materials entering the premises are traceable to the supplier.

Each and every individual incoming unit of raw material, ingredient and packaging material shall carry a means of tracing its source of supply and history (e.g. batch code).

Suppliers (including suppliers of finished products) should have comparable traceability systems.

Traceability of food allergens, and those made into semi-finished product (including through reworking) and finished product shall be ensured and recorded.

4.2.4.2. Processing

Producers shall be able to ensure that foodstuffs produced are traceable back to the raw materials, ingredients and packaging used in the manufacturing process.

Important elements for process traceability are:

- A product batch must be identified;
- A unique batch code identifier shall always be applied to:
 - Each and every saleable unit comprising the product batch;
 - The outer packaging, if any;
 - Internal documentation accompanying the product batch.
- Information about the immediate FBO supplier and of the initial producer of the cheese which produced the cheese from milk.

The traceability codes of raw materials, ingredients and packaging materials used in the production of a product batch shall be recorded and associated with the product batch code.

Production and quality records shall contain all the necessary information relating to raw materials, ingredients, packaging and process times to allow traceability of the finished product.

4.2.4.3. Released products

Product release procedures shall be in place that ensures that the traceability system is maintained.

Producers/third parties engaged in rework shall ensure that the documentation associated with a product batch contains all the information necessary to allow traceability of any rework incorporated.

Producers/third parties involved in re-wrapping products shall ensure that traceability back to the original supplier is maintained.

Each producer shall be able to ensure that products leaving the control of the business are traceable to the customers.

A system shall be in place to deal with product that is rejected by the customer for food safety reasons.

4.2.4.4. Verification of performance

The traceability system shall be reviewed and audited at least annually to ensure that it is delivering the required level of traceability (e.g. upstream and downstream traceability tests such as mock recalls).

It is recommended that operators set a fixed maximum period within which tracking and tracing operations shall be completed.

The traceability system must be able to deliver key traceability data (product type and names, production/reception dates) for delivered and received products and materials within a few hours from the time of a request. The system must be capable of delivering the remaining details (lot numbers, amount, etc.) within a maximum of 24 hours.

4.2.5. Documentation

Documentation related to Section 4.2 includes:

Documents:

- A description of the traceability system, including lot identification system;
- An updated register of suppliers with full contact details;
- An updated customer register with full contact details and history of purchase;
- Procedure for verifying performance.

Records of purchased goods:

- Description of the goods;
- Supplier name and contact details (and owner of the supplying business, if different from supplier);
- Any supplier batch codes;
- The delivery date;
- Allergen content (type, amount);
- Confirmation of acceptance;
- Batch size (amount received);
- Reference to any in-house quality control records associated with the delivery.
- Traceability information (trade documents with the consignments) as a minimum fulfils Regulation (EU) No. 931/2011.

Records along the whole production process:

- All raw materials received, stored and used;

- Packing materials received, stored and used;
- Additives and processing aids received, stored and used;
- Semi-finished products stored and used;
- Finished products produced, stored and delivered;
- The process used (e.g. the production line) and treatments relevant to the labelling;
- Any out sourced processing or use of finished products from third parties.

Records of delivered products:

- Product name;
- Product batch code;
- Date of production;
- Time of start and end of production;
- Product specification (by reference to where details can be found);
- Any in-house process and packaging control records associated with product batch (by reference to where details can be found);
- Results of verification of performance

Traceability data shall be registered in a format that can be used to link them to the finished product identification.

Records shall be kept for at least the shelf life period with a minimum of two years. In case local legislation demands longer periods these rules shall be followed.

4.3. EMERGENCY AND CRISIS

Crises are emergency situations and potential accidents which can be of very different natures (for example: the presence of unacceptable levels of contaminants, a break in the supply of raw materials, break-downs or accidents, strikes by personnel, natural disasters, etc.).

A written crisis management procedure available in line with regulation EU 178/2002 should be established to assist the personnel confronted with emergency situations and potential accidents to act effectively and consistently, thereby avoiding improvisation.

The procedure should include:

- Contact details of relevant staff with allocated responsibilities for decision taking;
- Contact details of external organisations (e.g. authorities, fire services) as per the emergency plan;
- How to identify the product/area that is affected by the emergency situation, e.g. potential contamination from the activities of the first responders e.g. fire fighter, rescue team;
- How to handle this/these product/s as potentially unsafe food;
- How to evaluate and restore the affected area through correction and corrective action processes.

4.4. STAFF TRAINING AND DEVELOPMENT

4.4.1. General

The purpose of training employees is to ensure that staff have the competences needed to meet the objectives specified for each person and to meet the corporate objectives for food safety.

Training of all staff - whether permanent or temporary or sub-contractor - shall at least address the following:

- good hygiene practices;
- food safety, including carrying out monitoring, corrections and corrective actions;
- safety of people;
- specific competences related to the operations carried out.

Newcomers to the organisation shall receive specific training according to a hygiene training schedule in place and appropriate to the competences of the person engaged.

The main objective of the frequent (annual) training schedule is to ensure that every employee has the required level of skills, taking into account the evaluation of every employee as well as the hazard analysis resulting from the annual HACCP review.

Management of competences lies within a scheme of continuous improvement and making sure through frequent evaluation of each person that he/she has the competences necessary to meet the objectives (particularly food safety) set up for his/her responsibilities and tasks.

The effectiveness of staff training shall be regularly evaluated.

4.4.2. Hygiene training

Hygiene training is fundamental to minimise employees' direct or indirect contact with processed cheese, and consequently the likelihood of contamination, through ensuring a constant degree of personal hygiene and correct behaviour.

Consequently, at least all manufacturing staff must be trained in hygiene and regularly re-trained, (for instance once a year, or more often if necessary).

Hygiene training must be targeted at the level of skills of the individual and be relevant to the operations carried out. It shall address, as appropriate, the following issues:

- regulatory requirements;
- processed cheese manufacturing;
- hazard analysis and the HACCP system in place;
- data specific to the company (goals, customers' complaints, indicators, ...).

Training shall enable employees to understand basic microbiology, where micro-organisms come from, how they grow and what can be done to prevent them from multiplying. They shall know the causes of food-borne disease or injury (foreign matter, allergens, microbiology, chemical, ...) and how to prevent it.

It is important to be trained in temperature control and to understand the needs for suitable facilities and efficient stock rotation. In most cases, staff shall be trained in understanding:

- The different Critical Control Points (CCPs) of the factory;
- All relevant foreign matter control procedures;
- The procedures for process and personnel flow;
- Individual and collective behaviours (prohibitions on eating, smoking, ...);
- Reporting their illnesses and protecting their skin infections, ...

Short term or temporary employees, visitors working or entering premises where products are handled, must respect the hygiene rules of the food business (e.g. clothing, personal hygiene, jewels). Displaying hygiene rules/ instructions or handing out a hygiene rules booklet is helpful.

The indicators for demonstrating the effectiveness of hygiene training include:

- Results of periodic hygiene audits;

- Results of microbiological tests.

The annual hygiene training schedule has to be updated according to the food safety data resulting from the above-mentioned indicators, without waiting for the annual review.

4.4.3. Documentation

Documentation related to Section 4.4 includes:

- List of required/acquired skills and competencies for staff with food safety related tasks & operations;
- Training plan / request forms for training;
- Training attendance sheets / proof of training;
- Curriculum Vitae.

5. PREREQUISITE PROGRAMMES (PRPS)

The PRPs constitute the basic conditions and activities that are necessary to maintain hygienic conditions on which specific hazard controls (HACCP plan) can be based upon. If PRPs are properly implemented and verified, it is possible to reduce the likelihood of hazard occurrence.

5.1. MAINTENANCE OF BUILDINGS, PREMISES AND EQUIPMENT

5.1.1. Maintenance programmes

A register of equipment shall be maintained in a form which contains at least technical information for each machine, date of delivery, mark, model, repairs and its preventive maintenance programme.

Buildings, premises, equipment, vehicles, conveyances, containers, supporting services and supply utilities, and monitoring devices shall be maintained in a state of repair, cleanliness, and condition consistent with their specifications. Maintenance programmes shall be in place and shall include:

- Preventive maintenance (keeping in good repair);

The preventive maintenance programme shall be performed according to the recommendations of the manufacturer. Alternatively, the preventive maintenance programme can be based on authenticated operating experience.

- Corrective maintenance (e.g. leaks, breakdown of machinery, wear and tear of building parts);

Breakdowns of machinery and building surfaces shall be recorded in a register, which is used for planning of corrective maintenance. Maintenance requests which impact on product safety shall be given priority. Temporary repairs shall not put product safety at risk.

- Improvements (e.g. renovation, moving equipment etc.).

5.1.2. Maintenance procedures

Maintenance operations shall be recorded and their correct conduct must be verified.

Protection of food processing areas shall be planned prior to and maintained during maintenance and renovation operations. Specific and temporary procedures may be required.

The procedure for running-in maintained equipment shall include clean up, sanitising, and pre-use inspection. When the test run is complete the responsible manager must be informed and documents must be updated.

Maintenance personnel shall be trained in the food safety hazards associated with their activities. Vehicles, conveyances, and containers shall be maintained in a state of repair, cleanliness, and condition consistent with specifications for the material.

5.1.3. Documentation

Documentation relevant to maintenance includes:

Documents:

- A register of equipment with relevant technical information;
- Maintenance programmes for buildings, premises, equipment, vehicles, conveyances, containers, supporting services and supply utilities, and monitoring devices.

Records:

- Breakdowns of machinery and building surfaces;
- Maintenance operations carried out.

5.2. PEST CONTROL

5.2.1. Pest control programme

Pests (such as birds, insects, spiders, rodents and other small mammals) represent a hazard for the safety of foodstuffs. That is why a documented pest control programme shall be in place to prevent pests' activity inside the facility and within the boundaries of the outer grounds.

All manufacturing plants shall have trained personnel for the detection of infestations or a contract with an external competent professional infestation control organisation for regular inspections, advice and treatments to deter and destroy any infestation.

External contractor(s) shall be consulted to determine the appropriate pest control programme. Documented internal procedures for controlling the activities of the contractor must be in place (e.g. the appointment of a pest control manager).

Plants must be designed and maintained so as to deter pests. Potential breeding sites must be removed, any orifices sealed off or hermetically blocked, and windows, doors, and air vents fitted with appropriate devices.

The most effective contribution towards infestation control is maintaining good housekeeping and standards, i.e. controlling the accumulation of food and paper debris, keeping gangways and passages clear, removing redundant equipment and materials from production areas, good stock rotation, keeping organic and soiled waste containers covered, etc. (the presence of foodstuffs, and water, even as mere trails, unprotected from contact with ambient air is liable to attract pests and shall be always avoided to prevent attracting pests).

The presence of infestation must be checked regularly and the monitoring plan must be reviewed according to the results of inspections.

If rodent baits are used in the factory for the control of rats and mice, they shall be based on fatty and waxy substrates and shall be placed in a solid box. The use of poison baits for rodents shall be limited along the external walls of the facility (Unsecured bait stations).

Electric flying insect killers (insectocutors) must not attract outside insects and must be placed more than 3 meters away from unprotected products.

No domestic animals should be allowed to gain entrance in food preparation or storage areas.

5.2.2. Corrective action

When rodents' pest activity demands, programmes may be set up to utilise poison within the manufacturing site. In this case the programme shall be controlled in respect of authorised

handling of poison bait and great care taken to prevent any bait spillage and subsequent food safety risks:

- All bait stations must be clearly identified/coded at point of use;
- The bait station must be contained in a secure metal trap;
- The poison must be of a solid block type (not loose granulates).

Usage and handling of pesticides must be done in accordance with regulations.

5.2.3. Documentation

- The contract with the infestation control organisation specifying the nature of the services;
- Inspection reports, describing infestation levels and the corrective actions recommended;
- Instructions for use of all the pesticides;
- Labels and safety data sheets for pesticides used;
- A traceability log book to record details of all pesticide treatments applied;
- A map reporting the locations of traps, glue boards, insectocutors, bait stations etc.;
- Evidence of approval from the pest control plant representative and the competent authority, where required.

5.3. SUPPORTING SERVICES AND SUPPLY UTILITIES

5.3.1. Water supply

The supply of potable water shall be sufficient to meet the needs of the production process(es). A large water supply, under pressure and at adequate temperature, is required as well as adequate facilities and equipment for its storage and distribution. Potable water shall be protected against contamination.

The processing establishment shall have a supply of potable water, which prior to its first use (including ice), shall meet all applicable local and national regulatory requirements. Plant water including cooling and process water shall meet quality and microbiological requirements appropriate to the intended usage.

Water directly and indirectly in contact with food shall be sampled from appropriate locations (point of usage) and microbiologically tested (TVC and coliforms) at defined frequencies (preferably monthly).

Where water supplies are chlorinated, checks shall ensure that the residual chlorine level at the point of use remains within limits given in relevant specifications.

Reclaiming, recycling, reconditioning and reuse of water shall be managed in accordance with HACCP principles. Any reuse of water shall therefore be subject to a hazard analysis including assessment of its suitability for reconditioning, and critical control points shall be identified, as appropriate, to monitor compliance with limits identified and appropriate to the intended use.

Reclaimed and recycled process water shall, prior to any reuse, be reconditioned by appropriate treatment(s) according to its intended use so as to ensure the safety and suitability of the food manufactured.

Non-potable water which has not undergone any treatment or reconditioning is generally authorised for steam production, and for anti-fire equipment or refrigeration, provided that:

- It is stored and distributed in separate system that prevents accidental usage for any other purpose,
- It will not present any risk, direct or indirect, of contamination of the production, and

- Pipes and equipment for storage and distribution are clearly distinguishable from the pipe work used for potable water.

5.3.2. Steam supply

Steam delivered to the point of use shall be of the suitable quality and purity. When steam is incorporated into product (steam injects in cookers and sterilisers) or used in contact with product or primary packaging, it must be of “culinary steam” quality and produced from potable water. This type of steam is produced using only legally approved boiler chemicals (consult the appropriate authorities), and is subjected to sedimentation (separator), filtered and delivered through stainless steel pipe work after filtration.

Steam used in direct contact with food or on surface areas in contact with food must not contain any substances presenting a health risk. Steam condensate quality shall be routinely tested (turbidity, off flavours and particulates).

Steam hose outlets shall not be in contact with the floor.

5.3.3. Air supply

Room air must not be a source of microbiological contamination and the microbiological air quality shall be monitored in areas where sterilised or pasteurised product is exposed to air, to verify suitable values for microbiological quality.

Where possible, pre and post pasteurisation areas shall have separate air supplies.

Where needed, the temperature and the humidity shall be controlled (e.g. cold storage rooms). Exterior air intake entries shall be examined periodically for physical integrity.

In cold fill lines, HEPA¹ or similar air filtration systems to reduce recontamination is necessary, if the desired shelf lives are similar to those of products from hot fill lines. Otherwise, the effect of post-process contamination on shelf life and corresponding storage conditions shall be taken into account.

5.3.4. Ventilation

Adequate ventilation shall be provided to remove excess or unwanted steam, dust and odours from processing rooms, to facilitate drying after wet cleaning, to counteract steam condensation and to replace used air.

The air conducted into high risk areas shall be filtered in order to remove particulate matter and condensate. The filters shall be kept clean and replaced according to a documented maintenance procedure.

The air flow shall move in the direction towards areas of lower risk (e.g. from the production area towards the service area).

To prevent access of pests, ventilation ducts shall be equipped with a screen or other protection device made of corrosion resistant material. These screens shall be easy to remove for cleaning.

Ventilation systems shall be accessible for cleaning, filter changing and maintenance.

5.3.5. Lighting

All the areas shall be equipped with a natural or artificial lighting system of sufficient intensity to enable staff to operate in a hygienic manner.

Unbreakable bulbs shall be used in order to prevent broken glass falling onto and contaminating products or packaging material. If breakable bulbs are used, they must have protective covers.

¹ High-Efficiency Particulate Air. Specifications can be found in the EN 1822:2009. It defines several classes of HEPA filters.

5.3.6. Compressed air and gas supplies

The quality of compressed air needed differs according to its intended use. Examples of appropriate quality are provided below.

The compressed air supply shall be dimensioned and installed with filters and moisture/oil traps necessary for the intended quality.

Quality classes of compressed air according to ISO 8573-1:2001

Quality class	Solid particles: max no. of particles per m ³ of air			Water		Oil Max content (mg/m ³)
	0.1 μ < d < 0.5 μ	0.5 μ < d < 1.0 μ	1 μ < d < 5 μ	Max dew point (°C)	Content (g/m ³)	
1	100	1	0	-70	0.003	0.01
2	100,000	1,000	10	-40	0.12	0.1
3	-	10,000	500	-20	0.88	1.0
4	-	-	1,000	+3	6	5.0
5	-	-	20,000	+7	7.8	-
6	-	-	-	+10	9.4	-

Appropriate classes for various usages in a processed cheese plant

	Automatically operated cylinders, valves etc.			Packaging machines			Direct product contact *		
	Freeze	Chill	Other	Freeze	Chill	Other	Freeze	Chill	Other
Solid particles	1-2			1-2			1		
Water	2	3	4	2	3	4	2	3	4
Oil	1-3	1-3	1-3	1	1	1	1	1	1

*) E.g. pneumatic emptying of pipes

Compressed air in direct contact with finished processed cheese shall also be microfiltered as close to the point of usage as possible.

Compressed air deriving from equipment using lubricant oils and which is used in contact with product or packaging (or used as ingredient) shall be oil free (to avoid contamination with potential allergens) and filtered² at the point of use to assure it is clean and exempt from odours and any other undesirable contamination.

5.3.7. Documentation

Documentation relevant to supporting services and supply utilities include:

Documents:

- Applicable requirements for potable water;
- Procedures for sampling and microbiological testing of water, routine testing of steam condensate and sampling and testing of microbiological air quality;
- Maintenance procedure for air filters;
- Specifications for compressed air qualities;
- Hazard analysis and corresponding HACCP plan for reused water.

Records:

Results of test of water (microbial and, where appropriate, chlorine), steam (turbidity, off flavours and particulates), and air (microbial).

² E.g. an activated carbon filters followed by a 0.01 μ particle filter.

5.4. WASTE DISPOSAL AND CONTROL OF WASTE AND EFFLUENTS

5.4.1. Solid waste

Accumulation of waste shall be avoided in food-handling or storage areas. Waste gathered at the site shall be, if possible, sorted and regularly removed from the production zone. Removal frequencies shall be managed to avoid waste accumulating, with a minimum of daily removal.

The use of disposable bags is recommended.

The bins used for the refuse and non-edible material shall be reserved for this usage and clearly identified as such (e.g. labelled). Bins shall be fitted with lids if organic waste is present.

The company shall have a documented waste disposal plan in place that describes the processing of the waste stocked in the bins.

The waste disposal area shall be placed as far as possible from:

- Air and water sources;
- The production zone;
- The raw materials entry area.

The waste disposal area shall be washed and the bins cleaned after each collection.

Products that are not in conformity to product specification and which are intended to be disposed of or used as feed or other non-food usage shall be stored separately and clearly identified (labels, signs, etc) in accordance with the animal by-products Regulation (EC) 1069/2009.

5.4.2. Drains and sewage systems

The sewage treatment collector/plant shall be placed as far as possible from:

- Air and water sources;
- The production zone;
- The raw materials entry area.

The drainage of waste water, including rinsing and cleaning water used for the process, premises and equipment, must be planned and carried out in a manner that avoids contamination of finished products, drinking water, and the processing environment. The drainage capacity shall be greater than the potential water volume.

5.4.3. Documentation

Documentation relevant to waste includes a waste disposal plan.

5.5. PREVENTION OF FOREIGN MATTER

5.5.1. Contaminants

Although machines and equipment shall be designed and built of durable and unbreakable materials, pieces of the equipment or raw materials previously contaminated are the main source of foreign matter present in products. Examples are:

- Glass from unsecured windows, lamps, bulbs, neon tubes, thermometers, laboratory glass, spy holes on the tanks, insect killing tubes or other glass equipment;
- Wood from pallets or wooden equipment;
- Metal from improperly built or maintained machines or equipment;
- Plastic from buckets, boxes, brushes;
- Stones from damaged floors or walls;

- Utensils used in the production zone and lost by staff (pencils, knives, keys).

5.5.2. Prevention

In order to prevent and control foreign matter the following actions shall be carried out:

- Eliminate or replace articles causing potential risks (e.g. pins);
- Cover glass with break resistant foil or use safety glass;
- Use colours totally different from those used for raw materials and finished products;
- Properly and regularly maintain or exchange worn out equipment;
- Inspection of first-off product after cleaning;
- Perform internal inspections of used equipment (lists of glass, plastic and other items creating risk are recommended);
- Train staff about the risks from foreign matter, glass and wood.

Wood and cardboard shall not be in contact with non-packed food.

5.5.3. Verification

In order to avoid and reduce the foreign contamination in the product it is recommended to use filters, sieves, metal detectors and/or X-rays. Being technically limited they are not absolutely reliable, but they can help to minimise the risks and to identify weak points in the process.

5.5.4. Documentation

See [6.4](#) (HACCP Plan).

5.6. ALLERGEN CONTROL

5.6.1. Assessment

An allergen management programme shall be in place based on an assessment of the sources and the nature of potential allergens.

The assessment shall include the type and amounts of allergens in:

- Purchased raw materials and ingredients;
- Lubricant oils for equipment in contact with product or packaging (or possibly used as ingredient) shall be allergen free;
- Rinsing water post disinfection;
- Compressed air.

The assessment is best carried out as part of the hazard analysis (see [6.3](#)) and shall include assessment of the possible content of those substances listed in Annex II to Regulation (EU) No 1169/2011.

5.6.2. Prevention

Cross contamination may be minimised and controlled by:

- Visual inspection of packaging of incoming raw materials containing allergens at the entry (all spilled or poured out materials must be secured);
- Separate storage of raw materials containing allergens;
- Ensuring care is taken during the production process (e.g. boxes with covers are recommended);

- Use of the same equipment or production lines for products both with and without allergens requires a full cleaning process, if entire separation is not possible.

The equipment used in contact with allergens shall be easily recognisable (labels, colours...).

5.6.3. Documentation

Documentation relevant to allergen control includes:

- Results of assessment;
- List of equipment using lubricants with potential allergens;
- Description of control measures in place.

Traceability of food allergens, and those made into semi-finished product (including through reworking) and finished product shall be ensured and recorded. Finished Product Specification documents (see [5.12](#)) shall specify any allergens contained in the list of ingredients.

5.7. CLEANING AND DISINFECTION

The aim of cleaning is to remove waste material, bacteria (including spores) and mould from process equipment and environment whilst preventing dispersion of micro-organisms (through aerosols generation) throughout the production area. Cleaning alone cannot remove all bacteria from equipment and so a separate disinfection stage is required and can be achieved by the use of chemicals, the application of heat or a combination of both.

5.7.1. Cleaning procedures

All equipment, utensils and food handling environment shall be cleaned and sanitised as necessary in order to prevent product contamination.

Appropriate written cleaning and disinfection procedures must be described and in place for all food-processing equipment and environment (floors, walls, ceilings and drains in the production areas).

The procedures shall, as appropriate to the purpose, include specifications and details on:

- The subject of the programme (which area, items of equipment or utensils to be cleaned and/or disinfected);
- The detergents and sanitisers used and their concentration(s);
- The method (e.g. duration, temperature, flow rates and pressure of cleaning solutions, number and order of cleaning steps);
- Frequency;
- Monitoring procedures;
- Verification procedure.
- Responsibilities (who is in charge of what)

Cleaning is generally performed by manual cleaning or Cleaning in Place (C.I.P.).

Process equipment that cannot be cleaned in place, and also floors, drains, walls and ceilings must be cleaned manually.

Equipment that requires dismantling shall be soaked in hot detergents and soil removed by manual scrubbing; the equipment shall then be rinsed with water (see section [5.3.1](#)) and sanitized before re-assembly.

All surfaces intended to be disinfected must be well cleaned to prevent inactivation of sanitising agents by organic substances.

Cleaning shall take place immediately after the end of production. Disinfection, if carried out separately, shall take place immediately before starting production.

Equipment occasionally used – such as extra lines, parts, fittings, etc.- shall be cleaned and/or disinfected again before use.

Where the same vehicles, conveyances, and containers are used for food and non-food products, cleaning shall be carried out between loads. Bulk containers shall be dedicated to food use only, unless appropriate cleaning and disinfection has been validated as effective and is monitored during operation and is verified.

Where disinfectants are used for disinfection of product contact surfaces, these shall normally be followed by appropriate rinsing with potable water unless this is not required by the instructions for use of the disinfectant in question, as approved by the competent authority.

Where manufacture takes place occasionally, post-production as well as start-up cleaning procedures shall be in place.

5.7.2. Cleaning and sanitising agents and tools

The first stage in the process of cleaning is the selection of the appropriate cleaning agent. This relates to the type of soiling, the surface to be cleaned and its safety. In a processed cheese plant, product soiling will normally consist of organic material (mainly in form of fat and proteins) and inorganic material in the form of calcium salts (milk stone).

The removal of organic material is normally achieved by the use of caustic detergents containing wetting agents; the removal of inorganic soils is facilitated by the use of acids (nitric, phosphoric mainly).

All cleaning and sanitising compounds must be approved as suitable for food use. These materials shall preferably be stored in their original containers, clearly identified and stored separately from production areas to avoid contamination of packaging materials and products and harm to production personnel. Cleaning agents needed during the day may be placed close to the place of usage, if clearly identified.

Brushes shall not be of bristle or wood but made of plastic (polypropylene, high density nylon). Buckets shall be made of similar materials or stainless steel. For plastic brushes and buckets an appropriate regular replacement interval should be defined. Cleaning cloths shall be avoided in favour of disposable paper towels.

Production personnel must be trained in the correct handling and use of cleaning materials, which are normally hazardous materials. They shall be used only in accordance with the manufacturer's instructions.

When not in use, cleaning tools shall be stored in a hygienic manner (e.g. hung on the wall, placed in closets, etc.).

5.7.3. Monitoring and verification of cleaning and disinfection

All cleaning and disinfection operations and relevant parameters shall be recorded at each cleaning cycle, records kept and reviewed and immediate corrective actions shall be taken in case of any equipment/procedure failure. CIP (Cleaning-in-Place) working parameters shall be continuously recorded: temperature, time, concentration and flow rate.

Cleaning and disinfection performance shall be verified on a regular basis to assess the effectiveness of procedures, detergents and sanitisers. Verification shall include equipment dismantling, visual inspection, microbiological swabs and/or contact plates taken from process equipment after cleaning and disinfection (particularly from product contact surfaces and points identified as difficult to clean) and checks for the absence of disinfection chemicals before production.

5.7.4. Documentation

Documents:

- Cleaning procedures, including verification procedure for each circuit, equipment and area;
- Specifications for detergents and sanitisers (e.g. data sheets).

Records:

- Monitoring of cleaning operations (monitoring parameters);
- Verification results.

5.8. PERSONNEL HYGIENE

A fundamental condition for maintaining hygiene and ensuring food safety is to achieve awareness of all personnel, from senior management to every operator, of the central importance of hygiene and good hygienic practices in all activities: suppliers and personnel selection and management, new products development, manufacturing operations, products storage, handling and distribution. That is why an effective training procedure on food safety and hygiene must be implemented in order to always have the staff very alert to these matters (see [4.4](#)).

5.8.1. Personal health

Operators handling or who may come in contact with foodstuffs must always be in good health. Personnel shall be instructed by their supervisors to report poor health conditions such as all communicable diseases, illness, open lesions or any other abnormal source of microbiological contamination by which there is possibility to contaminate food, food-contact surfaces or food-packaging materials.

Supervisors shall verify that staff have understood the instructions.

People who report or are shown to have the above symptoms shall be excluded from any operations involving food handling until the condition is corrected.

Personnel must be aware of the diseases which must be reported to management. The management will in turn submit the declaration in case of health problems e.g.

- Gastroenteritis;
- Vomiting;
- Carrying Salmonella;
- High temperature;
- Sore throat with a fever;
- Infected skin lesions;
- Nose, eyes or ear discharges.

Subject to legal restrictions in the country of operation, employees shall undergo a medical examination prior to employment in food contact operations, unless documented hazard or medical assessment indicates otherwise.

Additional medical examinations, where permitted, shall be carried out at intervals defined by the FBO.

5.8.2. Personal hygiene and behaviour

To minimise the risk of product contamination by human activity the following rules must be observed and implemented:

- All employees must maintain a high degree of personal cleanliness, with hands and fingernails clean and properly trimmed;
- All cuts and scratches on exposed skin must be covered by a metal detectable sticky plaster in a given colour. The effectiveness of their detection by metal detector must be regularly checked;
- Employees must wash and sanitize hands before starting work, after each absence from the working area and at any times when hands become soiled or contaminated, including after sneezing, coughing, touching waste, etc;
- Employees shall be clean shaven or wear, in working areas, beard restraints. A head covering restraint to contain hair completely (hairnets close mesh type) is also necessary in working areas to prevent food contamination by hairs;
- Perfumed hand lotions, fingernail polish, false fingernails, eyelashes etc. shall be prohibited;
- Rings, earrings, watches and other jewellery shall not be worn on the job; wearing gloves is required if wedding rings cannot be removed.
- All employees in food processing areas shall wear clean, washable, light-coloured protective clothing without external pockets. Clothing, including shoes, must be kept clean and in good repair. In specific areas defined by management, according to risk analysis, changing of shoes and clothing may be required. Boots should be worn in wet areas. No buttons are permitted on working clothes (to prevent physical contamination), only press-on buttons. Overshoes should be provided for visitors;
- Eating, drinking and tobacco usage are prohibited on the job (they are permitted in designated rest areas only); adequate provision of drinking water to staff is accepted provided that its use does not become a source of contamination (e.g. capsules).
- To prevent articles from falling into products, employees shall not carry pens, thermometers, glasses, tools, etc., in shirts, coats, and clothes above the belt or waistline;
- Unwrapped products, packaging materials and product-contact surfaces shall not be handled with injured or bandaged hands, unless protected by gloves, or with cut and open sores in fingers, unless covered by band-aid and plastic finger protection (all accidents / injuries must be reported to the direct supervisor in order that appropriate treatment can be obtained before returning to work);
- In the case of the use of gloves, they must be of a sanitary and impermeable material and maintained clean, intact and sanitary;
- Food for employees intended as meals and breaks is only permitted in designated areas and must be stored in closed rigid containers (food is not permitted in employee lockers in production areas);
- Living plants or flowers shall not be brought into production areas and offices or corridors directly opening into production areas;
- Ear plug protection devices shall be attached by a cord to prevent product contamination.

Responsibility and authority for ensuring compliance by all personnel with the above rules shall be specifically allocated to competent supervisory personnel.

To prevent any employee with food disease causing possible product contamination the company must take overall responsibility for food safety, hygiene and pest control in on-site catering units.

5.8.3. Staff catering

Staff canteens and designated areas for food storage and consumption shall be situated so that the potential for cross-contamination of production areas is minimised.

Staff canteens shall be managed to ensure hygienic storage of ingredients and preparation, storage and serving of prepared foods.

Employees' own food shall be stored and consumed in designated areas only.

Where staff catering is managed by a contractor, the contractor has to be made responsible for all his activities and the hygiene system in place shall be included in regular auditing activities.

5.8.4. Documentation

Staff hygiene instruction(s).

5.9. MANAGEMENT OF PURCHASED MATERIALS (RAW MATERIALS AND INGREDIENTS)

5.9.1. Management of purchased raw materials and ingredients

The quality of raw materials and ingredients (including salt, flavouring substances, additives, processing aids and gases) is fundamental to obtaining a high quality of finished product, i.e. product that is not only compliant with all applicable regulations but also always constituted from quality-controlled materials and meeting the nutritional and health needs of the consumers.

5.9.1.1. Selection and management of suppliers

All raw materials and ingredients shall be purchased from approved and registered suppliers. This register shall be periodically evaluated taking into account suppliers' previous performance (ability to meet quality and food safety expectations, requirements and specifications), and the hazards associated with the material and production sites.

An example of a supplier's assessment approach is provided in Annex IV, part A.

5.9.1.2. Specifications

Specification documents shall be maintained for all raw materials and ingredients used. These shall, in addition to basic product characteristics (chemical composition, organoleptic parameters, designation, etc.), include specification of the following:

- Traceability data and information: name and origin of purchased material, approval/registration numbers production lot numbers and expiry dates;
- Storage conditions: temperature, humidity and lighting conditions and all other applicable elements which can affect product quality and food safety;
- Microbiological criteria;
- Maximum levels for pesticides, dioxins, PCBs, heavy metals, aflatoxin M₁, antibiotics and other veterinary drugs³;
- Allergens content;
- Physical contaminants: the raw material must be free from any kind of extraneous matter (metals, plastic, rubber, etc.).

In the case of cheese material intended for further processing only, additional information needed to enable adequate handling, preparation and treatment must be required from the supplier as may be necessary. Further details are provided in section 5.1.3 of the EDA/EUCOLAIT Guidance on Cheese as Raw Material.

5.9.1.3. Incoming material inspection

³ It should be noted that the maximum levels set for milk also applies for processed and compound foodstuffs by way of calculation (Article 2 of Reg. 1881/2006) and that prohibitions on use, mixing and detoxification apply (Article 3 of Reg. 1881/2006).

There shall be in place a documented incoming material inspection procedure that specifies how compliance with requirements and specifications are checked and verified.

The extent in which the following checks shall be carried out depends on supplier reliability, the nature of the material, the impact it may have on effective processing and finished product quality:

- Visual inspections, prior to and during unloading, that the quality and safety of the material has been maintained during transport (e.g. integrity of seals, freedom from infestation, existence of temperature records), product and vehicle cleanliness, correct transportation conditions (temperature, presence of prohibited materials in the shipping), etc.;
- Checking that documents correspond to order (quantity and quality), e.g. presence of certificates of analysis required, records of required transportation temperatures;
- Organoleptic tests to assess appearance, colour, odour, taste;
- Physical tests, i.e. temperature on delivery;
- Chemical and microbiological analyses to verify compliance with specifications.

Materials which conform to specifications are approved for use. Materials which do not conform to specifications or have been transported in unacceptable conditions (dirty, damaged or out-of-date) must be handled in a way which ensures that they are prevented from unintended use until returned to the supplier.

In the case of cheese material intended for further processing only, the following must be checked:

- Type of raw material;
- Visual state of cheese material (e.g. visible mould, cheese mites, dirt, etc);
- State of packaging material;
- Additional information needed to enable decisions as regards its acceptance and any restrictions on its usage, including adequate handling, preparation and treatment, nature of any contamination and any previous treatment.

The Guidance provided in Section 5.3.1 of the EDA/EUCOLAIT Guidance on Cheese as Raw Material must be followed.

An example of a record form for reception of raw material is provided in Annex IV, part B.

5.9.1.4. Storage and Handling Conditions

Incoming materials must be clearly identified and appropriately handled and stored until use, in accordance with any storage specifications applicable.

Storage of cheese material used as raw material shall follow the guidance provided in section 5.3.2 of the EDA/EUCOLAIT Guidance on Cheese as Raw Material.

Storage facilities shall be neat and orderly.

To enable cleaning and for pest control purposes, consideration must be given to the distance from walls, sealed doors and windows, cleanable floors, walls and overhead structures.

Damaged bags or drums must be sealed to prevent product spillage and contamination. Ingredients contaminated through damage must not be used due to possible microbiological or foreign body contamination.

Glass containers shall be stored separately from other materials.

Storage of food material shall follow the principle of first in – first out (FIFO), in particular where the durability of the material impacts on food safety and suitability. It is important to train staff always to dispatch the oldest stock first. Non-cheese food material should also follow the principle of first expired – first out (FEFO).

Batch coding shall be used to enforce correct stock rotation.

5.9.2. Management of purchased packaging

Packaging includes primary packaging (product contact materials such as plastic containers, tubs, form-fill-seal materials), secondary packaging (non-product contact materials like cardboard outers) as well as shrink wrap plastics and pallets.

5.9.2.1. Selection and management of suppliers

All packaging materials shall be purchased from approved and registered suppliers. This register shall be periodically audited according to an audit plan and taking into account the suppliers' previous performance (ability to meet specifications) and the hazards associated with the material.

5.9.2.2. Compliance with Regulations

Primary packaging must be suitable for contact with food. It shall not:

- Be a hazard for human health;
- Result in an unacceptable modification of the composition of food products;
- Result in a deterioration of organoleptic characteristics of food products.

All packaging, either product contact or outer protective wrapping and crates, must comply with EU Regulation 1935/2004. Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

When required by regulations, packaging materials suppliers must carry out the global migration test provided for the type of material, and the specific migration tests for constituents. Guarantees must take into account the nature of the product to be packaged and the physical treatments (thermoforming) or chemical ones (disinfection) carried out by the manufacturer during the packaging operations.

5.9.2.3. Incoming material inspection

On delivery, packaging shall undergo a visual inspection for outer cleanliness and dirty items shall be rejected.

Wooden pallets which are not clean and damaged are to be excluded from the process flow.

5.9.2.4. Storage and Handling

Packaging materials must be stored in clean and dry areas. Since these materials are not generally cleaned before use, particular attention must be paid during storage in warehouses and in production rooms, to avoid contamination by dirt, infestations and any contaminating agent.

Wooden pallets can be a source of microbiological contamination, particularly pallets used to deliver packaging and raw materials, which are often quite dirty. They shall be kept out of processing areas and confined to areas where the product is already packed and cannot be contaminated. In processing areas, either racks, pallets and trolleys made of cleanable materials (plastics, metals) or those intended for single-use shall be used.

5.9.3. Documentation

Documents:

- Register of suppliers, including their registration or approval numbers;
- Specification documents for all raw materials and ingredients;
- Incoming material inspection procedure;
- Guarantees that the primary packaging materials can be used without any food safety concerns for the intended product to be packaged and the physical treatments (thermoforming) or chemical treatments (disinfection) carried out by the manufacturer during the packaging operations.

Records:

- Detected deviations from specifications;
- Results of sampling and analysis and of other tests carried out;

To assist in effective traceability, records of received cheese material intended for further processing only must be linked to the original lot identification provided by the original manufacturer.

5.10. LABELLING

5.10.1. Food safety related information

End products shall be labelled with the following:

- Identification mark (see Reg. 853/2004);
- Origin of the product (name and address of manufacturer, packer or distributor);
- Shelf life, date of minimum durability or use-by date (Regulation 1169/2011);
- Recommended storage conditions;
- List of ingredients (A label reconciliation programme shall be developed to ensure that the labelling of allergens is in full conformity with product recipes. Any allergenic substance in the recipe must be recognized).

Relevant labelling requirements shall be consulted and complied with (Regulation 1169/2011).

5.10.2. Documentation

- Results of shelf life studies.

5.11. STORAGE & WAREHOUSING

5.11.1. Storage procedures

Raw materials and ingredients shall be stored at temperatures as specified by the food establishment responsible for their manufacture. Storage management of non-cheese material should follow the principle of first expired – first out (FEFO).

Storage of cheese shall be carried out in accordance with the EDA/EUCOLAIT Guidance on Cheese as Raw Material.

Material that requires cold storage shall be placed under chilled conditions without any necessary delay.

Finished products must be clearly identified and appropriately handled and stored following the requirements specified (See [5.12](#)).

Finished product warehouse management shall be made following the principle of first in – first out (FIFO).

An indicating thermometer must be fitted in a prominent position on an external wall of the warehouse. Recording thermometers or manual temperature follow-up must be performed.

The safety of the area shall be secured by traffic arrangement. Pedestrianized areas should be clearly marked.

5.11.2. Documentation

- Storage instructions;
- Results of calibration of thermometers.

5.12. RELEASE OF END PRODUCTS

A Finished Product Specification document (often referred to as “birth certificate”) shall be issued for each batch, specifying all the following requirements:

- Product description and composition;
- Ingredient list to be put on the label;
- Chemical, physical and sensory requirements and characteristics;
- Microbiological criteria applied to verify microbial controls.
- Any allergens content;
- Product packaging (including traceability data and information to be put on the pack);
- Shelf-life and corresponding storage and transport conditions (temperature, humidity and lighting conditions and all other applicable elements which can affect product quality and food safety)
- Any conditions of use.

6. HACCP SYSTEM

6.1. THE HACCP PRINCIPLES

Each producer must have a functioning HACCP system according to the 7 HACCP principles established by Codex Alimentarius.

PRINCIPLE 1: Conduct a hazard analysis. This includes the identification of potential hazards and the need for their control (i.e. prevention or reduction to acceptable levels or elimination).

PRINCIPLE 2: Determine the Critical Control Points (CCPs). Determination is based on the assessment of available control measures as regards their effect against hazards and their ability to be monitored in time for immediate corrective action. CCPs are identified as those steps where control measures essential for achieving the required level of control (cf. principle 1) are located.

PRINCIPLE 3: Establish critical limit(s). Limits are established at each CCP for relevant parameters used for monitoring the correct functioning of the control measures(s). The value of the limit determines whether the control measure is functioning as intended or control has been lost.

PRINCIPLE 4: Establish a system to monitor control of the CCP.

PRINCIPLE 5: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control. A CCP is not under control when one or more critical limit(s) are exceeded.

PRINCIPLE 6: Establish procedures for verification to confirm that the HACCP system is working effectively. Verification activities also include verification of the system in its entity (prerequisites and HACCP).

PRINCIPLE 7: Establish documentation concerning all procedures and records appropriate to these principles and their application.

The establishment of a HACCP team is central to the performance of the HACCP/PRP system.

The HACCP team shall have a combination of multi-disciplinary knowledge with processed cheese manufacture, quality assurance, microbiology and processing technology, and have experience in developing and implementing a HACCP system.

The responsibility of the HACCP team leader is as follows:

- To manage the HACCP team and organise its work;
- To ensure training and education of the HACCP team members;
- To ensure that the HACCP/PRP system is established, implemented, maintained and kept updated; and
- To liaise with external parties on matters relating to the HACCP/PRP system.

6.2. DATA AND INFORMATION NEEDED TO CONDUCT THE HAZARD ANALYSIS

6.2.1. Characteristics of raw materials and ingredients

A description of each type of raw material, ingredient and additive used shall be maintained. Each shall adequately describe microbiological, chemical or physical aspects that may be important to identify their food safety status and possible hazards (e.g. composition, origin, shelf life, previous processing and handling, any acceptance criteria and specifications applicable).

6.2.1.1. Raw materials

Raw materials may be classified in the following categories:

- Cheese, of any fat and moisture content and manufactured at the same or at a different site, and where the product is obtained. Cheese material includes cheese material that during manufacture or distribution does not meet the intended commercial or hygienic specifications (recovered cheese material) in accordance with the EDA/EUCOLAIT Guidance on Cheese as Raw Material. The origin and the history (processing and handling) of the cheese material used are of particular importance for hazard analysis. This applies in particular to raw material that is recovered from other processing or distribution lines.
- Milk fat products, which are added for upwards standardization of fat content of the raw materials to meet the desired fat content of the finished product (e.g. cream, butter, butter oil and ghee).
- Milk and milk products other than cheese and milk products rich in fat, i.e. products that are added for downwards standardization of the fat content and/or standardization of the dry matter content of the ingoing raw material to meet the desired composition of the final product (e.g. milk concentrates, buttermilk, milk powders, milk proteins, whey powders, lactose).
- Vegetable fat (only in the case of blended products).

6.2.1.2. Food ingredients

Each food ingredient used shall be described. The description shall include information of the microbiological status and specifications, how it was prepared/processed prior to delivery-

Ingredients include:

- Sodium chloride and salt substitutes (e.g. potassium chloride);
- Water;
- Gelatine and starches, which can be used to carry out the same function as stabilisers, provided they are added only in amounts functionally necessary as stabilizers or thickeners;
- Vinegar;
- Other ingredients used to characterize (flavour) the product, such as spices and other vegetables and other prepared foods.

6.2.1.3. Food additives

Each additive used shall be described. The description shall specify the amount of each additive added, a list of any substances added as carriers together with the additive, and the maximum level specified by legislation. Product data sheets from the producer shall be kept as documentation.

Different kinds of additives can be used with different functional roles in the production process and for product stability during shelf-life. The following are normally used:

- Emulsifying salts (e.g. sodium polyphosphates, sodium citrates): they facilitate the melting phase while transforming the casein gel of cheese into a soluble phase to get a fat-in-water emulsion;
- Acidity regulators (e.g. organic acids such as citric, lactic or acetic acid or sodium hydrogen carbonate and/or calcium carbonate);
- Colours (e.g. annatto, beta-carotene, chlorophyll, riboflavin);
- Preservatives (e.g. potassium or sodium sorbate, potassium or sodium propionate, nisin): their antimicrobial action combined with adequate heat treatment enables several months of product shelf-life;
- Stabilisers and thickeners;
- Anticaking agents.

6.2.1.4. Processing aids

Each processing aid used shall be described. Processing aids shall be suitable for their purpose and of food grade quality. Their description shall specify the amount of each substance added and a list of any substances added as carriers together with the additive.

6.2.1.5. Packaging materials

The primary packaging material shall be described. The description shall specify the material, and any coating and printing colours. Product data sheets from the producer shall be kept as documentation.

6.2.2. **Manufacturing steps and flow diagrams**

The main steps of the production process shall be described and maintained together with a clear process flow chart/diagrams of the sequence and interaction of the processing steps.

Any legal requirements applicable to the steps shall be identified.

Process steps specific to the manufacture of processed cheese include:**6.2.2.1. Melting and emulsification**

Cheese consists of a para-casein gel with occluded fat globules and moisture. Emulsifying salts function indirectly, by promoting (together with heat and shearing) a number of physicochemical changes⁴ in the blend which convert insoluble para-casein into sodium para-caseinate, which binds water and emulsifies the free oil during processing.

6.2.2.2. Heat processing

Heat treatment of processed cheese is normally carried out using a scraped surface heat exchanger, a tubular heat exchanger or a direct injection UHT system.

In the manufacture of processed cheese, the design of the heat process varies considerably depending on the raw materials used, the type of processed cheese (e.g. spread or block), and flavouring foods. However, all heat processes applied shall include a heating step of above 80 °C for more than 1 minute.

Examples of applied heat processing:

1. 135 °C for not less than 5 minutes (a commercial sterilization), followed by hot filling;
2. 130 °C for 5 or 8 seconds (a UHT treatment), followed by hot filling;
3. 106 °C for not less than 2 minutes (a pasteurisation), followed by cooling to 90 °C and storage (at least 30 minutes) with natural cooling until filling at above 60 °C;
4. 90 °C for not less than 1 minute (a pasteurisation), followed by storage with natural cooling until filling at above 60 °C.

Examples 1 and 3 are typically applied where control of Lactobacilli is desired.

6.2.2.3. Filling process

In hot fill production lines, processed cheese is filled into a primary packing material at a temperature that minimises the consequences of any recontamination (contact or airborne) due to the pasteurisation effect resulting from the temperature of the product itself. Typical examples are processed cheese portions or individually wrapped slices.

In a cold fill production process, the heat-treated cheese is cooled down below pasteurisation temperature before entering the primary packaging. All typical ubiquitous germs and spore-like yeasts and moulds present in a normal production environment may re-contaminate the product surface.

Another cold process technology involves extrusion of hot (e.g. 80°C) molten cheese onto a cold stainless-steel roller from which it is delivered in a flat strip on a conveyor to a slicer and packaging unit. During this period the product is exposed to ambient air for a period of approximately 1 minute.

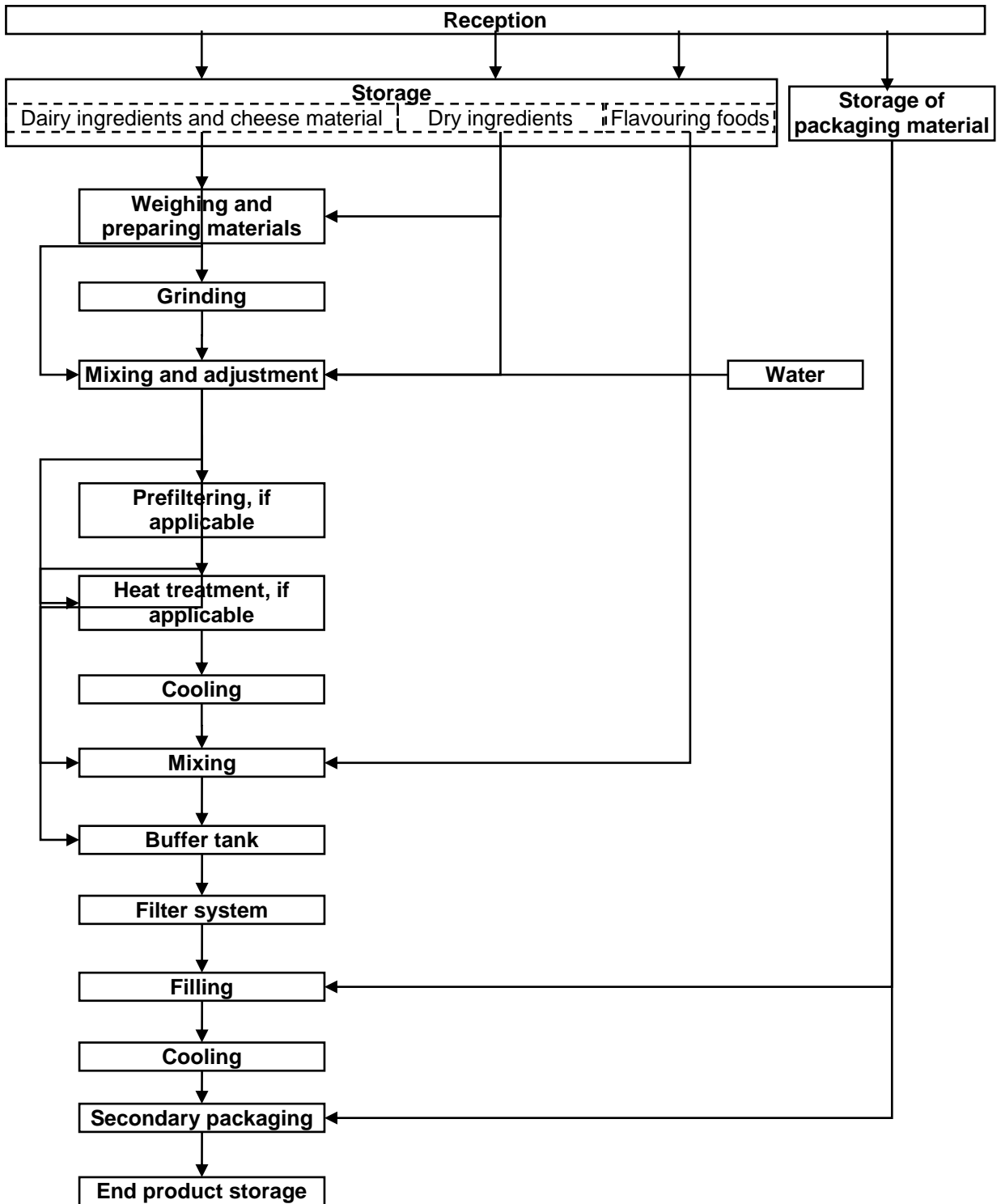
6.2.2.4. Flow diagram

The flow diagram shall also show:

- Where raw materials, ingredients and intermediate products enter the flow;
- Where reworking and recycling take place;
- Where end products, intermediate products, by-products and waste are released or removed.

A schematic overview of the process flow for processed cheese is provided below:

⁴ E.g. calcium sequestration (ion exchange), para-casein hydration and dispersion, emulsification of free fat, and structure formation (fat crystallisation, protein-protein interactions, and interactions between para-caseinate-coated fat globules and dispersed para-caseinate).



6.2.3. Characteristics of the end products

A description of the characteristics of each end product (intrinsic factors) shall be maintained that adequately describes the composition, the packaging, the intended shelf life with the storage conditions, the designation, the intended use of the product, and the expected distribution method.

Intrinsic factors of processed cheese are typically:

- pH: 5.2 to 5.8 (spreads are typically more acidic than blocks);
- Melting salts up to 3 %;
- Any preservatives, e.g. nisin, at concentrations up to the maximum levels specified by legislation.

Organoleptic aspects such as appearance, structure, taste and odour shall be specified. These are all important characters for evaluating the overall quality of the process.

6.3. HAZARD ANALYSIS (PRINCIPLE 1)

The objective of the hazard analysis is to determine which biological, physical and chemical hazards need to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required. The analysis shall include all hazards coming from raw material and ingredients including allergens, from the process and staff, from the processing environment, and from the packaging and storage.

A model hazard analysis for processed cheese is provided in [Annex III](#) for training purposes.

6.3.1. Identification of hazards

The objective of the hazard identification step is to identify those hazards that, taking into account the prerequisite programme in place, are likely to occur at all steps during the manufacturing of processed cheese.

The identification shall be based on:

- The information and data available on raw materials, ingredients, and processing;
- Experience;
- Epidemiological and other historical data;
- Information from the food chain on food safety hazards that may be of relevance for the control of hazards (see section 5.1.3 of EDA/EUCOLAIT Guidance on Cheese as Raw Material).

Hazards that normally are associated with the manufacture of processed cheese are:

- Microbiological hazards:
 - Pathogenic bacteria from raw materials (*L. monocytogenes*, verotoxigenic *E. coli*, *S. aureus* and *Salmonella*) and from ingredients (*Salmonella*, *Cl. perfringens*, *Cl. Botulinum*, *B. cereus*, *L. monocytogenes*);
 - Mycotoxins that may be present in cheese (see Annex II to the EDA/EUCOLAIT Guide);
 - Bacterial toxins that may be present in raw materials (e.g. staphylococcal enterotoxin in certain raw milk cheese) and ingredients;
 - Additional hazards associated with flavouring foods (e.g. spices, herbs, ham, fruit, mushrooms, etc.);
 - Pathogens that may be transferred from staff;
 - Re-contaminating moulds and pathogenic bacteria from the processing and packaging environment.

- Other biological hazards
 - Allergens in ingredients and from equipment (e.g. lubricants);
- Chemical hazards:
 - Pesticide residues in raw materials and ingredient (e.g. products rich in fat);
 - Environmental contaminants in raw materials and ingredients (e.g. dioxins and dioxin-like PCBs, heavy metals);
 - Contaminants from processing activities (coolants, lubricants, sanitisers);
 - Carry over additives (with numerical ADIs specified) from raw materials and ingredients;
 - Contaminants from food contact materials, including coating, waxes and soft plastic such as ripening films (e.g. mineral oils);
 - Additional hazards associated with flavouring foods (e.g. spices, herbs, ham, fruit, mushrooms, etc.).
- Physical hazards: (glass, bone or insect debris, metal fragments, hard plastic etc.)
 - Glass from unsecured windows, lamps, bulbs, neon tubes, thermometers, laboratory glass, spy holes on the tanks, insect killing tubes or other glass equipment;
 - Insect debris from raw materials, ingredients and packaging material;
 - Wood from pallets or wooden equipment;
 - Metal from improperly built or maintained machines or equipment;
 - Plastic from buckets, boxes, brushes;
 - Stones from damaged floors or walls;
 - Utensils used in the production zone and lost by staff (pencils, knives, keys, etc.).

6.3.2. Determination of acceptable levels

Whenever possible, the acceptable level of each hazard in processed cheese shall be determined. The level shall take into account regulatory requirements and the intended use of the product.

For manufacturers of consumer products, the “acceptable level” refers to the acceptable level of a particular hazard in the final product.

The justification for, and the result of, the determination of other acceptable levels shall be maintained in a written document.

6.3.2.1. Limits established for ingredients and raw materials

Contaminants	Foods to which the criterion applies	Max. Levels
Aflatoxin B1, B2, G1 and G2 (sum)	A number of dry ingredients and spices	See Commission regulation 1881/2006
Aflatoxin M1	Raw milk	
Other mycotoxins (eoxynivalenol, zearalenone, and T-2 & HT-2 toxin)	Flours etc	
Lead	Meats, vegetables, berries, fruits, oils and milk fats	
Cadmium	Meats Vegetables, fresh herbs, cultivated fungi	
Dioxin	Vegetable oils and fats Meat Raw milk	
Benzo(a)pyrene	Oils and fats	

Dioxins Sum of dioxins (WHOPCDD/ F-TEQ)	Dairy products >2% fat (incl. processed cheese)	2,5 pg/g fat (Commission regulation 1259/2011)
Contaminants	Foods to which the criterion applies	Max. Levels
Sum of dioxins and dioxin-like PCBs (WHOPCDD/F-PCB-TEQ)	Dairy products >2% fat (incl. processed cheese)	5,5 pg/g fat (Commission regulation 1259/2011)
Residues of pesticides	Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	Consult the Regulation 396/2005 and the EU Pesticides database http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

6.3.2.2. Limits established for processed cheese

The following microbiological criterion has been established by Commission regulation 2073/2005:

				Prerequisites for application		
Organism	n	c	M	Step of application	Nature of product	Other conditions
<i>L. monocytogenes</i>	5	0	100 cfu/g	Products placed on the market during their shelf-life.	Products that support growth of <i>L. monocytogenes</i>	This criterion applies only, if the manufacturer has demonstrated, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may establish limits for verification during the process if they are low enough to guarantee that the limit is not exceeded at the end of shelf-life.
	5	0	Not detected in 25g	Before the product has left the immediate control of the manufacturer	(likely to be the case for products with relative high moisture content)	This criterion applies, if the manufacturer has not carried out studies to demonstrate whether the product will not exceed the limit 100 cfu/g throughout the shelf-life.
	5	0	100 cfu/g	Products placed on the market during their shelf-life.	Products that do not support growth of <i>L. monocytogenes</i> (likely to be the case for products with relative low moisture content)	This criterion applies only, if the manufacturer has demonstrated, to the satisfaction of the competent authority, that the product does not support growth of <i>L. monocytogenes</i> . The operator may establish limits for verification during the process if they are low enough to guarantee that the limit is not exceeded at the end of shelf-life.

<i>E. coli</i>	5	2	100 cfu/g	1000 cfu/g	At the time during the manufacturing process, when the <i>E. coli</i> count is expected to be highest	The criterion applies when milk or whey is used directly as raw material. Due to heat treatment quickly after mixing with other ingredients, any <i>E. coli</i> will be destroyed. Therefore, testing is not useful as a means to verify processing hygiene.
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Substance		Max. level
<i>Tin (inorganic)</i>	Canned processed cheese	200 mg/kg (Commission regulation 1881/2006)
<i>Dioxins Sum of dioxins (WHOPCDD/F-TEQ)</i>	Processed cheese with >2% fat	2,5 pg/g fat (Commission regulation 1259/2011)
<i>Sum of dioxins and dioxin-like PCBs (WHOPCDD/F-PCB-TEQ)</i>	Processed cheese with >2% fat	5,5 pg/g fat (Commission regulation 1259/2011)
<i>Residues of pesticides</i>		Consult the EU Pesticides database http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=commodity.selection

6.3.2.3. Other guidance

The following microorganisms may be significant hazards, and should therefore be assessed as to whether they need be controlled by control measures managed by the HACCP Plan.

Pathogen	Reported minimum infective doses	Other targets
<i>Aeromonas hydrophila</i>	10 ⁸ - 10 ¹¹ cells/serving ⁵	
<i>Campylobacter jejuni</i>	500 cells/serving ⁶	
<i>Clostridium perfringens</i>	10 ⁸ cells/serving ⁷	
<i>Pathogenic E. coli</i>		
- <i>EPEC</i> ⁸ / <i>EIEC</i> ⁹	10 ⁶ – 10 ⁸ cells/serving ¹⁰	
- <i>ETEC</i> ¹¹	10 ⁸ - 10 ¹⁰ cells/serving ¹²	
- <i>VTEC</i> ¹³ / <i>EHEC</i> ¹⁴	10-100 cells/serving ¹⁵	
<i>Salmonella spp.</i>	10 ¹ – 10 ⁴ cells/serving ¹⁶	not detected in 5x25 g ¹⁷
<i>Staphylococcal enterotoxin</i>	0.02-0.1 µg/serving ¹⁸	Nd

⁵ FDA

⁶ EFSA (2004a); WHO-ICD (2000)

⁷ EFSA (2004b); FDA; FSANZ (2006); WHO-ICD (2000)

⁸ Enteropathogenic *Escherichia coli*

⁹ Enteroinvasive *Escherichia coli*

¹⁰ FSANZ (2006); WHO-ICD (2000)

¹¹ Enterotoxigenic *Escherichia coli*

¹² FSANZ (2006)

¹³ Verotoxin producing *Escherichia coli*

¹⁴ Enterohaemorrhagic *Escherichia coli*

¹⁵ FDA; ILSI (2001); Tilden et al (1996); Lahti (2003).

¹⁶ FAO/WHO (2004); FDA; FSANZ (2006)

¹⁷ Reg. (EC) No 2073/2005

¹⁸ EC (2003)

<i>Staphylococcus aureus</i> (veg. cells)	-	Should never exceed 100.000 cfu/g
<i>Yersinia enterocolitica</i>	10 ⁶ – 10 ⁷ cells/serving ¹⁹	
<i>Cryptosporidium parvum</i>	10-80 cells/serving ²⁰	

Further, Reg. 1935/2004 on materials and articles intended to come into contact with food and associated databases provide guidance on contaminants in food contact materials.

6.3.3. Hazard assessment

The purpose of hazard assessment is to assess the hazards identified in section 6.3.1 in order to identify those hazards that need to be controlled. A hazard assessment determines whether elimination or reduction to acceptable levels of each hazard is needed to obtain a safe end product, and whether specific control is needed to enable acceptable levels to be met.

The HACCP team shall evaluate each food safety hazard according to the possible severity of adverse health effects and the likelihood of their occurrence. The results and their reasons shall be recorded.

The hazards can be ranked according to their weighted significance based upon the probability of occurrence in the food, the expected levels in the food and the severity of the adverse health effects that can be caused by the hazard, e.g. as follows:

Relative weight Parameter	4	3	2	1
Probability of occurrence (P)	Likely	Often	Occasional	Seldom
Expected levels (L)	High (above infectious/injurious dose)	Moderate (close to acceptable levels)	Low (well below acceptable levels)	Very low (insignificant levels, hardly detectable)
Severity of the adverse health effects that can be caused by the hazard (S)	Very serious (mortal, chronically diseased, disabled)	Serious (hospitalized, diseased for longer periods)	Moderate (bloody diarrhoea, dehydration, carcinogenic, allergic)	Mild (uncomplicated diarrhoea, discomfort, hypersensitivity)

The information required to conduct the hazard assessment can be obtained from scientific literature, databases, statutory and regulatory authorities, and external competences.

The hazard analysis may determine that control of a hazard will not be needed. This may occur when, for example, the introduction or occurrence of the hazard does not exceed the acceptable level even without any control measures being assigned to control it. This may, for instance, be the case where prerequisite programmes result in the introduction or occurrence of the hazard being unlikely or so low that the acceptable level will be met in every case. A typical prerequisite programme used for that purpose is monitoring and verification of adherence to specifications for raw materials and ingredients.

¹⁹ FSANZ (2006)

²⁰ Dawson (2005); IFST (2001); FDA; FSANZ (2006)

6.3.4. Documentation of the hazard analysis (Principle 7 – in part)

Documents and records shall be kept until they are no longer relevant.

Documents shall be dated and signed by a responsible person.

The HACCP documentation shall contain the following:

- Members of the HACCP team;
- The hazard analysis:
 - List of hazards and justifications for their choice (e.g. this Guide);
 - Definition of the expected use of the product and the vulnerable consumer groups;
 - Acceptable levels of hazards in the final product;
 - Justification for, and results of, the determination of other acceptable levels;
 - Results of hazard assessment;
- Specifications for raw materials, ingredients, including supplier specifications;
- Specifications for finished products;
- Certificates of conformity for materials in contact with the product.

HACCP records shall include:

- Minutes of meetings of the HACCP team.

6.4. HACCP PLAN (PRINCIPLES 2-5)

A model HACCP plan for processed cheese is provided in [Annex III](#) for training purposes.

6.4.1. Selection of control measures and identification of critical control points (CCPs)

CCPs are those steps where the identified control measures are located.

The combination of control measures that is chosen shall be capable of controlling the hazards so that the acceptable levels are not exceeded. More than one control measures are often required to control specific food safety hazard(s) and more than one food safety hazard may be controlled by the same control measure.

Control is either preventing a hazard from occurring, preventing or delaying its increase, or reducing its concentration and/or its frequency of occurrence.

For each hazard that has to be controlled, it shall be assessed which control measures (including processing steps) that are capable of, either alone or in combination, effectively ensuring that the identified acceptable levels in the end product will not be exceeded.

The information required to assess the effect of a control measure includes the following:

- How the hazards are affected by the control measure (i.e. reduction, controlling increases, and/or controlling the frequency of occurrence).

For instance, heat treatments at relative low temperature may trigger sporulation and are not recommended where *B. cereus* or *C. botulinum* are likely to be present (e.g. certain spices).

- To what extent the levels of hazards are affected (qualitatively, semi-quantitatively or quantitatively).

Very often the effect depends upon the rigorousness of the control measure (e.g. temperature, time, concentration, frequency). In carrying out the assessment it is therefore useful to obtain data on the intensity-effect relationships (e.g. D-values of a heat treatment);

- Operational parameters, including their operational uncertainty (e.g. fluctuation and/or probability of operational failure), and practical operational range of intensity.

Each CCP identified shall be described as follows:

- Location (process step) and CCP number;
- The control measure(s) pegged to the CCP;
- Hazards that the CCP is intended to control;
- The critical limits and how it will be controlled;
- Monitoring procedure, i.e. nature of the monitoring, frequency, responsibility and documentation;
- Calibration of the monitoring equipment (procedure, frequency and documentation);
- Corrective action(s), i.e. what to do in a case where the critical limit is exceeded.

6.4.2. Establishment of critical limits for each CCP

Monitoring of a CCP is based on the monitoring of determined critical limits.

A critical limit determines when corrective action is required, and it shall:

- Be used to demonstrate whether the control measure(s) applied at a CCP is in control;
- Be established to ensure that the identified acceptable levels of the food safety hazard in the end product (see [6.3.2](#)) are not exceeded;
- Correspond to the operational parameters used, however taking into account any variation during its operation (e.g. temperature fluctuation) and measurement uncertainty;
- Be measurable or observable in a timely manner to enable immediate action.

The rationale for the chosen critical limits shall be documented.

Critical limits based on subjective data (such as visual inspection of product, process, handling, etc.) shall be supported by instructions or specifications and/or education and training.

For CCPs intended to control more than one hazard, the critical limit(s) shall be determined relative to each hazard, and the most stringent limit is the one to be applied.

6.4.3. System for the monitoring of critical control points

The monitoring system shall consist of relevant procedures, instructions and records that cover the following:

- Who is to perform monitoring and checking (responsibility and authority related to monitoring and evaluation of monitoring results);
- When monitoring and checking is performed (monitoring frequency);
- How monitoring and checking is performed (monitoring devices used, applicable calibration methods);
- A record of requirements and methods.

The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in sufficient time for the product to be isolated before it is used or consumed.

Physical and chemical measurements that give information about the degree of microbiological control are often preferred to microbiological testing because they can be done rapidly. For verification purposes, microbiological testing may be useful depending on the uncertainty of the control measure performance and of the monitoring system.

6.4.4. Actions when monitoring results exceed critical limits

For each critical limit, corrective actions shall be planned in advance, so that the actions can be taken without any delay when monitoring indicates loss of control.

Corrective actions are developed to help operators make the proper decisions to bring the process back into control so that production can resume.

Corrective actions typically have three parts:

- The containment action which are the actions that are immediately taken:
 - to prevent further production of potentially unsafe food, and
 - to control products that may have been affected during the period when the CCP was out of control
- The short term corrective actions which are the short term solutions to regain control and prevent recurrence of the problem, and
- The long term corrective action or actions that are taken to greatly reduce the risk of recurrence or prevent recurrence.

An appropriate description of a corrective action includes:

- Identification of the person(s) responsible for the implementation of the corrective action;
- Description of the nature of the action;
- Record requirements (for example: date, time, type of action(s) taken, and any subsequent verification check).

6.4.5. HACCP plan documentation (Principle 7 – partly)

Documents and records shall be kept for a sufficient time to allow audit of the HACCP system, and at least until the end of shelf life of the product.

Documents shall be dated and signed by a responsible person.

The HACCP documentation shall contain the following:

- Certificates of compliance for packaging;
- Certificates of conformity for materials in contact with the product;
- The rationale for selection of control measures;
- The rationale for the determination of CCPs and corresponding critical limits;
- Flow diagram and description of the steps of the procedure;
- A HACCP plan.

HACCP records shall include:

- Minutes of meetings of the HACCP team;
- CCP monitoring results;
- Deviations and corrective actions carried out;
- Evaluations as regards the handling, use and release of affected batches;
- Results of verification activities;
- Any modifications to the HACCP system.

6.5. REVIEW

The hazard analysis and consequential modifications of the HACCP plan shall be repeated once per year or whenever changes to any of the following occur:

- Recipes or new products;
- Raw materials and ingredients;
- Processing technology and equipment;
- Processing premises;
- Cleaning programmes;
- Packaging, storage and expected distribution;
- Regulatory requirements;
- Knowledge regarding food safety hazards and control measures;
- Complaints indicating unexpected food safety hazards associated with the product.

7. HANDLING OF NON-CONFORMING PRODUCTS

Non-conformance occurs when raw material, process material or finished product does not meet the requirements stated (for example specification, quality plan, analytical values, contracts).

When critical limits for CCP(s) are exceeded, or there is a loss of control of PRP(s) that may affect the food safety status of the end product, the products affected shall be identified as “potentially unsafe products” with regard to their handling, use and release.

7.1. HANDLING

All lots of product that are potentially unsafe, shall be held under control to prevent all unintentional uses, and be prevented from entering the food chain until they have been evaluated or disposed of for other (non-food) usage.

Personnel detecting non-conforming product must be made responsible for immediately blocking and reporting the deviation. A deviation report must be sent to the person responsible for corrective actions and follow-up.

See example of a deviation report in [Annex IV, part C](#).

Non-conforming products shall be marked or placed in a marked area immediately after the non-conformity is detected.

7.2. DECISION OF FATE

A potentially unsafe product may be released only when:

- Evidence other than the monitoring results demonstrates that the control measures have been effective;
- Evidence shows that the combined effect of the control measures for that particular product complies with the performance intended (i.e. identified acceptable levels);
- Results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the hazard(s) concerned.

If the lot of product is not acceptable for release it shall be handled by one of the following, as appropriate to the nature of the non-conformity:

- Reprocessing to ensure that the hazard of concern will be reduced to the determined acceptable level;
- Further processing, e.g. by another food business that will reduce the hazard of concern to the determined acceptable levels prior to entering the food chain as a ready-to-eat food (see EDA/EUCOLAIT Guidance on Cheese as Raw Material);
- Destruction and/or disposal and use as animal by-product.

If products that have left the control of the manufacturer are subsequently determined to be unsafe, the manufacturer shall notify relevant interested parties and initiate a recall/withdrawal.

An example of a record form for the handling of potentially unsafe products is in [Annex IV, part D](#).

7.3. RECALLS/WITHDRAWALS

There shall be a written withdrawal/recall procedure in place, and it shall be capable of being put into operation at short notice, at any time, inside or outside working hours.

The withdrawal/recall procedure shall be shown to be practicable and operable within a reasonable time by carrying out suitable testing of the procedures.

A withdrawal is carried out when no affected product has been displayed to the consumer and it aims at preventing the distribution, display or offer to the consumer. A recall is needed, if any of the affected products may be in the possession of the consumer.

The procedure(s) shall include:

- Notification to relevant interested parties (e.g. competent²¹ authorities, customers and/or consumers) of the reason for its withdrawal/recall, the action taken to prevent risks to the final consumer, and if necessary, any actions that the consumer should take;
- Handling of withdrawn/recalled products as well as affected lots of the products still in stock;
- The sequence of actions to be taken.

A procedure for handling unsafe products which are the subject of the withdrawal/recall shall also be in place. The procedure must ensure that products withdrawn/recalled from sources beyond the control of the organisation (e.g. distributors, wholesalers, retailers, and consumers) do not accidentally re-enter the food chain and do not contaminate other foods during handling.

Withdrawn/recalled products shall be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or some other) intended use, or reprocessed in a manner to ensure they become safe.

The cause, extent and result of a withdrawal shall be recorded.

The organisation shall verify and record the effectiveness of the withdrawal/recall procedure through the use of appropriate techniques (e.g. mock withdrawal/recall or practice withdrawal/recall).

The withdrawal/recall procedure shall be reviewed regularly to check whether there is need for revision in the light of changes in circumstances of the responsible person.

²¹ In the case of a recall, this shall be done immediately. In the case of a withdrawal, it is for competent authorities in individual Member States to determine what methods of notification are appropriate (e.g. upon request, as part of an audit, or specific communication)

7.4. DOCUMENTATION

Documents:

- Withdrawal/recall procedure;
- Procedure for handling unsafe products.

Records:

- Deviation report for each incident of a potentially unsafe product that includes:
 - Time and nature of deviation;
 - Affected lots;
 - Result of evaluation (if any);
 - Rationale for release, including evidence, or alternative use or disposal;
 - Decision of fate of the lot;(See example in [Annex IV](#))
- The cause, extent and result of a withdrawal/recall;
- Results of verification of the effectiveness of the withdrawal/recall programme.

8. VERIFICATION (PRINCIPLE 6)

8.1. GENERAL

Several levels of checking activities are needed to assure food safety and build trust in the manufacturer's performance:

- Verification that the operations and the system are functioning correctly;
- Evaluation of trends that can lead to problems or which may indicate problems that are not detected by the existing set-up.

The following shall be verified but not necessarily all at the same time:

- That the site, buildings, equipment and facilities are in good repair;
- That the traceability system delivers the required level of traceability;
- That the PRP(s) are implemented;
- That the elements of the HACCP plan are implemented and effective; the elements are the control measures, the corresponding monitoring procedures, and the corrective actions.
- That hazard levels are within identified acceptable levels;
- That the withdrawal/recall procedure is effective (e.g. mock withdrawal/recall)

A verification plan shall be developed that identifies the following:

- Verification activity;
- Purpose;
- Verification method;
- Frequency;
- Responsibility;
- Reporting requirements;

Verification shall be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in-house, verification shall be performed on behalf of the business by external experts or qualified third parties.

Examples of verification methods are:

- internal audit;
- visual site inspection;
- environmental monitoring;
- microbiological testing of surfaces and products (raw materials, finished products);
- review of monitoring records including trend analysis.

The frequency of verification depends on the degree of uncertainty in the effect of the object to verification. Such consideration shall be taken into account in regard of:

- The uncertainty in the effect of a control measure applied relative to the predetermined performance (e.g. log reduction of a pathogen);
- The uncertainty in the effect of the key control measures applied relative to the determined acceptable level(s) of food safety hazard(s);
- The uncertainty in monitoring, i.e. ability of the monitoring procedures to detect loss of control.

Where knowledge of the effect against hazards is lacking or insignificant, documentation of the food safety outcome may depend on verification, which therefore needs to be carried out at relatively high frequency.

8.2. INTERNAL AUDIT

Internal audits shall be conducted at planned intervals to determine whether the management system adheres to the plans and is effectively implemented and updated.

The audit scope, frequency and methods shall be defined. Auditors shall be objective and impartial and shall not audit their own work.

The person responsible for the area being audited shall ensure that any detected nonconformities are followed up without undue delay. Follow-up activities shall include the verification of the actions taken and the reporting of the verification results.

8.3. ENVIRONMENTAL MONITORING

An environmental monitoring programme for *Salmonella* and *L. monocytogenes* is required in packaging areas where products are exposed to the environment after the heat treatment. *Salmonella* may be replaced by *Enterobacteriaceae*.

Appropriate sampling locations can be based on either experience or in-plant surveys. Sampling locations shall be reviewed on a regular basis. Additional locations may need to be sampled depending on special situations such as major maintenance or construction or when new or modified equipment has been installed.

The type of sampling tools and techniques shall be adapted to the type of surfaces and sampling locations. For example, sponges may be used for large flat surfaces, swabs may be more appropriate for cracks and crevices or scrapers for hard residues. Vacuum cleaner sampling may be useful in dry areas. Also, air precipitation samples may be useful.

Results of environmental monitoring shall not be assessed individually but as trends.

8.4. VERIFICATION OF THE HACCP PLAN

The verification of the HACCP plan shall confirm that the elements are implemented and effective, i.e. that hazard levels are in control.

Monitoring results shall be frequently reviewed. Unexplained patterns in monitoring results may indicate that PRPs and other preventive measures (e.g. equipment, the behaviour of the operator, the efficacy of previous corrective measures, etc.) need to be reviewed.

8.5. VERIFICATION OF FINISHED PRODUCT

In order to ensure the manufacturing process continuously delivers finished products in compliance with the specification, an appropriate quality control plan shall be set and implemented. The quality control plan shall include quality checks of critical parameters to be performed, either along the production lines and or on the finished product, to assess its conformity to the requirements at the final stage.

It is advisable to at least determine dry matter, fat content and pH of finished products. Organoleptic aspects such as appearance, structure, taste and odour shall be monitored according to specifications. Organoleptic evaluation can be taught to everyone assessing product quality. At least a basic taste test shall be passed by a person assessing the quality.

A procedure of control of finished product shall be in place to ensure that finished product is delivered to the market only after passing all quality checks prescribed in the quality control plan.

8.6. CONTROL OF MONITORING AND MEASURING

Thermometers shall be checked against a traceable reference thermometer. Electronic thermometers can be adjusted, whilst mercury thermometers shall be labelled with the deviation from the reference. It may be sufficient to calibrate annually or biannually.

Metal detection units can be verified or calibrated by the use of metal controls with a known topography/mass/iron content and adjusted on site. The frequency of verification/calibration can be substantially higher than for thermometers due to unit stability and changes in the monitored product (e.g. moisture content).

9. REFERENCES

9.1 Legislation

Note: It is always the most recent (consolidated) versions that apply.

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules on the hygiene of foodstuffs

Regulation (EC) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004

Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs

Regulation (EU) 396/2005 of 23 February 2005, on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

Commission Regulation (EC) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin

Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006

9.2 Other

EC (2003): Opinion of the Scientific Committee on Veterinary Measures relating to Public Health on Staphylococcal Enterotoxins in Milk Products, particularly Cheeses (adopted on 26-27 March 2003)

EFSA (2004a): *Campylobacter* in animals and foodstuffs. The EFSA Journal 177, 1-104;

EFSA (2004b): *Clostridium* spp in foodstuffs. The EFSA Journal 199, 1-65;

FAO/WHO (2004): Risk assessment of *Listeria monocytogenes* in ready-to-eat foods: technical report. (Microbiological risk assessment series no. 5). ISBN 92 4 156262 5);

FDA: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook (the “Bad Bug Book”). U.S. Food & Drug Administration, Center for Food Safety & Applied Nutrition

FSANZ (2006): A Risk Profile of Dairy Products in Australia. Food Standards Australia New Zealand;

ILSI (2001): Approach to the control of Entero-haemorrhagic *Escherichia coli* (EHEC). ILSI Europe Report Series. International Life Sciences Institutes. ISBN 1-57881-119-8);

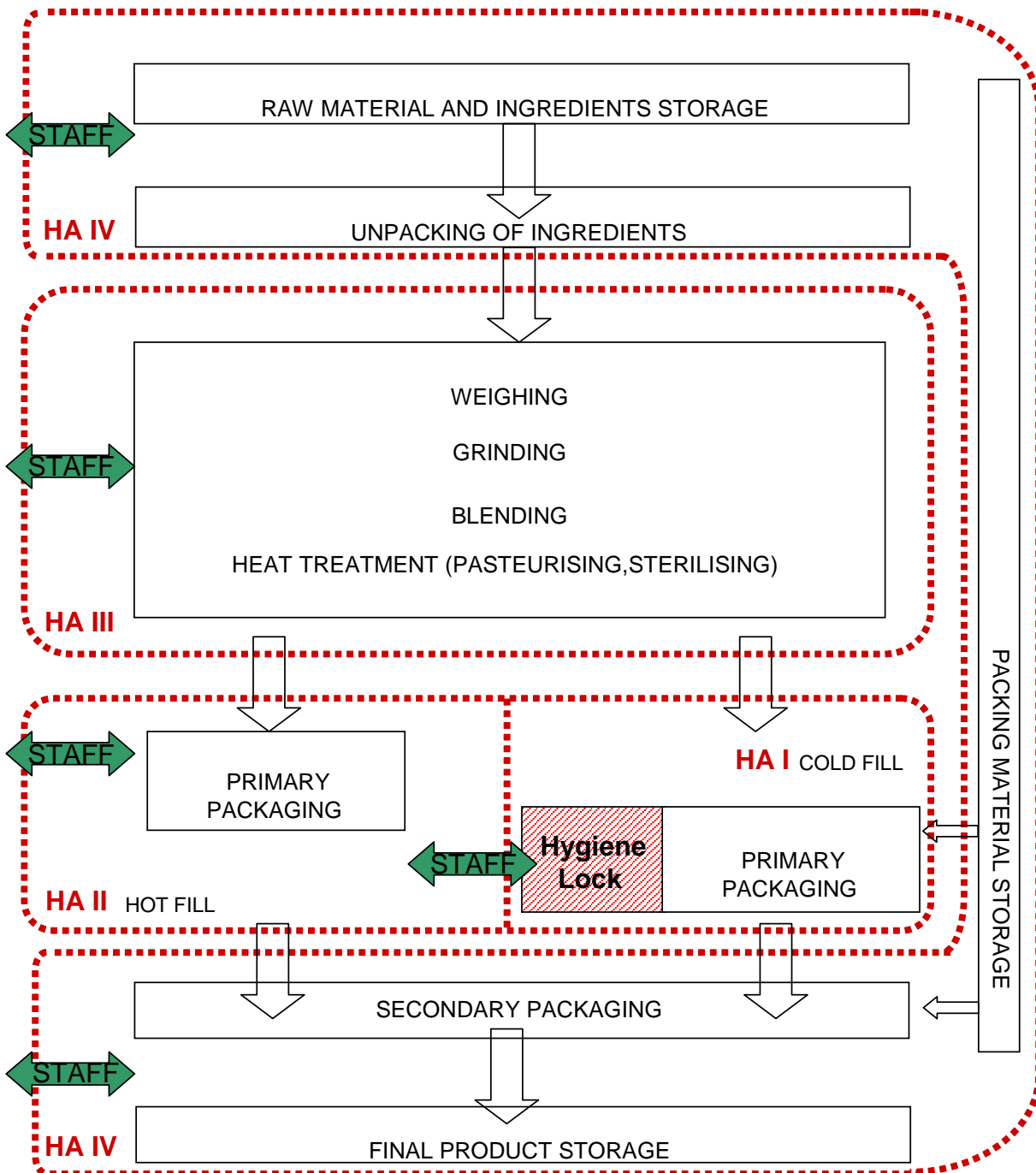
Lahti (2003): Cattle and reindeer as possible sources of *Escherichia Coli* O157 infection in humans. Academic dissertation to be presented with the permission of the Faculty of Veterinary Medicine, University of Helsinki for public criticism, Helsinki October 7th, 2003.

Tilden et al (1996): A new route of transmission for *Escherichia coli*: infection from dry fermented salami. Am. J. Public Health, 86: 1142-1145;

WHO-ICD (2000): Foodborne disease profiles. Appendix 11 to WHO/ICD training manual “Food Safety for Nutritionists and other Health Professionals.

ANNEX I:

Layout of Processed Cheese Plant



HA (HYGIENE AREA) I – area, where products are very likely to support growth if contaminated. Special conditions for air filtration, staff access procedure and packaging material supply.

HA II – area, where products are not very likely to support growth if contaminated because of temperature.

HA III – area, where products are very likely to support growth if contaminated but pasteurisation steps follows.

HA IV - area, where products have a low risk of contamination (packed goods).

ANNEX II: DEVELOPING A MODEL HACCP PLAN

The information in this Annex is for training purposes, only. It is intended for HACCP team members responsible for conducting a plan-product specific hazard analysis and for establishing the corresponding HACCP Plan.

Hazard analysis (see section 6.3)

Step/ingredient	Hazard(s)	Hazard assessment	Key PRPs in place	Need for control by HACCP plan?																
Raw materials																				
Cheese suitable for direct consumption	<u>Biological:</u> L. monocytogenes VTEC ²² S. aureus Salmonella	<p>In <u>firm and hard cheeses and some fresh cheeses</u>, these pathogens do not grow.</p> <table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Occasional</td> </tr> <tr> <td>Expected levels:</td> <td>Very low</td> </tr> <tr> <td>Severity of adverse effect:</td> <td>Very serious</td> </tr> </table> <p>In <u>other fresh cheese (pH>5)</u>, growth can occur, if temperature and shelf life specifications are not respected.</p> <table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Occasional</td> </tr> <tr> <td>Expected levels:</td> <td>Moderate</td> </tr> <tr> <td>Severity of adverse effect:</td> <td>Very serious</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Occasional	Expected levels:	Very low	Severity of adverse effect:	Very serious	If no control was in place:		Probability of occurrence:	Occasional	Expected levels:	Moderate	Severity of adverse effect:	Very serious	Partly controlled by selection and management of suppliers, specifications for and inspection of purchased material, and handling and storage conditions (see 5.9.1), and by traceability (see 4.2).	Yes, reduction of levels and control of growth of any surviving organisms
If no control was in place:																				
Probability of occurrence:	Occasional																			
Expected levels:	Very low																			
Severity of adverse effect:	Very serious																			
If no control was in place:																				
Probability of occurrence:	Occasional																			
Expected levels:	Moderate																			
Severity of adverse effect:	Very serious																			
Cheese material intended for further processing only	<u>Physical:</u> Fragments of metal, hard plastic and glass <u>Chemical:</u> Drug and pesticide residues, heavy metals <u>Biological:</u> Pathogens, bacterial toxins, mycotoxins, mites and vermin	See EDA/EUCOLAIT Guidance on Cheese as Raw Material	Partly controlled by selection and management of suppliers, specifications for and inspection of purchased material, and handling and storage conditions (see 5.9.1), and by traceability (see 4.2).	Yes, see EDA/EUCOLAIT Guidance on Cheese as Raw Material																

²² Verotoxin producing Escherichia coli



Step/ingredient	Hazard(s)	Hazard assessment	Key PRPs in place	Need for control by HACCP plan?								
Dried dairy products (milk powder, whey powder, dried whey protein concentrates)	<u>Biological:</u> Salmonella	No growth occurs. <table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Seldom</td> </tr> <tr> <td>Expected levels:</td> <td>Very low</td> </tr> <tr> <td>Severity of adverse effect:</td> <td>Serious</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels:	Very low	Severity of adverse effect:	Serious	Controlled by selection and management of suppliers, specifications for and inspection of purchased material, and handling and storage conditions (see 5.9.1), and by traceability (see 4.2).	No
If no control was in place:												
Probability of occurrence:	Seldom											
Expected levels:	Very low											
Severity of adverse effect:	Serious											
Liquid dairy products (aw >0.92)	<u>Biological:</u> L. monocytogenes	Growth can occur, if temperature and shelf life specifications are not respected. <table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Seldom</td> </tr> <tr> <td>Expected levels:</td> <td>Low</td> </tr> <tr> <td>Severity of adverse effect:</td> <td>Very serious</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels:	Low	Severity of adverse effect:	Very serious	Partly controlled by selection and management of suppliers, specifications for and inspection of purchased material, and handling and storage conditions (see 5.9.1), and by traceability (see 4.2).	Yes, reduction of levels and control of growth of any surviving organisms
If no control was in place:												
Probability of occurrence:	Seldom											
Expected levels:	Low											
Severity of adverse effect:	Very serious											
Ingredients												
Vegetable oils and milk fat products	<u>Chemical:</u> Lead Certain pesticide residues Dioxins PCBs	Fatty food may contain detectable levels of originating from certain geographical areas <table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Seldom</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>Low</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Serious</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels, if occurrence:	Low	Severity, if not controlled	Serious	Controlled by specifications adapted to the origin of materials and inspection of purchased materials (see 5.9.1), and by traceability (see 4.2).	No, the PRPs are sufficiently effective to prevent unacceptable levels in the food
If no control was in place:												
Probability of occurrence:	Seldom											
Expected levels, if occurrence:	Low											
Severity, if not controlled	Serious											
Starches	<u>Biological:</u> Salmonella Thermophilic spores	<table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Occasional</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>Very low</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Serious</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Occasional	Expected levels, if occurrence:	Very low	Severity, if not controlled	Serious	Partly controlled by selection and management of suppliers, specifications for and inspection of purchased material, and handling and storage conditions (see 5.9.1), and by traceability (see 4.2).	Yes, reduction of levels and control of growth of any surviving organisms/spores
If no control was in place:												
Probability of occurrence:	Occasional											
Expected levels, if occurrence:	Very low											
Severity, if not controlled	Serious											
Spices (untreated) and dried herbs	<u>Biological:</u> Salmonella Spores of Cl. perfringens, Cl. botulinum and/or B. cereus.	<table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Often</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>Low</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Very serious</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Often	Expected levels, if occurrence:	Low	Severity, if not controlled	Very serious	Partly controlled by selection and management of suppliers, specifications for and inspection of purchased material, and handling and storage conditions (see 5.9.1), and by traceability (see 4.2).	Yes, reduction of levels and control of growth of any surviving organisms/spores
If no control was in place:												
Probability of occurrence:	Often											
Expected levels, if occurrence:	Low											
Severity, if not controlled	Very serious											
Spices, herbs and similar ingredients (harvested)	<u>Physical:</u> Small stones	<table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Occasional</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>High</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Mild</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Occasional	Expected levels, if occurrence:	High	Severity, if not controlled	Mild	Controlled by selection and management of suppliers, specifications for and inspection of purchased material (see 5.9.1), any pre-filtration steps prior to reception and by traceability (see 4.2).	No, the PRPs are sufficiently effective to prevent contamination of food
If no control was in place:												
Probability of occurrence:	Occasional											
Expected levels, if occurrence:	High											
Severity, if not controlled	Mild											



Step/ingredient	Hazard(s)	Hazard assessment	Key PRPs in place	Need for control by HACCP plan?								
Additives	Biological: Allergens	Certain additives may contain allergens <table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Occasional</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>High</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Mild</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Occasional	Expected levels, if occurrence:	High	Severity, if not controlled	Mild	Controlled by specifications for purchased material (see 5.9.1.3), and by traceability (see 4.2).	No, the PRPs are sufficiently effective to prevent unacceptable levels in the food
If no control was in place:												
Probability of occurrence:	Occasional											
Expected levels, if occurrence:	High											
Severity, if not controlled	Mild											
Grinding and mixing												
Processing equipment	Physical: Metal fragments	<table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Seldom</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>High</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Mild</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels, if occurrence:	High	Severity, if not controlled	Mild	Partly controlled by proper design (see 4.1.5.1) adequate maintenance of equipment (see 5.1) and prevention of foreign material (see 5.5).	Yes, removal of fragments of hazardous size
	If no control was in place:											
Probability of occurrence:	Seldom											
Expected levels, if occurrence:	High											
Severity, if not controlled	Mild											
	Chemical: Residues of sanitisers	<table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Seldom</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>High</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Mild</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels, if occurrence:	High	Severity, if not controlled	Mild	Controlled by designing and following the cleaning procedures (see 5.7.1).	No, the PRPs are sufficiently effective to prevent contamination of the food
If no control was in place:												
Probability of occurrence:	Seldom											
Expected levels, if occurrence:	High											
Severity, if not controlled	Mild											
Process environment	Physical: Fragments (metal, plastic)	<table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Seldom</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>High</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Mild</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels, if occurrence:	High	Severity, if not controlled	Mild	Partly controlled by proper maintenance of processing environment (see 5.1) and prevention of foreign material (see 5.5).	Yes, removal of fragments of hazardous size
If no control was in place:												
Probability of occurrence:	Seldom											
Expected levels, if occurrence:	High											
Severity, if not controlled	Mild											
Staff	Biological: Zoonoses	<table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Seldom</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>Low</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Serious</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels, if occurrence:	Low	Severity, if not controlled	Serious	Controlled by personnel health and hygiene procedures (see 5.8) and training (see 4.4).	No, the PRPs are sufficiently effective to prevent contamination of the food
If no control was in place:												
Probability of occurrence:	Seldom											
Expected levels, if occurrence:	Low											
Severity, if not controlled	Serious											



Step/ingredient	Hazard(s)	Hazard assessment	Key PRPs in place	Need for control by HACCP plan?								
Heating												
Processing equipment	Physical: Metal fragments	<table border="1"> <tr><td colspan="2">If no control was in place:</td></tr> <tr><td>Probability of occurrence:</td><td>Seldom</td></tr> <tr><td>Expected levels, if occurrence:</td><td>High</td></tr> <tr><td>Severity, if not controlled</td><td>Mild</td></tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels, if occurrence:	High	Severity, if not controlled	Mild	Partly controlled by proper design (see 4.1.5.1) and adequate maintenance of equipment (see 5.1)	Yes, removal of fragments of hazardous size
	If no control was in place:											
	Probability of occurrence:	Seldom										
Expected levels, if occurrence:	High											
Severity, if not controlled	Mild											
Chemical: Residues of sanitisers	<table border="1"> <tr><td colspan="2">If no control was in place:</td></tr> <tr><td>Probability of occurrence:</td><td>Seldom</td></tr> <tr><td>Expected levels, if occurrence:</td><td>High</td></tr> <tr><td>Severity, if not controlled</td><td>Mild</td></tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels, if occurrence:	High	Severity, if not controlled	Mild	Controlled by designing and following the cleaning procedures (see 5.7.1).	No, the PRPs are sufficiently effective to prevent contamination of the food	
If no control was in place:												
Probability of occurrence:	Seldom											
Expected levels, if occurrence:	High											
Severity, if not controlled	Mild											
Thermotolerant bacteria such as B. cereus	<p>May contaminate from generated biofilm</p> <table border="1"> <tr><td colspan="2">If no control was in place:</td></tr> <tr><td>Probability of occurrence:</td><td>Occasional</td></tr> <tr><td>Expected levels, if occurrence:</td><td>Low</td></tr> <tr><td>Severity, if not controlled</td><td>Moderate</td></tr> </table>	If no control was in place:		Probability of occurrence:	Occasional	Expected levels, if occurrence:	Low	Severity, if not controlled	Moderate	Controlled by designing and following the cleaning procedures (see 5.7.1).	No, the PRPs are sufficiently effective to prevent contamination of the food	
If no control was in place:												
Probability of occurrence:	Occasional											
Expected levels, if occurrence:	Low											
Severity, if not controlled	Moderate											
Filling/packaging												
Filling equipment	Physical: Metal fragments	<table border="1"> <tr><td colspan="2">If no control was in place:</td></tr> <tr><td>Probability of occurrence:</td><td>Seldom</td></tr> <tr><td>Expected levels, if occurrence:</td><td>High</td></tr> <tr><td>Severity, if not controlled</td><td>Mild</td></tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels, if occurrence:	High	Severity, if not controlled	Mild	Partly controlled by proper design (see 4.1.5.1) adequate maintenance of equipment (see 5.1) and prevention of foreign material (see 5.5).	Yes, removal of packaged units containing fragments of hazardous size
	If no control was in place:											
	Probability of occurrence:	Seldom										
Expected levels, if occurrence:	High											
Severity, if not controlled	Mild											
Chemical: Residues of sanitisers	<table border="1"> <tr><td colspan="2">If no control was in place:</td></tr> <tr><td>Probability of occurrence:</td><td>Seldom</td></tr> <tr><td>Expected levels, if occurrence:</td><td>High</td></tr> <tr><td>Severity, if not controlled</td><td>Mild</td></tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels, if occurrence:	High	Severity, if not controlled	Mild	Controlled by designing and following the cleaning procedures (see 5.7.1).	No, the PRPs are sufficiently effective to prevent contamination of the food	
If no control was in place:												
Probability of occurrence:	Seldom											
Expected levels, if occurrence:	High											
Severity, if not controlled	Mild											
Allergenic lubricants	<table border="1"> <tr><td colspan="2">If no control was in place:</td></tr> <tr><td>Probability of occurrence:</td><td>Seldom</td></tr> <tr><td>Expected levels, if occurrence:</td><td>Moderate</td></tr> <tr><td>Severity, if not controlled</td><td>Moderate</td></tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels, if occurrence:	Moderate	Severity, if not controlled	Moderate	Controlled by prevention of foreign material (see 5.5) and limiting oil from compressed air and gas (see 5.3.6).	No, the PRPs are sufficiently effective to prevent contamination of the food	
If no control was in place:												
Probability of occurrence:	Seldom											
Expected levels, if occurrence:	Moderate											
Severity, if not controlled	Moderate											



Step/ingredient	Hazard(s)	Hazard assessment	Key PRPs in place	Need for control by HACCP plan?								
	<i>S. aureus</i> and/or <i>L. monocytogenes</i>	May contaminate from biofilm in pipes, valves etc. <table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Occasional</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>Low</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Very serious</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Occasional	Expected levels, if occurrence:	Low	Severity, if not controlled	Very serious	Controlled by designing and following the cleaning procedures (see 5.7.1).	No, the PRPs are sufficiently effective to prevent contamination of the food
If no control was in place:												
Probability of occurrence:	Occasional											
Expected levels, if occurrence:	Low											
Severity, if not controlled	Very serious											
Packaging environment.	Wood fragments	From handling of wooden pallets. <table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Occasional</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>High</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Mild</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Occasional	Expected levels, if occurrence:	High	Severity, if not controlled	Mild	Controlled by designing and following the floor cleaning procedures (see 5.7.1) and prevention of foreign material (see 5.5).	No, the PRPs are sufficiently effective to prevent contamination of the food
	If no control was in place:											
	Probability of occurrence:	Occasional										
Expected levels, if occurrence:	High											
Severity, if not controlled	Mild											
Salmonella	<table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Occasional</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>Low</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Very serious</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Occasional	Expected levels, if occurrence:	Low	Severity, if not controlled	Very serious	Controlled by proper layout and design of premises (see 4.1.3 and 4.1.4), maintenance of packaging environment (see 5.1), establishing and maintaining adequate ventilation (see 5.3.4), designing and following the cleaning procedures for ventilation ducts and similar places (see 5.7.1), and filtration of the air supply to cold fill lines (see 5.3.3).	No, the PRPs are sufficiently effective to prevent contamination of the food	
If no control was in place:												
Probability of occurrence:	Occasional											
Expected levels, if occurrence:	Low											
Severity, if not controlled	Very serious											
Mycotoxin forming moulds	<table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Occasional</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>Low</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Moderate</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Occasional	Expected levels, if occurrence:	Low	Severity, if not controlled	Moderate	No, the PRPs are sufficiently effective to prevent contamination of the food		
If no control was in place:												
Probability of occurrence:	Occasional											
Expected levels, if occurrence:	Low											
Severity, if not controlled	Moderate											
Packaging material	<u>Chemical:</u> Acrylamides Print colours	<table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Occasional</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>Low</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Moderate</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Occasional	Expected levels, if occurrence:	Low	Severity, if not controlled	Moderate	Controlled by selection and management of suppliers, specifications for and inspection of purchased material (see 5.9.1), and by traceability (see 4.2).	No, the PRPs are sufficiently effective to prevent contamination of the food
If no control was in place:												
Probability of occurrence:	Occasional											
Expected levels, if occurrence:	Low											
Severity, if not controlled	Moderate											
Staff	<u>Biological:</u> Zoonoses	<table border="1"> <tr> <td colspan="2">If no control was in place:</td> </tr> <tr> <td>Probability of occurrence:</td> <td>Seldom</td> </tr> <tr> <td>Expected levels, if occurrence:</td> <td>Low</td> </tr> <tr> <td>Severity, if not controlled</td> <td>Serious</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Seldom	Expected levels, if occurrence:	Low	Severity, if not controlled	Serious	Controlled by personnel health and hygiene procedures (see 5.8) and training (see 4.4).	No, the PRPs are sufficiently effective to prevent contamination of the food
If no control was in place:												
Probability of occurrence:	Seldom											
Expected levels, if occurrence:	Low											
Severity, if not controlled	Serious											



Step/ingredient	Hazard(s)	Hazard assessment	Key PRPs in place	Need for control by HACCP plan?								
End products												
Storage of end products	<i>S. aureus</i> <i>L. monocytogenes</i> Salmonella spp. <i>Cl. perfringens</i> <i>Cl. botulinum</i>	Growth to unacceptable levels. <table border="1" data-bbox="763 384 1332 539"> <tr> <th colspan="2" data-bbox="763 384 1332 427">If no control was in place:</th> </tr> <tr> <td data-bbox="763 427 1144 464">Probability of occurrence:</td> <td data-bbox="1144 427 1332 464">Occasional</td> </tr> <tr> <td data-bbox="763 464 1144 501">Expected levels, if occurrence:</td> <td data-bbox="1144 464 1332 501">Moderate</td> </tr> <tr> <td data-bbox="763 501 1144 539">Severity, if not controlled</td> <td data-bbox="1144 501 1332 539">Very serious</td> </tr> </table>	If no control was in place:		Probability of occurrence:	Occasional	Expected levels, if occurrence:	Moderate	Severity, if not controlled	Very serious	Partly controlled by lot identification (see 5.10.1), traceability (see 4.2), controlled storage and warehousing (see 5.11), and finished product specification document (see 5.12)	Yes, storage instructions in the label (temperature and shelf life) that ensure that these organisms do not grow to unacceptable levels. Where required, instructions of use.
If no control was in place:												
Probability of occurrence:	Occasional											
Expected levels, if occurrence:	Moderate											
Severity, if not controlled	Very serious											

The hazard assessment above demonstrates that additional control that is capable of preventing, eliminating or reducing certain hazards to acceptable levels is required for the following and are to be managed by the HACCP plan:

- Microbiocidal treatment(s) to reduce:
 - The low levels of *L. monocytogenes*, verotoxin producing Escherichia coli (VTEC), *S. aureus* and Salmonella from cheese;
 - The very low levels of *L. monocytogenes* from liquid dairy products ($a_w > 0.92$);
 - The low levels of Salmonella, *Cl. perfringens*, *Cl. botulinum* and/or *B. cereus* from spices (untreated) and dried herbs;
 - The very low levels of Salmonella and thermophilic spores in starches.
- Control measures to detect metal fragments from processing equipment and process environment that may accidentally contaminate the food;
- Control measures to control growth of any *S. aureus*, *L. monocytogenes* Salmonella, *Cl. perfringens*, and/or *Cl. botulinum* in the end product during shelf life.

Establishing the HACCP plan (see section 6.4)

Microbiocidal heat treatments

The following data are summarised in [Annex III](#):

- D-values for the relevant pathogens under heat treatment conditions relevant for assessing the effect on processed cheese;
- Relationship between the D-values and processing temperature for each pathogen.

From this information, the following is concluded:

- Keeping the processed cheese mass hot in buffer tanks, e.g. at 90 °C with a declining temperature during at least 30 min and with a filling temperature of at least 60 °C, will alone be much more than sufficient to eliminate any *Listeria*, *E. coli* and *Salmonella* that may be present in the product. However, the effect against spores of *B. cereus* and *C. botulinum* is insignificant;
- A specific heat treatment is required to control *B. cereus* and *C. botulinum*;
- Such heat treatment will also be required to control *Listeria*, *E. coli* and *Salmonella* where hot buffer storage is not included.

Critical limits: The following time-temperature combinations (critical limits) will guarantee a safe food (6 log kill):

6 log reductions	80 °C	90 °C	98°C	106 °C	110 °C	130 °C	135 °C
<i>L. monocytogenes</i>	0.31 s	<0.01 s					
<i>Salmonella</i>	29 s	6.3 s	1.9 s	0.5 s	0.3 s	0.01 s	<0.01 s
<i>E. coli</i>	0.14 s	<0.01 s					
<i>B. cereus</i>	38 h	266 min	47 min	8.4 min	3,5 min	2.9 s	1.0 s
<i>C. botulinum</i>	8.4 h	43 min	6 min	50 s	18.8 s	0.14 s	0.04 s

However, in many cases, a log kill lower than 6 will be sufficient to obtain a safe food. The use of lower log kills (shorter holding times) than provided above shall be documented.

Monitoring: The time and temperature shall be monitored, preferably on a continuous basis and in particular if safety margins beyond normal process variation are built into the critical limits. Calibration of temperature measuring instruments, such as thermometers, critical for food safety shall be calibrated prior to first use, and at

specified intervals thereafter, against measurement standards traceable to international or national measurement standards. Such calibration shall be carried out in accordance with a written protocol, and records should be retained for internal **(by a trained person only)** and external audit verification.

Corrective actions: Product rework and the restoration of treatment conditions (e.g. adjustment of flow, steam feed, etc, as appropriate to the system).

Control measures to detect metal fragments

In-line filters

The 200-800 µm filters used to separate any solid cheese, burnt particles, and calcium-lactate crystals from molten cheese blend shall be designed and operated to remove foreign bodies, including physical hazards.

Critical limits: The size of the filter (critical limit) depends on the viscosity of the molten cheese blend and the pressure created by the feeding pump.

Monitoring: (Automatic) removal of the foreign matter.

Corrective actions: Identification of the origin of removed foreign matter. Conduct a thorough analysis to establish the cause/source of the problem, why it occurred, and to put in place identified necessary corrective actions to eliminate or reduce the likelihood of a recurrence of the problem, such as pre-production inspections of the integrity of in-line filters.

Metal or hard material detection

Metal or hard material detection shall be carried out on packaged end products.

Critical limits: Typically 5 mm.

Monitoring: Checking of each primary packaging. The detector shall be calibrated using specified material and size of test bodies.

Corrective actions: Rejection of the package in question and handling it as a non-conforming product. Identification of the cause (origin of fragment). If origination from steps prior to the filter system, the reason why the filter system did not remove the fragment shall be investigated.

Consideration of actions to prevent or minimise further fragments from the source.

Control measures to control microbial growth in the end product during shelf life

Hot filled processed cheese that has been heat treated according to section **6.4.1.1**, i microbiologically shelf stable. Shelf life is determined by organoleptic quality factors and not by microbiology.

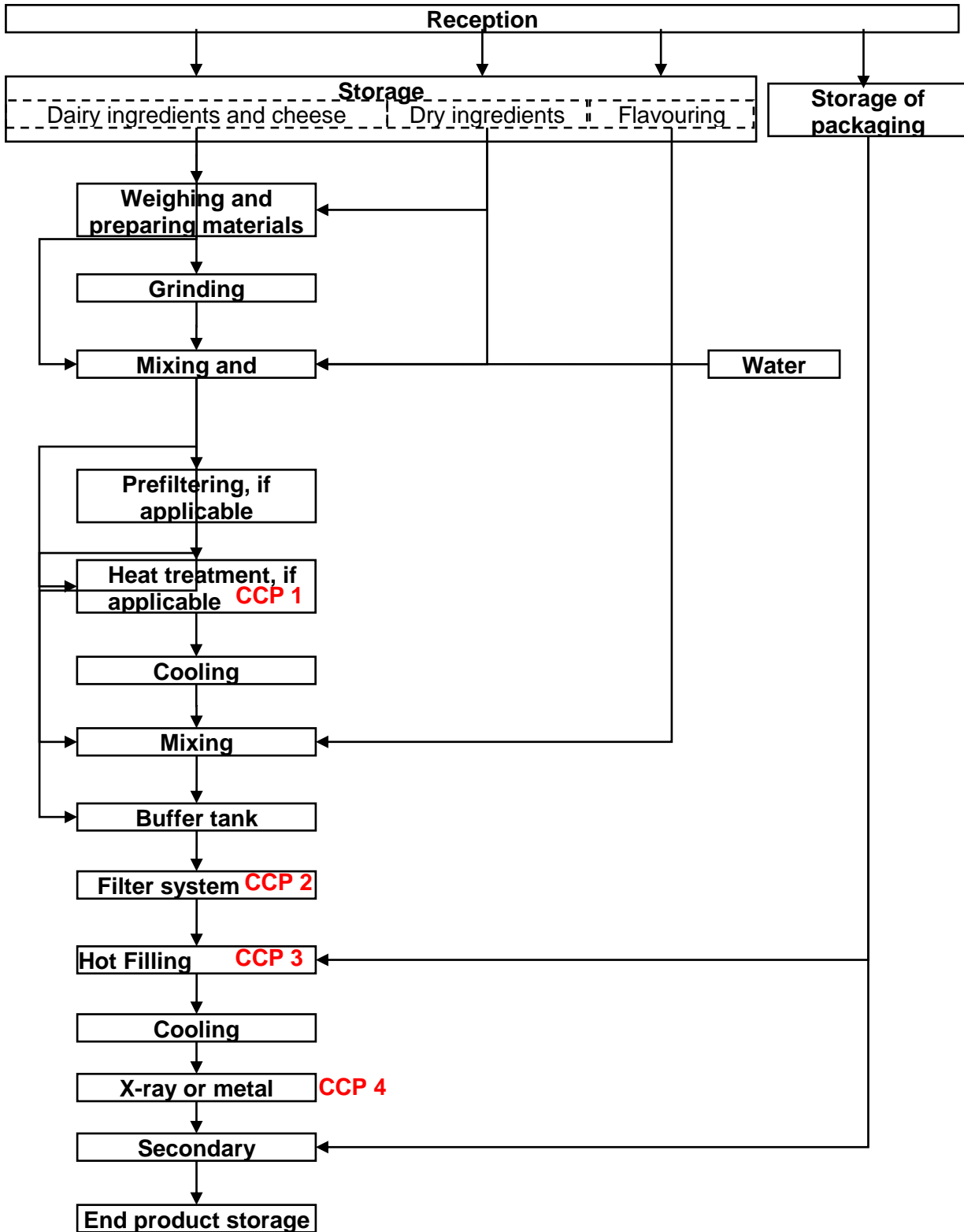
Appropriate storage temperatures and corresponding microbial shelf life shall be determined for cold filled products and labelled.

Critical limits: Correctly labelled storage temperature and shelf life.

Monitoring: Checking of each new packaging used.

Corrective actions: Rejection of the packaging material in question.

MODEL HACCP PLAN



HACCP plan for PC formula X, process line Y

Step	CCP No.	Targeted hazards	Control measure(s)	Parameter	Critical limit	Monitoring procedure				Corrective action(s)	
						Frequency	Responsible	Documentation	Verification	What to do	Responsible
After mixing, prior to filling	1	<i>B. cereus</i> <i>Cl. botulinum</i>	1 st heat treatment	Time	xx min	Continuously	Operator	Electronically	-	Rework Restore treatment conditions	Process manager
				Temperature	xx °C				Calibration protocol		
Prior to filling	2	Physical hazards	Filtering	Filter size	xx mm	Continuously	Operator	-	The integrity of all in-line filter(s) prior to the start-up of each production run	Removal of hazards	Process manager
Hot filling	3	Salmonella <i>L. monocytogenes</i> VTEC ²³	2 nd heat treatment	Time	30 min	Continuously or every 10 min	Operator	Log report	-	Prolong holding time	Process manager
				Temperature	60 °C				Calibration protocol	Rework	
		Any surviving pathogens	Labelling	Temperature	xx °C	Every packaging change	Operator	n.a.	n.a.	Rejection of packaging material	Packaging manager
				Time	xx months						
Prior to secondary packaging	4	Physical hazards	X-ray detector	Fragment size	5 mm	Every packaging	Operator	Log report	Calibration protocol	Rejection	Packaging manager
		Metal objects	Metal detector						Calibration protocol		

²³ Verotoxin producing *Escherichia coli*

ANNEX III: DATA ON EFFECT OF HEAT TREATMENT OF PROCESSED CHEESE

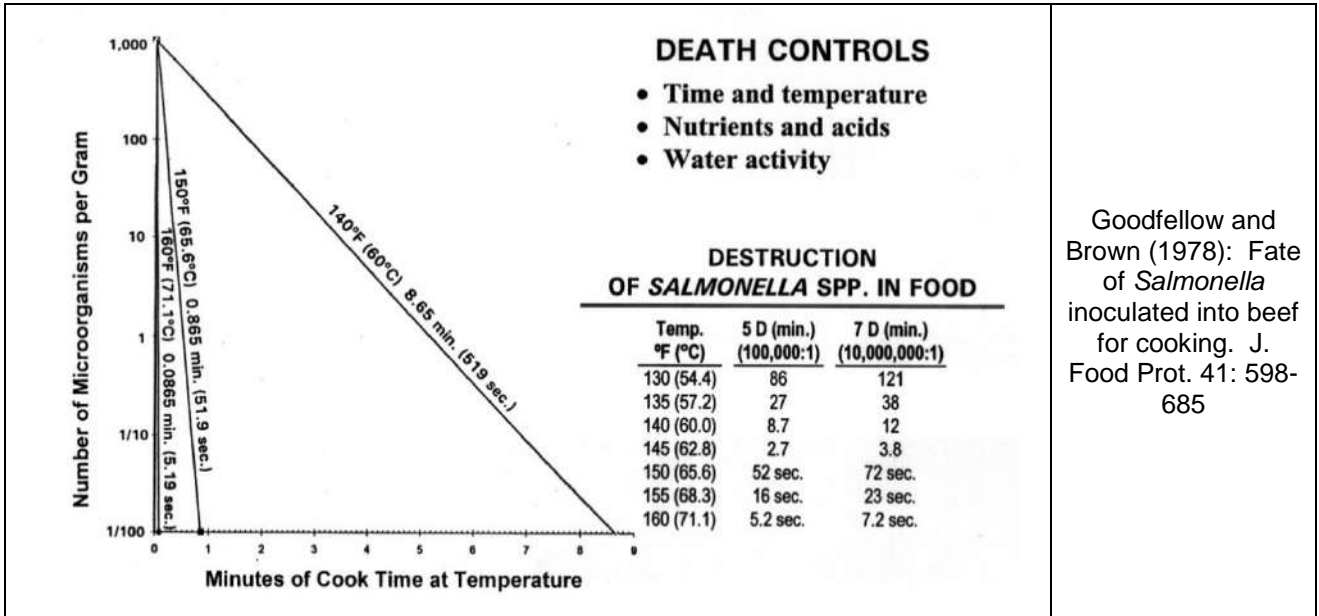
D-values for relevant pathogens under relevant processed cheese conditions

<i>Listeria monocytogenes</i>				
	Temperature °C	D-value (sec)	z-value °C	Reference
Broth with pH 5.4, 3% salt	60	108		ComBase Predictor
	64	36		
	68	8.1		
Broth with pH 5.8, 2% salt	60	98		ComBase Predictor
	64	26		
	68	7,2		
Cream	52.2	1710	6.76	ComBase
	57.8	238.2		
	63.3	30.6		
	66.1	14.6		
	68.9	6		
Cream 55%	52	3484; 4303	5.83; 6.08	Casadei et al (1998): Heat resistance of Lm in dairy products as affected by the growth medium. J Appl Micro 84, 234-239
	56	364; 513		
	60	38.9; 60.9		
	64	12.7; 20.5		
	68	7.86; 9.46		
Miscellaneous liquids, pH 6-8 based on 474 experimentally determined D-values	50	4766		Sörqvist (2003): Heat Resistance in Liquids of Enterococcus spp., Listeria spp., Escherichia coli, Yersinia enterocolitica, Salmonella spp. and Campylobacter spp.. Acta vet. Scand. 2003, 44, 1-19
	55	643		
	60	86.7		
	65	11.7		
	70	1.58		
	80	0.029		

<i>Bacillus cereus</i>				
	Temperature °C	D-value (min)	z-value °C	Reference
Broth with pH 5.4, 3% salt	90	45		ComBase Predictor
	95	10.8		
	100	5.4		
Broth with pH 5.8, 2% salt	90	56		ComBase Predictor
	95	13.2		
	100	6.0		
Ice cream	100	2,4-5,4		Wong et al (1988): Incidences and characteristics of Bacillus cereus isolates contaminating dairy products. Appl. Env. Microbiol. 54(3), 699-702
Spores				
Citrate/phosphate buffer, (pH 4.5-6.5, aw 0.80-1)	85-105	0.676	9.28	Gaillard et al (1998): Model for combined effects of temperature, pH and water activity on thermal inactivation of Bacillus cereus spores. J. Food Science 1998 63; 887-889
Psychrotrophic Mesophilic	90	4.6 – 14		Dufrenne et al. (1994) Int. J. Food Microbiol. 23:99-109
		4.8 - > 200		

E. coli			
	Temperature °C	D-value (s)	Reference
Broth with pH 5.4, 3% salt	55	1229	ComBase Predictor
	59	190	
	64	18,5	
Broth with pH 5.8, 2% salt	55	1161	ComBase Predictor
	59	169	
	64	15,2	
Raw cream 40%	51.7	2064	Read et al. (1961): Studies on Thermal Destruction of Escherichia coli in milk and milk products, Applied Microbiology 9:415-18
	54.4	600	
	57.2	210	
	75.6	0.056	
	76.7	0.048	
	77.8	0.041	
	78.9	0.026	
	80.0	0.022	
Ice cream mix	51.7	2358	
	54.4	912	
	57.2	306	
	76.7	0.088	
	77.8	0.072	
	78.9	0.047	
	80.0	0.042	
	81.1	0.032	

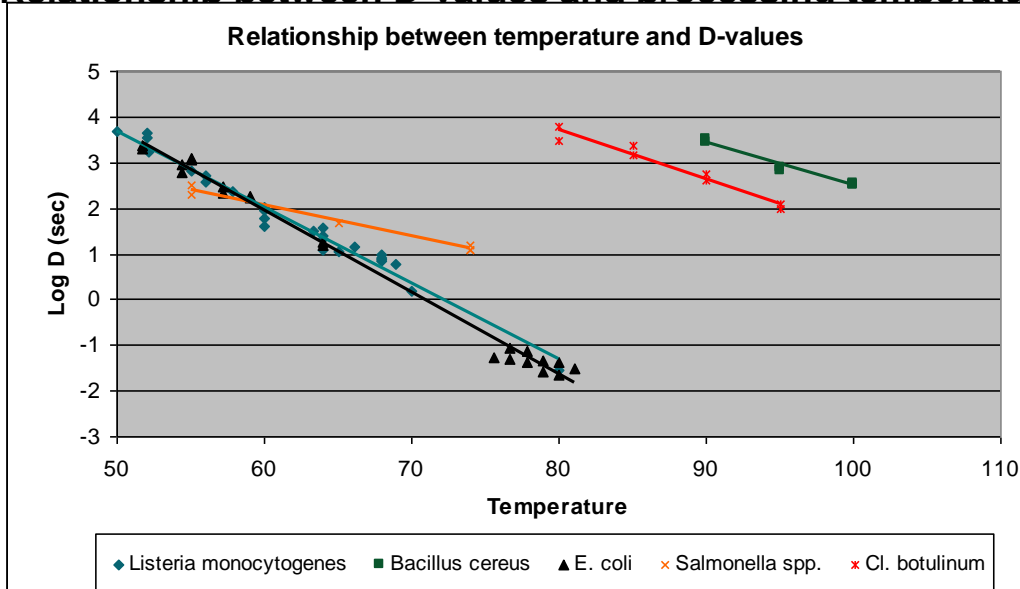
Salmonella spp.			
	Temperature °C	D-value (min)	Reference
Pecorino	55	4.17	Mattick (et al.), 2001: Effect of challenge temperature and solute type on heat Tolerance of Salmonella Serovars at low water activity. Applied and Environmental Microbiology, 67: 4128-4136
	65	0.63	
	74	0,23	



<i>Clostridium perfringens</i> toxins	
<p>The enterotoxin is heat labile, heating in saline at 60°C for 5 min destroying the biological activity</p>	<p>Bradshaw et al (1982); Thermal inactivation of <i>Clostridium perfringens</i> enterotoxin in buffer and in chicken gravy. J. Food Sci., 47(3), 914-916.</p>

<i>Clostridium botulinum</i>			
	Temperature °C	D-value (min)	Reference
Broth with pH 5.4, 3% salt	80	48	ComBase Predictor
	85	24,5	
	90	6.8	
	95	1,6	
Broth with pH 5.8, 2% salt	80	105	ComBase Predictor
	85	38	
	90	9,2	
	95	2,1	
<p>The toxins of <i>C. botulinum</i> are relatively sensitive to heat and are inactivated by heating for 10 min at 80°C or equivalent time/temperature conditions</p>	<ul style="list-style-type: none"> • Siegel (1993): Destruction of botulinum toxins in food and water, pp. 323-341 in “<i>Clostridium botulinum: Ecology and Control in Foods</i>”, (eds Hauschild and Dodds), Marcel Dekker Inc., New York. • Smart and Rush (1987): In-vitro heat denaturation of <i>Clostridium botulinum</i> toxins types A, B and C. Int. J. Food Sci. Technol., 22, 293-298 		

Relationship between D-values and processing temperature



Fitted linear relationships between temperature and D-values presented above	
<i>B. cereus</i>	Log D (s) = -0.0936*T + 11.849
<i>E. coli</i>	Log D (s) = -0.1796*T + 12.729
<i>Cl. botulinum</i>	Log D (s) = -0.107*T + 12.266
<i>Salmonella</i>	Log D (s) = -0.0672*T + 6.0872
<i>L monocytogenes</i>	Log D (s) = -0.166*T + 11.989

Calculation of log reduction

To calculate the number of log reductions, the following formula is used:

$$\text{Log reductions} = \text{holding time}/\text{D-value}$$

The holding time and the D-value are expressed in the same units (hours, minutes or seconds)

ANNEX IV: EXAMPLES OF RECORD FORMS

A. Supplier Assessment

The questions below are typical questions used in the assessment of raw material suppliers. This approach is suitable for the mainstream supply of raw materials.

Each supplier is asked to complete a questionnaire and attach any additional documentation and/or supporting evidence as deemed appropriate.

Suppliers name:	
Address:	
Tel No:	
E-mail address:	
Technical Contact:	
Sales Contact:	

Questionnaire:

- Q1: Does the Company operate a HACCP system?
- Q2: Does the Company operate a food safety management system (e.g. ISO 22000)?
 - If "yes", is it certified?
 - If "yes" please state certification body.
- Q3: Does the company have a product withdrawal/recall system
- Q4: What are the origin of raw materials and ingredients used in the above product?
- Q5: What level of traceability exists?
- Q6: What key process control procedures are in place?
- Q7: What procedures are in place to minimise foreign matter contamination? (pest control contract, glass policy, metal detection etc.)
- Q8: What checks are carried out to test the equipment used? By whom? Frequency?
- Q9: Is all the equipment designed and maintained to enable effective cleaning?
- Q10: What cleaning procedures for equipment are in place?
- Q11: How is cleaning of processing equipment monitored?
- Q12: Are all food rooms constructed to enable effective cleaning and in good structural condition?
- Q13: Is all the monitoring equipment regularly calibrated?
- Q14: Do you carry out routine sampling as evidence of the microbiological status of the end product
- Q15: What other inspection and tests are carried out on the end product? By whom? Frequency?
- Q16: Is the laboratory used accredited under a recognised standard?
- Q17: Does a documented complaints procedure exist?
- Q18: Do you have training records for all personnel?

B. Reception of raw material

Date	Product identification	Supplier	Inspection prior to unload ¹		Document control ³		Visual state of product ⁴		Visual state of packaging material		Additional information ⁶	Check carried out by (name):
			OK	Action taken ^{2, 8}	OK	Action taken ⁸	OK	Action taken ^{5, 8}	OK	Action taken ⁸		

- 1) Visual inspections prior to and during unloading, that the quality and safety of the material has been maintained during transport (e.g. integrity of seals, freedom from infestation, existence of temperature records), product and vehicle cleanliness, correct transportation conditions (temperature, presence of prohibited materials in the shipping), etc.;
- 2) Physical tests, i.e. temperature on delivery;
- 3) Checking that documents correspond to order (quantity and quality), e.g. presence of certificates of analysis required, records of required transportation temperatures;
- 4) E.g. visible mould, contamination, dirt, etc;
- 5) Organoleptic tests to assess appearance, colour, odour, taste; Chemical and microbiological analyses to verify compliance with specifications. Materials which do not conform to specifications or have been transported in unacceptable conditions (dirty, damaged or out of date) must be handled in a way which ensures that they are prevented from unintended use until returned to the supplier.
- 6) E.g. visible mould, contamination, dirt, etc;
- 7) Additional information needed to enable decisions as regards its acceptance and any restrictions on its usage, including adequate handling, preparation and treatment, nature of any contamination and any previous treatment.
- 8) Includes return to sender, disposal of, immediate use to reduce risk, etc.

C. Deviation report (non-conformity)

Deviation report for corrective action. ID no.:		Date: _____
Corrective action targeted the process:		
Deviating control measure:		
Time that the deviation occurred:		
Cause of deviation:		
Corrective actions taken (fill in as appropriate):	Containment actions: _____ Action to regain control: _____ Action to prevent reoccurrence	
Action was taken by (name):		
Corrective action targeted the product:		
Affected product type:		
Severity of the adverse health effects that can be caused by the hazard		
Evidence other than monitoring results that demonstrates that the product is suitable for release:		
Corrective action taken:	Released for sale: <input type="checkbox"/> Handled as potentially unsafe: <input type="checkbox"/>	
Reason for release (if so decided):		
Assessment was conducted by (name):		

D. Record for handling of potentially unsafe product

Record no.:		Date: _____	
Identification of related deviation report(s): _____			
Affected consignments (lots/batches):	Lot/batch number:	Location:	Intended use (if in conformity):
Decision of fate:	<input type="checkbox"/> Reprocessed at own plant through _____ (process) <input type="checkbox"/> Shipped for further processing at _____ (plant). The following information has accompanied the shipment <input type="checkbox"/> Nature of deviation _____ (e.g. contamination) <input type="checkbox"/> Recommended treatment to control or eliminate the hazard <input type="checkbox"/> Durability information <input type="checkbox"/> Labelled/identified as "Food for further (heat) processing, only" <input type="checkbox"/> Disposal as animal by-product, category _____ (specify number) <input type="checkbox"/> Label information: _____ <input type="checkbox"/> Disposed of as waste		
Reason for the decision on fate:			
Decision was taken by (name):			
Withdrawal/recalls (if required):			
External communication:	<input type="checkbox"/> _____ (competent authority) was informed _____ (date & time) <input type="checkbox"/> _____ (customer(s)) was(were) informed _____ (date & time) and instructed as follows: _____ <input type="checkbox"/> _____ (media) was/were informed _____ (date & time) and instructed as follows: _____		
Communication conducted by (name):			
Time of return of withdrawn/recalled product:	Lot/batch number:	Date and time:	