



GUIDANCE ON CHEESE AS RAW MATERIAL IN THE MANUFACTURE OF FOOD PRODUCTS

**(This guidance does not cover the manufacturing and
handling of cheese intended for direct consumption)**

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Foreword

With the overall objective to harmonise and further improve food safety, consumer protection and legal certainty on the Single Market, and in response to questions raised by the European Commission about the use of cheese as a raw material in the manufacturing food process EDA has indicated to the European Commission its intention to come forward with a proposal for an industry guide.

To progress the preparation for this Industry Guidance EDA and EUCOLAIT have developed this European Guidance based on already existing national guides.

We have the pleasure to present this “**Guidance on cheese as a raw material in the manufacture of food products**”, which aims to be used as an advisory document and to gives guidance to cheese manufacturers in all Member States.

We acknowledge the very constructive cooperation on this project with the EU Commission services and the competent authorities of the Member States over the last decade.

With huge gratitude we thank all involved experts for their time, energy and input.

Without the outstanding commitment and the unrivalled expertise of **Mr Claus Heggum**, chief consultant at the Danish Agricultural & Food Council, this document could not have been achieved. We are very grateful.



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CHAPTER 1 INTRODUCTION

This guidance has been developed by the European Dairy Association (EDA) and the European Association of the Dairy Trade (EUCOLAIT) to guide companies when handling cheese as a raw material.

The focus of cheese manufacturing is to produce quality and safe end products in accordance with the objectives of the legislation of the European Union. Despite all the efforts of FBOs (Food Business Operators) along the cheese chain to achieve this, it is unavoidable that a small side-stream of cheese material gets out of the intended commercial or hygienic specifications; most of this cheese material is still suitable for direct human consumption, whereas this may not be the case for other material. This guidance document is drafted primarily for the latter type of material and the objective is to assist FBOs in making decisions in line with the hygiene regulations. The guidance assists in deciding whether a cheese material is suitable for further food processing, directly or pending further treatment, or must be disposed of and used in accordance with the animal by-products legislation. This guidance complies with key principles of food law such as once a food has left the food chain, it can never be reintroduced into the food chain.

These products constituting this side stream are often referred to as “recovered cheese”. Recovered cheese may represent excellent raw materials for further processing into other foods, possibly after some form of treatment. Recovered cheese can be a valuable ingredient of the food sector, contributing to nutritious foods and a sustainable food sector by assisting in reducing food wastage.

The purpose of this guide is to assist companies along the food chain “cheese-to-food products” in ensuring that the cheese material used as a raw material is collected, handled, and prepared in a way that renders it safe for its intended use and that, in combination with the further processing, results in safe ready-to-eat products in accordance with applicable food hygiene legislation.

The collection, handling and preparation of recovered cheese material shall be done in full compliance with the general regulatory framework of food and feed safety (see chapter 3).

CHAPTER 2 SCOPE AND USE OF THE GUIDE

2.1 Scope

Recovered cheese material is raw material used in the manufacture of various foods. As these foods are typically manufactured by specialised food plants, procurement of raw materials involves domestic and international transport of and trade in selected cheese material for this purpose. Various companies, differing in nature and organisation, may be involved in the food chain “cheese plant to food plant”. Cheese material may be shipped directly from a cheese plant (or cheese packaging plant) to a food processing plant, pass through wholesale and retailing enterprises, or be subject to collection and preparation for its intended use at intermediate steps along the route to the food processing plant, involving cross-borders transport.

It is required that the quality of the raw material is appropriate for its intended use. This means that the material shall be of such quality that it, after processing, results in ready-to-eat foods that meets the specified safety requirements and is safe for consumption.

This guidance covers the use of recovered cheese used as raw material in the manufacture of foods; it primarily focuses on out-of-specification¹ cheeses and recovered cheese material used as raw material in the manufacture of foods. For each type of cheese material, guidance is provided as regards suitable uses and, where appropriate, as regards necessary preparation and/or treatment.

This guidance does not cover the manufacturing and handling of cheese intended for direct consumption. Consequently the issues of contaminants originating from the milk used by the cheese manufacturer (the FBO) are not covered, as any cheese made from such milk would not be suitable for human food. Its proper disposal would be the responsibility of the FBO that made such cheese, subject to the competent authority under which that FBO is registered and approved. This would include, for example, milk that fails to meet the requirements of Annex III, Section IX, Chapter I, of Regulation (EC) No. 853/2004 the Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuff and 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.

¹ The term “out-of-specification”, as used in this Guide refers to material which do not meet food safety and/or quality criteria stipulated by legislation or by the manufacturer.

Nevertheless, it is expected that cheese is manufactured and ripened in a way that ensures that its safety and suitability is not compromised and that cheese manufacturers have in place appropriate food safety management systems, based on the HACCP principles, that ensures that corrective measurements are taken when required, in a way that effectively leads to continuous good maintenance of cheese.

2.2 Use of the Guide

This guidance is not intended for cheese manufacturing.

The advice is intended for use by any FBO that uses recovery cheese as raw material in the manufacture of food. The Guide provides advice on the selection, handling and use of recovery cheese as raw material in the manufacture of food products, and recommends suitable control measures and procedures that are capable of controlling contamination and/or restoring control of material that is out of specification.

The Guide is prepared to be applied within the context of HACCP (Hazard Analysis and Critical Control Points) as guidance when the HACCP team establishes the plant specific GHP (Good Hygienic Practice) and raw material and product specific HACCP system.

This Guide does not address the use of other types of raw materials and ingredients, nor does it cover hygiene regulations that are not specifically related to the use of cheese, but which nevertheless are applicable (e.g. traceability system).

Therefore, food business operators should use this Guide in combination with applicable Codes of Hygienic Practices, such as the European Guide for the hygienic manufacture of Processed Cheese when they plan and design their own HACCP-based food safety management systems.

This guide provides good practices that are considered appropriate in the European Union. However, instructions of the competent authority having jurisdiction, as a matter of principle, always take priority over this Guide and should always be followed.

CHAPTER 3 REGULATORY CONTEXT

3.1 General framework for food safety and hygiene legislation

All FBOs shall comply with the legislation of the European Union.

The European Parliament and the Council have adopted Regulation 178/2002 laying down the General Principles and requirements of Food Law, which has come into effect during recent years. The General Food Law Regulation provides a framework to ensure a coherent approach in the Member States in the development and enforcement of food legislation.

The Hygiene regulations² cover all stages of the production, processing, distribution and placing on the market of food intended for human consumption and they stipulate the following principles:

- the food business operator has the primary responsibility for food safety;
- food safety must be ensured throughout the food chain, starting from primary production through distribution, and through general implementation of procedures based on the HACCP principles.
- HACCP procedures shall include the identification, evaluation and control of hazards that are significant to food safety, and apply the seven principles in conformity with the CODEX guidelines on HACCP³.

Under the European Food law and hygiene legislation, food business operators at each stage in the food chain are responsible for ensuring that EU hygiene rules on hygiene (e.g. Regulations 852/2004 and 853/2004) and food safety (e.g. Regulations 1881/2006, 1935/2004 and 2073/2005) are complied with, i.e. by farmers, processors, manufacturers, distributors, retailers and caterers.

The competent authority in the Member State supervises the FBOs through regular inspections, audit and on-the-spot checks. All food business operators need to be registered and/or be approved.

3.2 Relationship with use of cheese as raw material for further processing

In addition to the guidance provided by this Guide, food business operators at all stages of production, processing and distribution within the businesses under their control shall

- ensure that they meet those requirements of food law that are relevant to their activities, and
- verify that such requirements are met.

In particular, the following principles are prerequisites for the efficient implementation of this Guide:

- A traceability system that is capable of identification of lots received from any supplier and lots delivered to any consignee.
- Established, implemented and maintained procedures based on the HACCP principles.
- Established maximum levels for microbiological hazards (Regulation 2073/2005) and contaminants (Regulation 1881/2006), including contaminants from materials in contact with food (Regulation 1935/2004).
- Procedures for categorising and handling of animal-by-products in accordance with Regulation 1069/2009 and Regulation 142/2011.

One type of guidance provided in this Guide relates to assessing the suitability as food of cheese that is out of specification.

This guidance is based primarily on the following provisions in the EU food law and hygiene regulations:

- Articles 14.2, 14.3 (a) and 14.5 of Regulation 178/2002

² Regulation (EC) 852/2004 on the hygiene of foodstuffs, Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin, Regulation (EC) 854/2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption, Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

³ Annex to CAC/RCP 1-1969. Identification and assessment of hazards; Identification of critical control points that are essential to prevent or eliminate a hazard or to reduce it to acceptable levels; Establishment of critical limits that separate acceptability from unacceptability; Implementation of monitoring procedures at critical control points; Implementation of corrective actions when critical limits are exceeded; Establishment of procedures to verify that the HACCP system is working effectively and Establishment of documents and records.

- Annex II, Chapter IX, Section 1 of Regulation 852/2004

Article 14.2 of Regulation 178/2002 says that food shall be deemed to be unsafe if it is considered to be injurious to health or unfit for human consumption. Article 14.3 (a)⁴ of Regulation 178/2002 stipulates that the assessment of safety shall be based on the normal (intended and controlled) use of the food at each stage downstream the food chain, including further processing, and Article 14.5⁵ of Regulation 178/2002 stipulates similarly, that the assessment of suitability shall take regard of the intended (and controlled) use of the food.

Annex II, Chapter IX, Section 1⁶ of Regulation stipulates that raw material that is contaminated or decomposed is not suitable, if normal sorting and/or preparatory or processing procedures cannot render the material fit for human consumption. Accordingly, a further processing plant shall not accept out-of-specification cheese for further processing, unless the final processed (and cheese containing) product will be fit for human consumption, as obtained or controlled by appropriate sorting, preparatory and/or processing procedures.

The main objective of this Guide is to provide the operational means for complying with the above to all the food business operators involved in the part of the specific food chain that starts with the realisation that a particular consignment of cheese is out of specification and ends with putting on the market a further processed food that is fit for human consumption.

Accordingly, responsibility applies to each establishment involved in the handling and use of the recovery cheese, and includes:

- the responsibility of the supplier of the cheese intended for recovery to initially assess the suitability of the material of being fit for consumption when used as intended.
- the responsibility of the food business operator using the recovered cheese as raw material in the manufacture of other products to assure that all ingredients used are suitable for their purpose and that the final product put on the market is fit for human consumption.

Cheese not suitable or declared as not suitable as raw material in the manufacture of any other food has to follow the requirements of animal by-products legislation (Regulation 1169/2011) laying down health rules concerning animal by-products not intended for human consumption. Depending on the category of the by-product, they can be used for feed or for technical purposes or be destroyed.

The other type of guidance provided in this Guide relates to the hygienically application of normal sorting, preparatory procedures and processing of cheese that is out of specification in accordance with Regulation 852/2004, Annex II, Section IX, point 1.

This guidance is based primarily on the EU hygiene regulation Regulation 852/2004, in particular the provisions of Annex II, Chapter IX, Section 2⁷ and 5⁸ (first sentence) of Regulation 852/2004.

These provisions stipulate that cheese which is out of specification shall be kept in appropriate conditions and temperatures to prevent (further) deterioration and protect it from (further) contamination.

The main objective of this Guide is to provide the operational means for complying with the above for all the food business operators involved in the part of the specific food chain that starts with the handling, storage and transport of cheese which is out of specification and ends with the further processing.

⁴ Art 14.3 (a)

In determining whether any food is unsafe, regard shall be had to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution.

⁵ Article 14.5

In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

⁶ Section 1 of Ch. IX, Annex II:

A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.

⁷ Section 2 of Ch. IX, Annex II

Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.

⁸ Section 5 of Ch. IX, Annex II

CHAPTER 4 ASSESSMENT OF THE SUITABILITY OF CHEESE AS RAW MATERIAL FOR FURTHER FOOD PROCESSING

This section is intended as guidance to those food businesses that recover and market cheese material for industrial usage as raw materials for further processed foods.

A basic hygienic principle is that no raw material shall be used for the manufacture of any food if its use results in the food becoming injurious to health or otherwise unfit for human consumption, when consumed in reasonably expected quantities. In determining whether a raw material is suitable for food manufacturing, regard shall therefore be given to both the nature and quality of the raw material and the procedures of handling and processing carried out prior to and/or during manufacturing. The suitability of cheese for further food processing needs to be considered according to their specific nature.

To ensure that cheese that has been assessed as unsuitable for direct consumption but suitable for further food processing does not (re)enter the food chain as ready-to-eat food, accompanying documents or labelling must specify its intended use. The food business that releases or markets the cheese for further food processing must assess the suitability of each batch with respect to its suitability for further food processing. The result of the assessment and the rationale for the decision made accordingly shall be recorded. Guidance for such assessment for the most common types of cheese is provided below.

The examples of out-of-specification cheese are addressed on-a-case-by-case basis. More than one type of deviation may occur in practice (e.g. reference samples (4.3) exceeding labelled best before dates). In each case, the assessment of the suitability of the cheese must take into account all types of deviations occurring. The information in this chapter as it relates to the guidance provided in chapter 5 has been summarised in the Annex.

4.1 Ripened and unripened cheeses intended for direct consumption

4.1.1 Assessment

Ripened (incl. mould ripened) and unripened cheeses are put on the market as whole cheese, possibly wrapped, and as prepackaged whole, cut, shredded or grated cheese.

Cheese may be coated⁹ prior to the ripening, during the ripening process or when the ripening has been finished.

The most often-used mould species used in the manufacture of mould ripened cheeses include species of *Penicillium* (notably, *P. camembertii* and *P. roquefortii*) and *Geotrichium* (notably, *G. candidum*). Some cheese varieties are characterised by the use or natural occurrence of different mould species such as traditionally ripened cheddar, Gammelost (*Mucor*), Tomme (*Mucor*, *Cladosporium*, *Epicoccum*, *Sporothrichum*) or Saint Nectaire (*Mucor*, *Cladosporium*, *Epicoccum*, *Sporothrichum*).

Examples of cheeses intended for direct consumption are also mentioned in other parts of chapter 4 where necessary to specify requirements for the management of the product as raw material.

4.1.2 Guidance

Cheese intended for direct consumption is suitable for further processing without any restriction. See section 5.1 – 5.3 for guidance on the handling prior to release and during transport and storage.

Coating material must be kept intact during storage and transport and must not be removed until immediately before actual use.

4.2 Returns from wholesale enterprises and retailers

4.2.1 Assessment

Pre-packaged or cuts of cheese returned from wholesalers can be suitable for further food processing.

⁹ When coating is used during ripening, the purpose is to regulate the moisture content of the cheese and to protect the cheese against microorganisms. When coating is done after the ripening has been finished, the purpose is to protect the cheese against microorganisms and other contamination and from physical damage during transport and distribution and/or to give the cheese a specific appearance (e.g. coloured).

Coatings are made of non-cheese (whereas cheese rind is cheese). Cheese coatings include:

- A film, very often polyvinylacetate, but also other artificial material or material composed of natural ingredients, which helps to regulate the humidity during ripening and protects the cheese against microorganisms (for example, ripening films)
- A layer, mostly wax, paraffin or a plastic, which normally is impermeable to moisture.

To assess this possibility two aspects need to be considered: A) The legal aspect specific to handling animal food (approval via Regulation 853/ 2004 on hygiene), and B) the safety aspect with its specific legislation (Regulation 2073/2005 on microbiological food safety criteria). Both have certain restrictions.

- A) Only businesses approved in accordance with Regulation 853/2004 are permitted to market cheese. Distribution terminals, independent on ownership, are defined as a retail activity by Reg. 178/2002. As a general rule, retail activities are exempted from the approval via Reg. 853/2004. Nevertheless, that Reg 853/2004 mentions two specific situations in which the situation can differ:
 - 1) In accordance with Article 1.5, b.(i) of Regulation 853/2004 the provisions of that regulation also apply to retail establishments supplying animal or animal-derived foods for operations other than solely storage and transport of foods of animal origin. For retail establishments, esp. distribution terminals and centers, that only store cheese in its original packaging and at the right temperature, and even though these distribution establishments are registered but not approved according to the Regulation 853/2004 they can supply cheese to approved establishments.
 - 2) Article 1.5.c of the same Regulation permits Member States to adopt national measures to apply the requirements of this Regulation 853/2004 to retail establishments situated on their territory to which it would not apply pursuant to subparagraphs 1.5 (a) or (b). In Member States where retail establishments are approved in accordance with Regulation 853/2004, cheese can be used for further processing when the cheese supplied has been handled only in the approved part of the establishment.
- B) Returns of cheese from distribution terminals do not represent a risk, as long as the packaging has not been broken and that labelled storage conditions labelled by the manufacturer are adhered to, noting that any other types of non-spec issues associated with returned material must be assessed on a case-by-case basis. The only legal restriction is for the food safety criteria of Regulation 2073/2005 which does not permit returns from retail.

4.2.2 Guidance

If such returns are contaminated and/or have exceeded durability dates, an assessment of suitability should be conducted in accordance with the appropriate sections of this Guidance.

Pre-packaged or cuts of cheese that do not meet food safety criteria specified in Regulation 2073/2005 cannot be returned from retailers (Article 7 of Regulation 2073/2005).

See section 5.1 – 5.3 for guidance on the handling prior to release and during transport and storage.

4.3 Samples intended for testing and analysis

4.3.1 Assessment

There are different types of samples intended for testing and analysis:

- a) (Unopened) shelf-life reference samples that are held under controlled chilled storage within the manufacturing facilities, where the food safety is not compromised; however, these samples are likely to exceed any established durability dates, see chapter 4.12. Should information become available (e.g. complaints from the market) that the safety of the cheese represented by the sample may have been compromised, the corresponding reference sample shall be assessed with regard to all aspects that could lead to this deviation.
- b) (Unopened) accelerated reference shelf-life samples that are held under elevated controlled storage conditions within the manufacturing facilities, should be subject to a full food safety risk evaluation.
- c) Leftovers of samples used for professional sensory testing; these may be suitable if the safety can be retained during storage, handling and further distribution, and if the sensory testing is conducted at a facility approved in accordance with Regulation 853/2004.
- d) Laboratory samples for analysis, a similar approach can be taken for unopened samples held in controlled chilled storage.

- e) Laboratory samples that have been opened in laboratory facilities, constitutes removal from the food chain and subsequently, this material cannot re-enter the food chain. Such leftovers from testing and analysis must be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

4.3.2 Guidance

The process of removing cheese from processing lines and storage facilities as reference samples does not change the nature of the cheese nor does it, as such, compromise food safety.

Unopened reference samples (see (a) above) can be used without restriction, if kept under controlled conditions within the manufacturing facilities. However, should information become available (e.g. complaints from the market) that the safety of the cheese represented by the sample may have been compromised, the corresponding reference sample shall be assessed with regard to all aspects that could lead to this deviation. As these samples are likely to exceed any established durability dates, see section 4.12.

Unopened accelerated reference shelf-life samples (see (b) above) should be subject to a full food safety risk evaluation, prior to any further use.

A approach similar to reference samples can be taken for unopened laboratory samples for analysis (see (c) above) held in controlled chilled storage; however, for samples that have been opened in laboratory facilities, this constitutes removal from the food chain and subsequently, this material cannot re-enter the food chain. Such, leftovers from testing and analysis must be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

Samples used for sensory testing (see (d) above) may, despite short time temperature adjusted in accordance with testing protocols, in many cases still be suitable for recovery provided that they are returned to appropriate storage conditions and that they have been handled hygienically. A specific evaluation of these aspects is needed.

See section 5.1 – 5.3 for guidance on the handling prior to release and during transport and storage.

4.4 Cheeses not complying with quality specifications

4.4.1 Assessment

A vast number of quality or commercially related reasons exist for rejecting a cheese for direct consumption. A few are highlighted below:

Deviations from commercial eye's specifications:

Undesirable development of microorganisms present in cheese may lead to formation of non-soluble gas (e.g. hydrogen) or excessive gas resulting in vast amount of eyes and/or oversized eyes.

White crystallised surface:

White (non-microbial) layers or spots on the cheese surface may occur, typically due to calcium extracts or crystallized amino acids. This may occur in aged cheese with advanced decomposition of proteins. These developments are harmless.

4.4.2 Guidance

Cheese with the deviations in 4.4.1 above is suitable for further processing.

When microorganism causing the deviation from commercial quality specifications is identified as potentially hazardous and provided that the organism cannot be removed reduced to acceptable levels during subsequent processing, the material must be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

See section 5.1 – 5.3 for guidance on the handling prior to release and during transport and storage.

4.5 Physically contaminated cheese

4.5.1 Assessment

Contamination of cheese with foreign bodies may happen accidentally, despite proper GHP procedures. The type of contaminant, the firmness of the cheese mass, and whether the contamination is on the surface or within the cheese mass are factors that can be decisive for the ability to remove the contamination or otherwise correct the deviation.

If the type of contamination cannot be identified, the cheese will not be suitable for further food processing.

If the foreign material can be effectively removed, the cheese will be suitable for further food processing.

4.5.2 Guidance

Cheese contaminated with glass and hard plastic shall be removed from the food chain and be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

Cheese contaminated with single metal pieces can be used, if effective removal prior to or during the further food processing can be assured and provided the removal method is accepted by the competent authority. Otherwise, the material shall be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

See Section 5.4.8 for guidance on removal. See section 5.1 – 5.3 for guidance on the handling prior to release and during transport and storage.

If the nature of the foreign bodies is unknown/unspecified, the cheese must be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

4.6 Chemically contaminated cheese

4.6.1 Assessment

When chemical contamination of cheese occurs, it most often happens early in the food chain (primary production) and documentation for meeting legal limits (e.g. pesticide residues, dioxins, etc.) is often more efficiently based on testing of milk and not on the testing of ready-to-eat foods. If such contaminants are present in the milk it is likely to be present throughout the cheese mass.

However, chemical contamination may occur during processing or ingredients of possible concern may be added (e.g. natamycin in a depth of up to 5 mm). Also, migration from coating material, cheese wax and packaging material is of concern.

4.6.2 Guidance

Cheese that has been contaminated with chemicals that impact on food safety and in amounts that exceed established maximum levels (MLs) or maximum residue levels (MRLs) according to Regulation 1881/2006, as appropriate, cannot be used as raw materials for food production and shall be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

If a chemical contamination of cheese occurs, the responsibility to carry out any assessment falls upon the FBO, under whose control the cheese is at the time of the (possible) contamination; this could be the original cheese manufacturer, the cheese recovery facility, the user of the recovered cheese, or the relevant cheese storage facility, if separate from the other FBOs. Where a volatile chemical substance is involved, any such analysis should be undertaken before the chemical evaporates to a level that is below minimum detectable levels. Cheese suspected to be contaminated with chemical spill should be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

Coatings, waxes and packaging material should be safe for its intended use. The principle of Article 3.1 of Regulation 1935/2004¹⁰ on materials and articles intended to come into contact with food should apply. The manufacturer should obtain information on nature and contents of mineral oils¹¹ and any use of natamycin and ensure that this information is provided in accompanying documents (see section 5.1.3 (b)).

¹⁰ **Article 3.1:** Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- (a) endanger human health; or
- (b) bring about an unacceptable change in the composition of the food; or
- (c) bring about a deterioration in the organoleptic characteristics thereof.

¹¹ There are two main groups of mineral oils. One is the mineral oil saturated hydrocarbons (MOSH) consisting of alkanes and cyclic alkanes (mineral oil saturated hydrocarbons), and the mineral oil aromatic hydrocarbons (MOAH) consisting of aromatic hydrocarbons. MOAH are potential cancerogenic and genotoxic and contents in food should be minimised. See further details in EFSA Scientific Opinion on Mineral Oil Hydrocarbons in Food, EFSA Journal 2012;10(6):2704.

4.7 Cheese contaminated with yeast

4.7.1 Assessment

Yeast is not considered harmful. Human infection is primarily caused by non-food means of transmission (cuts, wounds).

EFSA concluded that although yeasts are part of the microbiota of many foods and beverages they are rarely (if ever) associated with outbreaks or cases of food-borne illness¹².

Cheese contaminated with yeast commonly occurring in cheese¹³ does not represent a food safety related problem.

4.7.2. Guidance

Such products can be classified as quality rejects (see 4.4) and can be used for further processing without any restriction.

See section 5.1 – 5.3 for guidance on the handling prior to release and during transport and storage.

4.8 Cheese exceeding established process hygiene (microbiological) criteria

4.8.1 Assessment

Coagulase positive staphylococci

A process hygiene criterion has been established for cheese for coagulase-positive staphylococci (amended EU Regulation 2073/2005). However, this criterion is related to a food safety criterion for staphylococcal enterotoxins. It is generally recognised that there is no risk of toxin formation as long as levels of *S. aureus* are kept below 100 000 cfu/g.

Generally, *S. aureus* does not grow in semi-hard, hard and extra hard ripened cheese. Such cheese can be used for further processing if documentation exist that levels are not and have not exceeded 100 000 cfu/g. In the case of other cheese, a specific assessment of history and potential for growth during subsequent transport and storage is required.

Other process hygiene criteria

A process hygiene criterion has been established for cheese for the microorganism *E. coli* (amended EU Regulation 2073/2005). Individual cheese manufacturers may have established alternative and/or additional hygiene indicator criteria, e.g. coliforms/ Enterobacteriaceae, thermotolerant bacteria. Exceeding these criteria does not represent a health hazard (and therefore does not trigger recalls nor restrictions on putting the affected cheese on the market for direct consumption).

Such cheese can be used for further processing without any restrictions.

4.8.2 Guidance

Coagulase positive staphylococci

When the cause of the deviation is based on exceeding the criterion for coagulase positive staphylococci, specific measures are needed during transport, storage and further processing to avoid toxin formation up to the point of consumption of the further processed food. Such measures would include growth control if the cheese supports the growth of staphylococci (see section 5.1 – 5.3 and 5.4.6 for guidance on the handling prior to release and during transport and storage) and heat treatment during further processing to reduce the number in the further processed end product (see 5.4.6 for guidance on heat treatment).

However, cheese in which the level is or has been above 10⁵ cfu/g can only be released for further processing if no staphylococcal enterotoxin has been detected.

Cheese, in which staphylococcal enterotoxins have been detected, cannot be used for any food purposes (heat treatment does not effectively destroy the toxins) and the affected cheese must be disposed of and used in accordance with Regulation 1069/2009 (on animal by-products).

¹² EFSA (2006): Appendix C of Introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA, The EFSA Journal (2007) 587, 1-16.

¹³ The most common are *Kluyveromyces lactis*, *Saccharomyces cerevisiae* and *Debaryomyces hansensi*.

Other process hygiene criteria

See section 5.1 – 5.3 for guidance on the handling prior to release and during transport & storage.

Cheese in which extremely high levels of hygiene indicators have been detected should not be released unless an assessment of potential content of pathogenic microorganisms has been conducted.

4.9 Exceeding established food safety (microbiological) criteria

4.9.1 Assessment

Food safety criteria have been established (amended EU Regulation 2073/2005) for *Listeria monocytogenes* (all cheeses), for *Salmonella* (cheeses made from milk that has not undergone a heat treatment at least equivalent to pasteurisation), and for staphylococcal enterotoxins (all cheese).

Individual cheese manufacturers responsible for the safety of a specific cheese may, in accordance with the HACCP principles, have established and apply alternative and/or additional food safety criteria. Exceeding these criteria also represents a health hazard (and therefore triggers recalls and restrictions on putting the affected cheese on the market).

4.9.2 Guidance

Cheese exceeding the criteria for *Listeria monocytogenes* and *Salmonella* and which has not yet been at retail level (see 4.2) can be released for further processing provided transport and use is kept under control (prevention of further growth, heat treatment during further processing, and clear identification as cheese intended for further processing involving heat treatment). See section 5.1 – 5.3 for guidance on the handling prior to release and during transport and storage.

Cheese, in which staphylococcal enterotoxins have been detected, cannot be used for any food purposes (heat treatment does not effectively destroy the toxins) and the affected cheese must be disposed of and used in accordance with Regulation 1069/2009 (on animal by-products).

Cheese exceeding other food safety criteria for pathogens that do not produce toxins in the cheese (established by the cheese manufacturer) can be used for further processing under the same conditions as for *Listeria* and *Salmonella*.

4.10 Cheese with undesired mould colonies

4.10.1 Assessment

Cheese is likely to contain undesirable moulds (contamination). Mould contamination is often caused by cross contamination from other processing lines or stores used for the manufacture of mould ripened cheese and/or derive from environmental contamination. As moulds are very common in any environment, it must be expected that most cheese contains moulds. Where mould ripened cheese is processed, ripened or stored together with other cheeses in the same facility, mould contamination is almost unavoidable.

If these moulds are allowed to grow, visible colonies (mouldy spots) occur and become visible when present in $>10^4$ cfu/g (Lund et al., 2000).

Mould contamination involves an aesthetic problem, and possibly a health hazard. The food safety issue is however strictly associated with the possible formation of mycotoxins by the mould.

The mycoflora of non-mould ripened cheese are mainly contaminating moulds of the species used as starter cultures (see above) and a limited number of other species of *Penicillium*¹⁴.

Cheese contaminated with mould species that are traditionally used in the manufacture of mould ripened cheeses (see 4.1.1) has a profile as regards public health risk that is equivalent to mould ripened cheeses. Most of the undesired white and blue moulds occurring on cheese are of such species.

¹⁴ *Penicillium* species count typically for 70-90% of the species found in cheese, whereas *Aspergillus* species (*A. versicolor*, *A. flavus*, *A. niger*, *A. parviticus*) count for 4-8% of the species found. Occasionally, species of *Cladosporium* (*C. cladosporoides*, *C. herbarum*), *Alternaria*, *Phoma*, *Scopulariopsis* (*S. brevicaulis*) and *Fusarium* (*F. dimerum*, *F. domesticum*, *F. oxysporum*) may be present.

Among the non-starter species that develop into visible colonies during chilled storage are almost all *Penicillium* species, (typically *P. brevicompactum*, *P. caseifulvum*, *P. citrinum*, *P. crysogenum*, *P. commune*, *P. discolor*, *P. expansum*, *P. nalgiovense*, *P. solitum*, *P. verrucosum*, *P. viridicatum* and *P. verrucosum*), as they in contrast to other relevant mycoflora, may grow at low temperatures. Among these, *P. commune* and *P. nalgiovense* are the most important.

P. commune and certain non-penicillium species such as *C. cladosporoides*, *C. herbarum* & and a few *Phoma* (e.g. *Phoma glomerata*) species produce a condition termed "thread mould" because they grow at low temperatures and tolerate low levels of oxygen.

Cheese contaminated with other mould species requires a specific assessment as regards its suitability for further food processing, in particular to ensure that controls are in place to minimise the possibility of mycotoxin formation. Cheese with visible mould of this kind can be used for further processing to the extent that measures are taken to control these moulds in a manner that avoids mycotoxin formation.

Adding flavouring foods to material may bring along different mould species, which may or may not grow in the cheese environment. This applies in particular to dried herbs, spices and fruits. If the cheese constitutes food combined of cheese and flavouring foods, a specific assessment must be conducted to determine whether any additional mould species may be introduced that is likely to produce mycotoxins on cheese, and whether controls in addition to those already in place will be needed to ensure that the possibility of mycotoxin formation is minimised.

4.10.2 Approach to mould control

Visible mould on cheese is an integral part of the identity of a number of cheese varieties.

Visible mould is not evidence of the presence of mycotoxins, but an indicator of an increased probability of toxin formation. The presence of visible mould becomes a food safety issue only if mycotoxins are produced by undesired moulds to an extent that would adversely affect human health. Consequently, the food safety target is to prevent toxin-formation and the means to achieve this is mould control.

Mould control is based on the following facts:

- a) Mycotoxins are secondary metabolites of certain mould species/strains, i.e. their formation does not play a role in the normal metabolism associated with the growth of colonies.
- b) Toxin production does not correlate with mould growth. The probability of toxin formation increases with temperature and access to oxygen, and the likely concentration of toxin, if present, increases with the ratio “surface area to volume of the cheese”.
- c) Not all strains of the same species are capable of producing mycotoxins, even under optimal conditions. For those strains that are capable of producing mycotoxins, the conditions often differ from the conditions permitting growth (typically, toxin formation requires higher temperature conditions).
- d) Mycotoxins, if developed at all, are formed by the mould filaments and will therefore be present near the surface. In some firm (<60% MFFB¹⁵) and all hard and extra hard cheeses, any mycotoxins formed near the surface will not diffuse into the interior of the cheese. There is a likelihood of diffusion in the case of cheese with higher moisture contents.
- e) Moulds relevant to cheese require oxygen to grow. Growth is also dependent on temperature and time, accessible humidity and other factors.
- f) Cheese contaminated with mould species that have a safe history of use in mould-ripened cheese types (starter cultures or secondary dairy cultures) is not of the same level of concern as contamination from other mould types.

4.10.3 Mould control strategy

In accordance with the above, the strategy for risk-based mould control, from procurement through to end use, constitutes of the following elements:

- a) Focusing on the non-dairy mould species (undesired mould).
- b) Minimisation of the occurrence of visible moulds (growth control measures, such as low temperature, limited oxygen, low surface moisture).
- c) Keeping mould populations young (colony age control measures such as growth control (see (b) above) and removal of colonies before they mature).
- d) Applying precautions to provide additional security in case the other measures fail. This includes control measures controlling the likelihood of diffusion of mycotoxins (if present) from the cheese surface to the inner material and/or to the end product such as the “surface area to volume” ratio, the texture of the cheese, and reduction of the concentration of any mycotoxins that nevertheless may have been formed.

When following the above strategy, there is no value in analysing for mycotoxins in raw materials or product following further processing as the probability of detection is extremely low. Further coverage of analytical methods and availability of toxins for calibration purposes makes a strategy based on testing non-practical.

¹⁵ Moisture on fat free basis

See further details in Annex II: Scientific documentation for control of mould and mycotoxins in cheese

4.10.4 Guidance for food businesses that recover cheese

These Guidelines differentiate between the following categories of moulds:

A. Mould species that most likely are species typically used in the manufacture of mould-ripened cheeses (see 4.1.1)

The cheese can be released under refrigerated conditions, if it can be substantiated that the mould colonies most likely derive from cross contamination of known starter cultures used in the manufacture or storage of mould ripened cheese. This can be assumed to be the case, if the cheese has been manufactured or stored within the same facility where mould ripened cheese is manufactured. It is the responsibility of the manufacturer to assess whether this is the case and to provide this information. If no information on the nature of the mould colonies is available, the cheese must be handled in accordance with the guidance in part (B) below.

B. Mould species where it cannot be substantiated that they are likely to be species typically used in the manufacture of mould-ripened cheeses

a) Cheese of hard/extra hard texture (MFFB <56%¹⁶):

If no more than approximately 10%* of the surface is covered with mould, the cheese can be released, provided that

- the material is kept under refrigerated conditions
- protection of the surface is provided.

If more than approximately 10%¹⁷ of the surface is covered with mould, the cheese can be released, provided that

- the contaminated surfaces are removed prior to release
- the material is kept under refrigerated conditions
- protection of the surface is provided.

b) Other cheeses:

If no more than approximately 10%¹⁷ of the surface is covered with mould, the cheese material can be released, provided that

- the contaminated surfaces are removed prior to release
- the material is kept under refrigerated conditions
- protection of the surface is provided.

The spread of mould to the interior of the cheese (e.g. through the structure of holes) shall be taken into account when evaluating the surface area covered.

If only smaller spots occur on the surface, the cheese can be released, provided that

- the spots in general do not exceed 2-3 cm in diameter
- the colonies are scraped off prior to release
- the material is kept under refrigerated conditions
- protection of the surface is provided.

C: Mould species originating from flavourings (e.g. herbs, spices and fruits)

If the assessment (see section 4.10.1) identifies any mould species that are likely to produce mycotoxins on cheese, the flavoured cheese in question should not be used but should be disposed of and used in accordance with Regulation 1069/2004 (animal by-products).

The removal can be carried out as an intermediate step by another food business.

¹⁶ Moisture on fat free basis

¹⁷ Checking compliance with an exact percentage is not practical. Therefore, the qualification "approximately" is used to indicate that tolerance around the percentage is granted.

The effectiveness of the removal step (see 5.4.8) increases with the size of the cheese blocks and depends on whether the mould is located in a manner that will allow effective removal. Material where the ratio “contaminated surface to cheese mass” is high must be assessed as regards the feasibility for mould removal. Cheese that is too small for the required mould removal and/or which has mould filaments deeply penetrating along holes or eyes shall not be considered for mould removal.

Measures to protect the cheese from further contamination and mould growth must be in place prior to release, in particular if no dry rind covers the surface. If mould removal has taken place, protection must be provided as quickly as possible and without any unnecessary delay and constitutes vacuum packaging and modified atmosphere packaging (see 5.4.8). Alternatively, the material can be kept frozen.

Growth needs to be kept under control during subsequent transport and storage (see 5.2 and 5.3.2).

Cheese that does not comply with the requirements listed above shall be disposed of and used in accordance with animal by-products legislation.

4.11 Line recoveries

4.11.1 Assessment

Cheese edges/off-cuts

Cut offs of excessive cheese during packaging, slicing and cutting operations, as well as cheese adhering to cutting devices, transport belts, etc. are suitable for further food processing.

It should be noted that cheese adhering to cutting devices and transport belts may be contaminated with foreign bodies (abrasion from the belts, material from coatings). If this is the case, such material shall be assessed as described in section 4.5.

In the case of larger pieces (>1 kg) of firm, hard and extra hard cheeses, smaller mouldy spots are often cut off or scraped off in order to restore the visual impression of the cheese. The restored cheese is suitable for further food processing.

With regard to the mouldy cut offs, see section 4.10 above.

Cheese curd

Cheese curd may be recovered from cheese vats, pipes and whey (e.g. separators) and is suitable for further food processing.

Floor sweepings

Cheese recovered from floors are not suitable for further food processing and must be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

Note: Catchments trays placed on the floor do not constitute floor sweepings.

4.11.2 Guidance

See section 5.1 – 5.3 for guidance on the handling prior to release and during transport and storage. Where curd is not used within short time (4 days under chilled conditions), it should be submitted to heat treatment prior to use.

4.12. Exceeding age specifications

4.12.1 Assessment

Durability shall be established on prepackaged products and shall take into account the intended usage, reasonably foreseeable storage and transport conditions at subsequent steps in the food chain, including any further processing, and any storage recommendation provided on the label.

Durability information on food may be presented in two forms, as follows:

- **A date of minimum durability (“best before”)**, applied to indicate when the food, when properly stored, starts losing its specific (quality) characteristics. Beyond this date, the food may still be perfectly safe and satisfactory.

The durability of many ripened cheeses, in particular whole firm, hard and extra hard ripened cheeses may be up to several years, as the cheeses can continue ripening until the full breakdown of proteins (and fat) occurs, and still constitute a suitable food.

In many such cases, durability dates specified for cheese are “best before dates” and primarily established to respond to taste characteristics of the specific type (variety characteristics, consumer information such as “mild”)¹⁸.

- **A use-by date (“use by”, “expire by”)** applied for highly perishable foods only and to indicate when the food is likely to constitute an immediate microbiological danger to human health. After this date, such highly perishable food must not be sold because it may represent an immediate danger to human health.

4.12.2 Guidance

Cheese which has exceeded pre-established durability (“best before”) dates can be released for further food processing, provided that an assessment¹⁹ of any other deviation demonstrates that the material is suitable for further processing.

Cheese which has exceeded pre-established use-by dates cannot be released for further food processing and the material must be disposed of and used in accordance with Regulation 1069/2009 (animal by-products). See section 5.1 – 5.3 for guidance on the handling prior to release and during transport and storage.

4.13 Cheese mites

4.13.1 Assessment

The cheese mite (*Acarus siro linnaeus*) is a relatively large translucent pearly white mite (0.30 to 0.66 mm) with stout, well-tanned, faintly wrinkled legs and tanned mouthparts. Males and females are similar except that females are larger. The time required to develop from egg to adult may be several months at refrigeration temperatures, 4 to 5 weeks at 15°C, but at 24°C it is only about 2 weeks.

For a few types of cheese, cheese mites are technological agents for ripening. For other cheeses, mites are considered as infestation. During storage of the latter, cheese mites are controlled by pest management schemes that include cleaning, vacuuming, scrubbing surfaces, prevention of infestation, and wax coating on cheeses.

4.13.2 Guidance

Cheese infested with mites should be cut off and disposed of and used as Category 3 material in accordance with Regulation 1069/2009 (animal by-products).

Non-infested parts of cheese are suitable for further processing. See section 5.1 – 5.3 for guidance on the handling prior to release and during transport & storage.

4.14 Deterioration

4.14.1. Assessment

Pests

Presence of vermin such as maggots makes cheese unsuitable for further use in the food chain and must be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

Compositional deterioration

With aging, the cheese components (protein, fat, etc.) may break down almost to the full extent, leading to liquid extracts, and a distinctive smell of aged cheese (ammonia, etc.). Such deterioration is harmless (sometimes even desired), and has no implications on the use for further food processing. However, deterioration to the extreme is not desirable, even it is not unsafe.

4.14.2 Guidance

Pests

Disposal and use in accordance with Regulation 1069/2009 (animal by-products). Visible traces (excrements, off-gnaw, etc.) of mice and rats must trigger disposal of the affected cheese.

¹⁸ As many cheese types do not have a technical durability, Codex labelling rules permit the replacement of the durability date with a date of manufacture in the case of ripened firm, hard and extra hard cheese which are not mould ripened and which are not intended to be purchased as whole cheeses by the final consumer.

¹⁹ Sensory/organoleptic testing, followed by additional investigation/testing if necessary, in accordance with this Guide

Compositional deterioration

Cheese that has deteriorated to the extreme should be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

For instance, if the cheese develops a nauseous taste and smell or otherwise appears unexplainably atypical, the decomposition may not have occurred correctly, and the cheese shall be disposed of and used in accordance with Regulation 1069/2009 (animal by-products). It may take a trained nose or a trained tongue to make correct judgement in this respect.

Staff responsible for sorting cheese should have the necessary competences, which would include training in sensory testing and grading of cheese as well as having received job training.

CHAPTER 5 PREPARING, HANDLING, TREATMENT AND USE OF RECOVERED CHEESE FOR FURTHER FOOD PROCESSING

This chapter addresses only raw material that has been assessed as suitable in accordance with Chapter 4.

The guidance addressing preparing for release is targeted at those food businesses that carry out recovering of cheese processing/distribution lines for industrial usage. Specific preparation steps may be outsourced to other food businesses and/or be carried out by other food businesses in the food chain. The related measures recommended by these Guidelines are intended to be applied in the early stages of the food chain “cheese as raw material-to-further processed food”.

The guidance addressing handling and storage is targeted at all food business operators involved. In general, recovered cheese must be handled in a manner that maintains or controls the suitability of the material according to its intended use. In case of failure, the cheese must be re-assessed in accordance with chapter 4.

The guidance addressing treatment is targeted at those food businesses that receive recovered cheese and use it as raw material for further processing and/or process it as intermediate products prior to use as raw materials. However, specific treatment steps may be outsourced to other food businesses and/or be carried out by other food businesses in the food chain. The related measures recommended by these Guidelines are intended to be applied in the food chain “cheese as raw material-to-further processed food”.

The types of deviation are addressed on a case-by-case basis. More than one type of deviation may occur in practice (e.g. visible mould on line recovered cheese curd). In each case, the assessment of the suitability of the recovered cheese must take into account all types of deviations occurring.

The information in this chapter as it relates to the guidance provided in chapter 4 has been summarised in the Annex.

As microbial growth in some recovered cheese can hardly be fully avoided during storage and transport, the microbial criteria for assessing the suitability of the material at the origin (Chapter 4) would normally be stricter than the corresponding microbial criteria used to assess this material at the point of use as raw material in further processed foods. Growth of pathogenic bacteria does not occur in semi-hard and hard cheeses.

5.1 General measures applicable prior to release as raw material for further processing

5.1.1 Protection of open surfaces prior to shipment

To minimise (further) contamination and development of visible mould during storage and transport, the open surfaces of recovered cheese must be protected.

Recovered cheese with intact packaging (e.g. returns from wholesale enterprises), with an intact dry rind (e.g. Emmental, hard cheeses) or with an intact coating need no further packaging during handling, transport and storage.

Cheese with broken packaging, rind or coating must be re-packaged, wrapped or otherwise protected from contamination during transport and storage. Freezing provides sufficient protection against microbial growth on and in cheese.

Specific measures for mould contaminated cheese are addressed in Section 5.4.8 below.

5.1.2 Physical handling

Recovered cheese must be handled in a way that does not result in physical damage to the protective cheese surface (packaging, coating or dry rind).

Dry cheese rind, packaging and coating must be kept intact.

Cheese surface that has been in contact with the floor should always be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

In particular, vacuum packagings and ripening films must be handled with care to avoid breakage of the bags (thus leading to mould access to oxygen). Broken packages shall be discarded unless used for further processing as quickly as possible and without unnecessary delay or frozen prior to further storage.

5.1.3 Specific information to follow certain products

a. Cheese suitable for further processing, only

When cheese is not suitable for direct consumption, but suitable as raw material for further food processing only, it shall be identified as “**Food for further (food) processing, only**” in an appropriate language, on the container (e.g. pallets, racks, etc) and/or in accompanying documents, as necessary to ensure traceability back to the original manufacturer. Such identification is also important, if the cheese material has exceeded pre-established durability dates, in particular if the durability date is still labelled on the packaging, as to avoid any misunderstanding as regards the status and intended usage of the material.

Where such recovered cheese is stored in facilities together with other foods, it must be kept separated from other raw material and clear marking of the area where the recovered cheese is located must be provided so as to avoid any mistakes regarding its nature and destination.

b. Additional information

In some cases, additional information must be provided in accompanying documents as it may be needed by the food establishments receiving the material to enable adequate handling, preparation and treatment, as appropriate to the nature of the raw material.

Such information is particularly important where:

- Metal contamination has caused the declassification (see Section 4.5). Such information is necessary to assist the further processing establishment in ensuring that equipment is in place that is capable of effectively removing the hazard.
- Passing on knowledge of any content of mineral oils and natamycin used in coating materials and/or in waxes is necessary to ensure proper handling, treatment and use of the recovered cheese at the subsequent steps in the food chain (see section 4.6).
- Bacterial contamination has caused the declassification (see Sections 4.8 and 4.9). Information must be provided so as to allow the implementation of correct handling procedures that control further proliferation and growth and the application of proper heat treatment as follows:
- where the cheese has exceeded or is likely to exceed, or has a history of exceeding levels of 10^5 cfu/g of coagulase-positive staphylococci.
- where cheese is contaminated with pathogenic bacteria, such information is necessary to implement handling procedures to control growth and proper heat treatment and to facilitate the prevention of cross contamination at every further step in the process, as appropriate.
- where cheese contains extremely high levels of hygiene indicators, such as E. coli or coliforms.
- In accordance with section 4.10.4, information that visible mould present is most likely of [... (*specify mould species*).....] used in the manufacture of [...(*specify cheese variety name*)....].
- Information that the material shall be subject to a heat treatment to re-establish its safety, must be provided when the cheese has been microbiologically contaminated with organisms which require significant reduction. Such information shall be integrated into the statement of intended use, as follows: “*Food Material for further heat processing, only*”

The manufacturer shall always communicate to the subsequent steps in the food chain (through accompanying documents and/or labelling, as appropriate), the temperature conditions as identified by the hazard analysis under which the material must be stored and transported, and – where needed to maintain or control the microbiological suitability of the material – the maximum duration of transport/storage prior to further processing. The communication should be based on the guidance provided in section 5.3.2 and 5.4.5 on how to maintain suitability for further processing during transport and storage.

Cheese that is rejected from the food chain, and which is disposed and used of in other ways, must be labelled in accordance with the requirements of Regulation 1069/2009 (animal by-products).

5.2 General measures applicable during storage and transport

Recovered cheese shall be stored and transported at temperatures as specified by the food establishment responsible for the manufacture.

Packaging material and soft plastic such as ripening film must be kept intact during storage and transport and must not be removed until immediately before actual use, in particular if the material plays a role in protecting

the surface from contamination and/or further deterioration (an exception is the case when the material is kept frozen).

All packaging material and soft plastic such as ripening film must be removed prior to use.

Where the FBO of the previous step of the food chain has specified a time limitation at which the recovered cheese shall have been subjected to further treatment, the subsequent step must respect this. Where no such specification has been made, durability assessment of the material should be conducted. In case of implementation problems, freezing can be introduced to prevent further deterioration in quality.

The manufacturer may specify that microbiologically stable cheese can be transported at temperatures up to 15°C.

Most unripened cheeses²⁰, cheese curd, cheese edges and off-cuts have reduced microbiological stability and must be stored in a cool environment with temperatures not exceeding the temperature specified by the manufacturer. Short time deviation from these temperature requirements does not constitute a microbiological problem and higher temperatures can be acceptable; examples include short time transport, loading/unloading and transport within a food establishment.

The information (section 5.1.3) shall accompany the recovered cheese during storage and transports.

It is important that the recovered cheese can be effectively traced backwards and forwards, from the original manufacturer to the end user. To assist in effective tracking, any registration²¹ made throughout the food chain “cheese as raw material-to-further processing” must be linked to the lot identification provided by the supplier.

Consideration of potential cross-contamination of material that supports the growth of pathogens should be taken into account in the handling of contaminated material and the management (including cleaning) of the storage and processing facilities and during transport.

Specific measures for microbiologically contaminated cheese are addressed in Section 5.4 below.

5.3 General measures applicable at the establishment for further processing

5.3.1 Reception

Upon reception, and prior to any use or storage, all material received must be visually inspected and decisions be taken as regards its acceptance and any restrictions on its usage.

The following must be registered at reception:

- Type of raw material
- Visual state of recovered cheese (e.g. visible mould, cheese mites, dirt, etc.)
- State of packaging material and ripening film
- Information in respect of usage, nature of any contamination and treatment
- Traceability information

Cheese intended for further processing should be traceable back to the original manufacturer. If not, it must not be further processed and be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

If doubts exist as to whether the cheese has been recovered, handled, transported and/or stored in accordance with this Guide, the cheese must be rejected and returned or be disposed of and used in accordance with the animal by-products Regulation 1069/2009. For instance, if doubts exist as to whether the level of coagulase-positive staphylococci exceeds or is likely to have exceeded 10⁵ cfu/g, the material must be rejected.

Any rejected lots and the reason for the rejection must be registered.

In case the recovered cheese fails to be handled in a manner that maintains or controls the suitability of the material according to its intended use, the material must be re-assessed in accordance with Chapter 4.

Any registration made throughout the food chain “cheese as raw material-to-further processing” must be linked to the lot identification provided by the supplier.

²⁰ Excluding cheese that has been subjected to warm-sealed packaging or similar methods that constitute a microbiocidal treatment after fermentation.

²¹ See Regulation (EC) No 931/2011

Specific measures for microbiologically contaminated cheese are addressed in Section 5.4 below.

5.3.2 Storage

Only material that is capable of maintaining suitability for further food processing must be considered for storage (see Chapter 4 for guidance).

Other material that has passed the reception check shall not be stored and shall be used as quickly as possible and without unnecessary delay.

Packaging material and ripening film must be kept intact during storage and must not be removed until immediately before actual use.

The information (section 5.1.3) shall accompany the recovered cheese during storage.

Cheese intended for storage must be handled in a way that does not result in physical damage of the protection of the cheese surface (packaging, coating or dry rind). Dry cheese rind, packaging and coating must be kept intact. In particular, vacuum packaging and ripening films must be handled with care to avoid breakage of the bags as any leak makes oxygen accessible to the moulds. Broken packages must be restored, or repackaging shall occur, unless they are used for further processing as quickly as possible and without unnecessary delay.

Consideration of potential cross-contamination should be taken into account in the planning and maintenance (including cleaning) of storage facilities.

As regards storage temperature, reference is made to Section 5.2.

Where the durability of the recovered cheese impacts on food safety and suitability, adequate stock rotation of each type of cheese shall apply, such as “first in, first out”, picking from the oldest part first, or other adequate approaches. Staff should be trained to dispatch the oldest stock first. Batch coding shall be used to enforce correct stock rotation.

Extended storage of recovered cheese (e.g. for sensory purposes) must be based on validation of historical data and practical experience.

5.3.3 Use

All packaging material and soft plastic including ripening film must be removed prior to use.

5.4 Specific measures according to type of cheese

5.4.1 Coated, waxed or packaged cheese

Storage and transport

Coating, waxes and packaging material must be kept intact during storage and transport.

Handling at destination and prior-to-use treatment

Coating, waxes and packaging material must be kept intact during storage and must not be removed until immediately before actual use.

Coating, waxes and packaging material must be removed prior to use, e.g. by peeling, brushing or rubbing it off. The food safety of the cheese must not be affected by unacceptable levels of residues of chemical food safety hazards such as natamycin and mineral oils²² in coating, waxes and packaging materials. In the case of coating and waxes containing natamycin, at least 5 mm should be removed. Where removal is carried out by applying a specific heat-based removal process, it should be ensured that natamycin and mineral oils present in the coating, waxes and packaging material is not carried over to the cheese.

Removed coating material shall be disposed of and used in accordance with Regulation 1069/2009 (animal by-products).

For further information, see section 4.6.

²² There are two main groups of mineral oils. One is the mineral oil saturated hydrocarbons (MOSH) consisting of alkanes and cyclic alkanes (mineral oil saturated hydrocarbons), and the mineral oil aromatic hydrocarbons (MOAH) consisting of aromatic hydrocarbons. MOAH are potential cancerogenic and genotoxic and contents in food should be minimised. See further details in EFSA Scientific Opinion on Mineral Oil Hydrocarbons in Food, EFSA Journal 2012;10(6):2704.

5.4.2 Unclean cheese

Prior-to-use treatment

Unclean spots that may be present on the surface or crust of cheese must be removed by cutting off, washing, brushing or scrubbing, in accordance with good hygiene practice.

Consideration to potential cross-contamination should be taken into account in the planning and implementation of the removal procedure.

5.4.3 Cheese contaminated with physical hazards

Reception and prior-to-use treatment

Cheese contaminated with hazardous fragments must only be accepted if equipment that effectively is capable of removing such fragments is installed (e.g. use of magnetic fields, sifters or filters) and accepted by the competent authority and/or that appropriate equipment that is capable of effectively detecting such fragments is installed and applied together with a specified sorting procedure that removes contaminated material.

Effective removal of metal is determined by performance of control measures to remove metal objects, e.g.

- filter/sifter sizes
- sensitivity of magnetic separators or magnetic filters

Verification of the removal process can be done by e.g. metal detectors or X-ray examiners.

In particular, verification is necessary when the cheese used is suspected to contain metal objects.

5.4.4 Yeast contaminated cheese

No specific restrictions are needed due to yeast contamination other than what is required to control off-taste (out of scope of the present Guidance).

From a food safety perspective, the time and temperature criteria normally used for the corresponding within-specification counterpart can apply.

5.4.5 Bacteria contaminated cheese– general measures

Storage and transport

Bacterial growth can generally be minimised through time and temperature control²³, which is of particular importance if a reasonable probability exists that the bacteria may produce toxins (e.g. *S. aureus*) while present in the cheese. Where this is an issue, measures include expeditious processing or storage below growth conditions.

5.4.6 Cheese exceeding microbiological criteria for hygiene indicators (including process hygiene criteria)

Coagulase positive staphylococci

Cheese that has been selected for use as raw material for further processing because the microbiological criterion for coagulase-positive staphylococci has been exceeded must be tested to verify that levels do not exceed 10⁵ cfu/g. If this is the case, the material shall be tested for the presence of staphylococcal enterotoxins (absence in 25 g, n=5, c=0, in accordance with Regulation 2073/2005) should be demonstrated.

If staphylococcal enterotoxins are detected, the cheese in question must be disposed of and used in accordance with animal by-products legislation.

For material exceeding the criterion for coagulase-positive staphylococci, time and temperature control shall be required to avoid further growth thus minimising the probability of formation of staphylococcal enterotoxins. The minimum temperature for growth of *S. aureus* is 5.7°C. If kept below such temperature, the duration of storage becomes a non-essential issue.

Integrated treatment to ensure suitability

Cheese exceeding the microbiological criterion for coagulase-positive staphylococci:

²³ Temperature can never be considered in isolation. The time is equally important in microbial control.

- The recovered cheese must be subjected to a heat treatment that delivers a log reduction of min. 8 Log₁₀ cfu/g, which corresponds to keeping the material at a temperature of at least 76°C for 15 sec. or 80°C for 6 sec.²⁴.
- The heat treatment must be monitored and verified as appropriate to the equipment.
- Such heat treatment can be carried out prior to further processing or as an integrated processing step in the manufacture of further processed products.
- Alternative technology (e.g. high pressure) with the same effect (min. 8 Log₁₀ cfu/g reductions of *S. aureus*) can be applied.
- For verification purposes, the end products prepared from recovered cheese of this type must regularly be tested for staphylococcal enterotoxins.

Cheese exceeding other hygiene indicators

No specific restrictions are normally needed other than what is required to control off-taste (out of scope of the present Guidance). From a food safety perspective, the time and temperature criteria normally used for the corresponding within-specification counterpart can apply. However, cheese in which extremely high levels of hygiene indicators have been detected should not be used unless an assessment of potential content of pathogenic microorganisms has been conducted.

Although not required by law, it is recommended to heat-treat recovered cheese that has exceeded microbiological criteria for *process hygiene indicators*. *E. coli* is relatively sensitive to heat, so a heat treatment similar to the one recommended for coagulase positive staphylococci or *L. monocytogenes* will suffice.

5.4.7 Cheese exceeding microbiological criteria for pathogens (including food safety criteria)

Time and temperature control is required to control further growth and thus ensure that heat treatment applied during further processing is actually capable of practically eliminating the pathogens. Time is an issue for the control of *L. monocytogenes* in material that supports the growth of *Listeria* at refrigerated temperatures. Therefore, such cheese contaminated with this pathogen shall be shipped to its destination as quickly as possible and without unnecessary delay. For material not supporting growth, this is not required.

The same approach applies to other pathogens

However, as the minimum temperature for growth of *Salmonella* is 5.7°C, the duration of storage becomes a non-essential issue for any salmonella-contaminated cheese, if it is effectively kept below 6°C.

Consideration should be given to potential cross-contamination of material that supports the growth of pathogens. This should be taken into account in the handling of contaminated material and management (including cleaning) of the storage and processing facilities.

Integrated treatment to ensure suitability

- The recovered cheese must be subjected to a heat treatment that delivers min. 8 Log₁₀ cfu/g reduction.
- For *L. monocytogenes*, this corresponds to keeping the cheese at a temperature of at least 75°C for 15 sec. or 80°C for 3 sec.²⁵.
- For *Salmonella*, heat treatment corresponding to pasteurization will deliver this effect in huge excess.
- For cheese, which has been diverted for further processing because of the criteria for other pathogens have been exceeded, the pathogen-specific time/temperature combinations resulting in 8 Log₁₀ cfu/g reductions should be documented.

Such heat treatment can be carried out prior to further processing or as an integrated processing step in the manufacture of further processed products.

Alternative technology (e.g. high pressure) with the same effect (min. 8 Log₁₀ cfu/g reductions) can be applied.

The heat treatment must be monitored and verified as appropriate to the equipment.

²⁴ Based on D-values for *S. aureus* in milk (Firstenberg-Eden et al: Death and Injury of *Staphylococcus aureus* during thermal treatment of milk, Canadian Journal of Microbiology 23 (1977), 1034-37) with additional +3 °C to compensate for higher fat, dry matter and salt contents (as recommended by US-FDA)

²⁵ Based on D-values for *L. monocytogenes* in milk (Combase data) with additional +3 °C to compensate for higher fat, dry matter and salt contents (as recommended by US-FDA)

5.4.8 Mould contaminated cheese

Preventative measures prior to release

a) Removal of visible mould colonies

Adequate measures must be in place to prevent moulds spreading. Cheeses that are too small for the required mould removal or which have mould filaments deeply penetrating along holes or eyes must not be considered for mould removal.

Small mould colonies on the surface can be scraped off. When removing larger (but few) mould colonies a minimum of 1.3 cm in depth and around the spot²⁶ must be cut off. Also, any discolouring material around the spot needs to be removed. In the case of more mouldy surfaces, a minimum of 1.3 cm in depth needs to be removed. In practice, 2-3 cm should be cut off in order to achieve effective removal. However, if the recovered cheese became mouldy when stored at temperatures above 7°C, a minimum of 2 cm must be removed.

The mould removal must be carried out carefully to minimise the possibility of contaminating the newly exposed cheese surface. Surface that is exposed due to mould removal must be protected through vacuum packaging or modified atmosphere packaging, unless it is frozen.

b) Vacuum or modified atmosphere packaging

Vacuum packaging reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside.

Generally, a combination of more than 50% carbon dioxide and less than 1% oxygen prevents mould growth. As carbon dioxide is typically produced within the package by the cheese itself, the main objective of the packaging process is to remove the oxygen.

Recovered cheese with an incipient development of visible mould need not be vacuum-packaged, provided that the colonies can be effectively removed (see above) and that the material is shipped to its destination and used for further processing as quickly as possible and without any unnecessary delay. However, if it is likely that visible mould colonies develop during transport and storage on recovered cheese that at the time of shipment is not mouldy, the recovered cheese must be effectively vacuum-packaged prior to shipment, as quickly as possible and without any unnecessary delay. The time factor is important, as some (oxygen-dependent) moulds continue growing until a controlled atmosphere is formed within the packaging.

Equipment used to vacuum pack the recovered cheese shall be sufficiently efficient (e.g. electrical pump systems) to achieve low air content and to allow the bags to shape themselves tightly around the material. When the material is vacuum packed in a jar, a vacuum gauge shall be applied.

The bags need to be of materials that provide an oxygen barrier and that are sufficiently flexible. The bags and sealing (heat sealed) must be sufficiently strong to protect against accidental breakage (mould development in vacuum packaging is almost always caused by breached bags or insufficient sealing).

Modified atmosphere packaging is an alternative to vacuum packaging and uses carbon dioxide alone or with nitrogen to achieve less than 0.5% oxygen.

Measures during storage and transport

Fungal growth can generally be minimised through time and temperature control²⁷, which is of particular importance if the fungi of concern are not eliminated during the intended further processing or if there is a reasonable probability that the microorganisms of concern may produce toxins while present in the recovered cheese. The latter relates in particular to specific strains of fungi, which are capable of producing toxins in food when the conditions for such production are met.

Transport and storage at refrigerated temperatures do not prevent mould development, but control growth and, in particular, minimise effectively the likelihood of mycotoxin formation.

Therefore, for recovered cheese with visible mould colonies, with mould colonies removed, or with increased likelihood of developing visible mould colonies, specific time and temperature criteria are required, taking into account minimum temperatures for growth and toxin production, respectively²⁸.

²⁶ Studies on the migration of mycotoxins into cheese rarely show greater than ½ inch/1.3 cm movement into the cheese

²⁷ Temperature can never be considered in isolation. The time is equally important in microbial control.

²⁸ Reported min. temperatures for growth and toxin production, respectively are summarized in the table below. It should be noted that the studies behind this are relatively limited and results of similar studies are hardly comparable and temperature is one aspect for toxin production only.

Microorganism	Min. temperature for growth	Min. temperature for toxin production Depending on toxins
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Such recovered cheese must, when appropriate, be shipped to its destination as quickly as possible and without unnecessary delay. The time and temperature conditions applied should be supported by hazard analysis.

Only a few species of moulds produce toxins at low temperatures and the accumulation of these mycotoxins in cheese is influenced by multiple variables, such as temperature, water activity (aw), pH, and time. Generally, relative humidity and temperature are considered to be the most critical factors. The potential to produce mycotoxin in cheese is lower than in laboratory media, and the lower the temperature the less the risk of mycotoxin production. Generally, storage at refrigerated temperatures, in combination with packaging formats using vacuum or modified atmosphere (MAP), which provides a relatively high concentration of carbon dioxide (>50%) and/or a low concentration of residual oxygen (<0.5%), which will prevent mould growth in cheese.

Consequently, it is important that such material is kept below 6°C until processed.

Handling and treatments intended to restore suitability for consumption

Despite the measures taken at the origin of the material and during transport and storage, mould may still grow, develop visible colonies on or extend the mouldy proportion of the surface of cheese, or may penetrate to the inside along air passages such as holes or eyes.

If the recovered cheese has been prepared, handled and stored according to the recommendations of this Guidance, the likelihood of mycotoxins being present in such recovered cheese is extremely low, and if at all present, will be at very low levels.

Mouldy cheese must be handled as follows:

- a) If the information provided by the supplier specifies that the visible mould species occurring are most likely species typically used in the manufacture of mould ripened cheeses (see 4.10.4), the material can be used in the recipe in amounts not exceeding 10% of the ingoing raw materials, and that the further processing includes an effective heat treatment (see below). If overgrown, it can for sensory reasons be considered feasible to remove all surface material prior to use.

- b) If the information referred to in (a) above is not available, the material can be used in the recipe as follows:

- Cheese with a hard/extra hard texture (MFFB <56%):

In amounts not exceeding 10% of the ingoing raw materials, provided that:

- the proportion of the surface covered with visible mould does not exceed 10%, and
- the further processing includes an effective heat treatment (see below).

If more of the surface is covered, visible mould shall be removed prior to use by cutting off cheese to a depth of a minimum of 1.3 cm.

- Other cheeses:

In unlimited amounts provided that visible mould is removed prior to use by cutting off cheese to a depth of a minimum of 1.3 cm. However, smaller spots occurring on the surface (not exceed 2-3 cm in diameter can be scraped off). In practice, 2-3 cm should be cut off in order to achieve effective removal.

Cheese that does not comply with the above after a possible removal step, shall not be used and must be disposed of and used in accordance with animal by-products legislation.

Broken vacuum packaging and ripening films must be rejected, or, if not mouldy, be used for further processing as quickly as possible and without unnecessary delay.

A. flavus	10 °C	13 °C
A. versicolor	4 °C	9 °C
A. ochraceus	8 °C	10 °C
P. citrinum	5 °C	15 °C
P. commune	0 °C; 10 °C (at 25% CO ₂)	12 °C
P. crustosum	2 °C	4 °C
P. cyclopium (= P. aurantiogriseum)	0 °C	16 °C
P. expansum	0 °C	> 4 °C*
P. nalgiovense	10 °C (at 25% CO ₂)	Not available
P. verrucosum	0 °C; 10 °C (at 25% CO ₂)	0 °C

*) Min. temperature reported reflects the actual conditions of the study. Thus, the real min. temperature has not been identified.

Moulds are readily killed by heat, whereas any concentrations of mycotoxins may be reduced, but not eliminated. Scientific information on heat destruction of mycotoxins is extremely limited only allowing for a default approach to heat treatment.

The processing must include steps that ensure a heat treatment that effectively destroy all filaments. In the absence of scientific evidence of the adequacy of lower process criteria, the default criteria of at least 75°C for a minimum of 1 minute will suffice.

CHAPTER 6 IMPLEMENTATION

6.1 The individual food business operator

In accordance with Regulation 852/2004, the procedure, actions and controls specified in this Guidance are to be implemented in HACCP-based food safety management systems designed and operated by the individual food business, in so far as appropriate to the nature of involvement in the recovery, handling, transport, storage and use of recovered cheese as a raw material.

This should include registration of all parameters specified and procedures that document the decision making that occurs in day-to-day operations.

Effective traceability systems are important for both commercial partners and for public authorities to ensure and subsequently document that the recovered cheese is used as intended. It is the food business operator who assesses the material as regards its suitability for further processing and determines how individual lots are defined. Traceability should be ensured forward and backwards from recovery through to use as an ingredient in the end product.

Conformity with this Guide should be stated in contracts between commercial parties.

6.2 Third party audits

Verification of conformity with this Guide is done through an audit of the documentation furnished by the individual food business operator, supplemented with physical inspection of the premises. It may be necessary to obtain additional information from the steps earlier and/or later in the food chain as part of an assessment of conformity.

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Regulatory references

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

Codex Stan 208/1999 - Codex group standard for cheeses in brine.

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) 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 854/2004 of the European Parliament and of the Council of 29 April 2004 on laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Regulation (EC) No 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 foodstuff.

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.

ANNEX I TO GUIDANCE FOR CHEESE AS A RAW MATERIAL

Overview of use, handling and treatment of recovered cheese for further processing

Type of raw material	Sub-group & type of deviation/ defect	Measures applicable prior to release				Measures applicable during storage & transport	Measures applicable prior to use		
		Assessment of suitable destiny/usage	Handling		Accompanying information		Handling and storage	Assessment of suitability for usage	Specific treatment
			Protection of surfaces	Preventative measures					
1. Cheeses intended for direct consumption	1.1 Non-coated	Suitable for further food processing. See 4.1.	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1.	None required.	No specific information required.	Keep at temperature and within time limits specified by the manufacturer. See 5.2. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Protect from cross contamination. See 5.2 & 5.3.2.	Keep dry rind, packaging and coating intact until actual use. Keep dry rind, packaging and coating intact until actual use. Protect from cross contamination. Adequate stock rotation. See 5.3.2.	Suitable.	Remove packaging material prior to use. Remove unclean spots.
	1.2 Coated				Any content of mineral oils and natamycin used in coating materials and/or in waxes				Remove coating material prior to use (peel, brush or scrub off, or apply a heat-based removal process). See 5.4.1.
2. Pre-packed cheese and cheese cuts returned from the market or retailers	2.1 From wholesale enterprises and retailers approved in accordance with Regulation 853/2004 as specified in section 4.2.1, item A and B	Suitable for further food processing.	Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	None required.	Traceability back to the original manufacturer	Keep at temperature and specified on the label (or in accompanying documents). Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Protect from cross contamination. See 5.2 & 5.3.2.	Keep at temperature and specified on the label (or in accompanying documents). Keep dry rind, packaging and coating intact until actual use. Protect from cross contamination. Adequate stock rotation. See 5.3.2.	Suitable.	Remove packaging and coating material prior to use. See 5.4.1.
	2.2 From other retailers (outlets)	Not permitted by current regulation							

Type of raw material	Sub-group & type of deviation/ defect	Measures applicable prior to release				Measures applicable during storage & transport	Measures applicable prior to use		
		Assessment of suitable destiny/usage	Handling		Accompanying information		Handling and storage	Assessment of suitability for usage	Specific treatment
			Protection of surfaces	Preventative measures					
3. Samples intended for testing and analysis	3.a) Unopened shelf-life reference samples that are held under controlled chilled storage within the manufacturing facilities,	Suitable for further food processing. See 4.3.	Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	None required	Intended usage, e.g. "food for further processing, only". Traceability back to the original manufacturer See 5.1.3.	Keep at temperature and within time limits specified by the manufacturer. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Protect from cross contamination. See 5.2 & 5.3.2.	Keep at temperature and specified on the label (or in accompanying documents). Keep dry rind, packaging and coating intact until actual use. Protect from cross contamination. Adequate stock rotation. See 5.3.2.	Suitable.	Remove packaging, unclean spots and coating material prior to use. Keep at temperature and specified on the label (or accompanying documents).
	3.b) Unopened accelerated reference shelf-life samples that are held under elevated controlled storage conditions within the manufacturing facilities	Suitable for further food processing, if supported by a full food safety evaluation. See 4.3.							
	3.c) Leftovers of samples used for professional sensory testing	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1.							
	3.d) Unopened laboratory samples held in controlled chilled storage	Suitable for further food processing. See 4.3.							
	3.e) Leftovers of laboratory samples that have been opened in laboratory facilities,				According to animal by-products legislation				

Type of raw material	Sub-group & type of deviation/ defect	Measures applicable prior to release				Measures applicable during storage & transport	Measures applicable prior to use		
		Assessment of suitable destiny/usage	Handling		Accompanying information		Handling and storage	Assessment of suitability for usage	Specific treatment
			Protection of surfaces	Preventative measures					
4. Cheese not complying with quality specifications	4.1 Erroneous texture	Suitable for further food processing.	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1.	None required.	No specific information required.	Keep at temperature and within time limits specified by the manufacturer. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Protect from cross contamination. See 5.2 & 5.3.2.	Keep at temperature and specified on the label (or in accompanying documents). Keep dry rind, packaging and coating intact until actual use. Protect from cross contamination. Adequate stock rotation. See 5.3.2.	Suitable.	Remove packaging, unclean spots and coating material prior to use. Keep at temperature and specified on the label (or accompanying documents).
	4.2 Structure defects (e.g. eyes)								
	4.3 White (crystallized) surface								
	4.4 Deviating taste								
	4.5 Compositional non-compliance								
	4.6 Physical damage or deformation of package or cheese								
	4.7 Mislabeled								
5. Physically contaminated cheeses	5.1 Unspecified foreign material	Not suitable for further processing. Disposal and use as ABP. See 4.5.			According to animal by-products legislation				
	5.2 Glass or hard plastic								
	5.3 Metal	Suitable for further food processing, if the fragments are of such nature that they are removable.	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	None required.	Intended usage, e.g. "food for further processing, only" and a statement on the type of contamination. Traceability back to the original manufacturer. See 5.1.3.	Keep at temperature and within time limits specified by the manufacturer. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Protect from cross contamination. See 5.2 & 5.3.2. Clear marking of storage area where the material is located.	Keep at temperature and specified on the label (or in accompanying documents). Keep dry rind, packaging and coating intact until actual use. Clear marking of storage area where the material is located. Protect from cross contamination. Adequate stock rotation. See 5.3.2.	Suitable	Remove effectively the fragments before or during further processing by methods accepted by the competent authority. In particular, metal detectors should be applied to end products if cheese suspected to contain metal objects is processed. See 5.4.3

Type of raw material	Sub-group & type of deviation/ defect	Measures applicable prior to release				Measures applicable during storage & transport	Measures applicable prior to use		
		Assessment of suitable destiny/usage	Handling		Accompanying information		Handling and storage	Assessment of suitability for usage	Specific treatment
			Protection of surfaces	Preventative measures					
6. Chemically contaminated cheeses	Established MLs or MRLs exceeded	Not suitable for further processing. Disposal and use as ABP. See 4.6.				According to animal by-products legislation.			
7. Cheese contaminated with yeast		Suitable for further food processing.	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	None required.	Traceability back to the original manufacturer	Keep at temperature and within time limits specified by the manufacturer. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Protect from cross contamination. See 5.2 & 5.3.2.	Keep at temperature and within time limits specified by the manufacturer. Keep dry rind, packaging and coating intact until actual use. Protect from cross contamination. Adequate stock rotation. See 5.3.2.	Suitable	None required. See 5.4.4

Type of raw material	Sub-group & type of deviation/ defect	Measures applicable prior to release				Measures applicable during storage & transport	Measures applicable prior to use		
		Assessment of suitable destiny/usage	Handling		Accompanying information		Handling and storage	Assessment of suitability for usage	Specific treatment
			Protection of surfaces	Preventative measures					
8. Cheese exceeding microbiological hygiene criteria	8.1 MC for coagulase positive staphylococci exceeded	Suitable for further processing if not exceeding 100,000 cfu/g.		None required.	A statement on the type of contamination. Traceability back to the original manufacturer See 5.1.3.	Keep refrigerated and below temperatures of 6 °C until the material has been received at its final destination. If the cheese supports growth of S. aureus prior to reception at the receiving plant, shipment to its destination should be carried out as quickly as possible and without unnecessary delay, or be stored at temperatures below 5.7°C (see 5.4.6). Clear marking of storage area where the material is located. Protect other product from being contaminated with S. aureus.	Keep dry rind, packaging and coating intact until actual use. Keep refrigerated and below temperatures of 6 °C. Adequate stock rotation. See 5.3.2. If the cheese supports growth of S. aureus it should be used as soon as possible. Protect other product from being contaminated with S. aureus.	Test the material for coagulase positive staphylococci. If exceeding 10 ⁵ , test for presence of staphylococcal enterotoxin. If toxin is detected, the cheese must be disposed and used in accordance with animal by-products legislation. If stored prior to use, test for presence of staphylococcal enterotoxin. If toxin is detected, the cheese must be disposed in accordance with animal by-products legislation	Heat treatment (or equivalent treatments) that delivers at least 8 log reductions of coagulase positive staphylococci.
		Cheese exceeding 100,000 cfu/g is suitable for further processing if detected free of staphylococcal enterotoxins. See 4.8.	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1 Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	Test for staphylococcal enterotoxins.	Intended usage, e.g. "food for further processing, only" and a statement on the type of contamination. Traceability back to the original manufacturer See 5.1.3.				
	8.2 MC for other hygiene indicators exceeded	Suitable for further food processing. See 4.8.	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	None required.	In the case of extremely high levels, a statement on the type of contamination. Traceability back to the original manufacturer See 5.1.3.				

Type of raw material	Sub-group & type of deviation/ defect	Measures applicable prior to release				Measures applicable during storage & transport	Measures applicable prior to use			
		Assessment of suitable destiny/usage	Handling		Accompanying information		Handling and storage	Assessment of suitability for usage	Specific treatment	
			Protection of surfaces	Preventative measures						
9. Cheese exceeding microbiological food safety criteria for micro-organisms	9.1 Cheese supporting growth of the pathogen causing the deviation	Suitable for further food processing. See 4.9.	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating See 5.1.1.	Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	None required.	Intended usage, e.g. "food for further processing, only" and a statement on the type of contamination. Traceability back to the original manufacturer See 5.1.3.	Keep refrigerated and below temperatures of 6 °C until the material has been received at its final destination. Shipment to its destination should be carried out as quickly as possible and without unnecessary delay. Where needed to assure this, a maximum time limit should be specified. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Clear marking of storage area where the material is located. Protect other product from being contaminated with pathogens. See 5.2 & 5.3.2.	Keep dry rind, packaging and coating intact until actual use. Keep refrigerated and below temperatures of 6 °C. Adequate stock rotation. See 5.3.2. The cheese material should be used as soon as possible. Protect other product from being contaminated with S. aureus and pathogens.	Suitable.	Heat treatment (or equivalent treatments) that delivers at least 8 log reductions of the pathogen(s) in question.
	9.1 Cheese not supporting growth of the pathogen causing the deviation					Keep at temperature and within time limits specified by the manufacturer. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Clear marking of storage area where the material is located. Protect other product from being contaminated with pathogens. See 5.2 & 5.3.2.	Keep at temperature and within time limits specified by the manufacturer. Keep dry rind, packaging and coating intact until actual use. Protect from cross contamination. Adequate stock rotation. See 5.3.2.	Suitable.		

Type of raw material	Sub-group & type of deviation/ defect	Measures applicable prior to release				Measures applicable during storage & transport	Measures applicable prior to use		
		Assessment of suitable destiny/usage	Handling		Accompanying information		Handling and storage	Assessment of suitability for usage	Specific treatment
			Protection of surfaces	Preventative measures					
10. Cheese with undesired mould colonies	10.1 Visible mould colonies that most likely are species typically used in the manufacture of mould ripened cheeses.	Suitable for further food processing. See 4.10.1.	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1 & 5.4.8.	None required.	Intended usage, e.g. "food for further heat processing, only". Traceability back to the original manufacturer See 5.1.3 A statement on the mould species most likely to constitute the contamination.	Keep refrigerated and below temperatures of 6 °C until the material has been received at its final destination. Shipment to its destination should be carried out as quickly as possible and without unnecessary delay. Where needed to assure this, a maximum time limit should be specified. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Handle with care to avoid breakage of vacuum packaging. See 5.2 & 5.3.2. Clear marking of storage area where the material is located.	Keep refrigerated and below temperatures of 6 °C. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Handle with care to avoid breakage of vacuum packaging. Clear marking of storage area where the material is located. Adequate stock rotation. See 5.3.2.	Mouldy material must not exceed 10% of ingoing raw materials used in the recipe. Excessive mould on the surface shall be removed. See 5.4.8.	Heat treatment at least 75 °C for at least 1 minute.

Type of raw material	Sub-group & type of deviation/ defect		Measures applicable prior to release				Measures applicable during storage & transport	Measures applicable prior to use					
			Assessment of suitable destiny/ usage	Handling		Accompanying information		Handling and storage	Assessment of suitability for usage	Specific treatment			
				Protection of surfaces	Preventative measures								
10. (cont'd) Cheese with undesired mould colonies	10.2 Visible mould where it cannot be substantiated that they are likely to be species typically used in the manufacture of mould-ripened cheese (i.e. not covered by 10.2 above).	Hard and extra hard cheese where no more than approx. 10% of the surface is covered with mould	Suitable for further food processing. See 4.10.4.	If protective rind is not present or has been removed, and unless frozen, the material should be vacuum packaged or packed in modified atmosphere as quickly as possible and without unnecessary delay in sufficiently strong bags and with effective sealing. See 5.4.8 (b). Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	None required.	Intended usage, e.g. "food for further heat processing, only". Traceability back to the original manufacturer See 5.1.3	Keep refrigerated and below temperatures of 6 °C until the material has been received at its final destination. Shipment to its destination should be carried out as quickly as possible and without unnecessary delay. Where needed to assure this, a maximum time limit should be specified.	Handle with care to avoid breakage of vacuum packaging. Clear marking of storage area where the material is located.	Handle with care to avoid breakage of vacuum packaging.	Mouldy material must not exceed 10% of ingoing raw materials used in the recipe. The proportion of the surface of the material covered with visual mould must not exceed 10%.	Heat treatment at least 75 °C for at least 1 minute. If more than 10% of the surface is covered, removal of 2-3 cm in depth of contaminated surface. See 5.4.8.		
		Hard and extra hard cheese where > approx. 10% of the surface is covered with mould		Unless frozen, the material should be vacuum packaged or packed in modified atmosphere as quickly as possible and without unnecessary delay in sufficiently strong bags and with effective sealing. See 5.4.8 (b). Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	Removal of contaminated surface See 5.4.8 (a).				Intended usage, e.g. "food for further heat processing, only". Traceability back to the original manufacturer See 5.1.3	Handle with care to avoid breakage of vacuum packaging. Clear marking of storage area where the material is located.	Unless frozen, do not store broken vacuum packaging.	Suitable, if visible mould has been removed to a practically extend.	Visible moulds must be removed by removing 2-3 cm in depth. See 5.4.8.
		Other cheese where ≤ approx. 10% of the surface is covered with mould		Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1 Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	Removal of contaminated surface See 5.4.8.						Clear marking of storage area where the material is located. Adequate stock rotation. See 5.3.2.	Suitable, if visible mould has been removed to a practically extend.	Visible moulds must be removed by removing 2-3 cm in depth. See 5.4.8.
		Other cheese with only smaller mould spots on the surface (<2-3cm in diameter)		Scraping of all spots.	Suitable, if no visible mould left.							Scrape off the mould spots. See 5.4.8.	

Type of raw material	Sub-group & type of deviation/ defect	Measures applicable prior to release				Measures applicable during storage & transport	Measures applicable prior to use		
		Assessment of suitable destiny/ usage	Handling		Accompanying information		Handling and storage	Assessment of suitability for usage	Specific treatment
			Protection of surfaces	Preventative measures					
10. (cont'd) Cheese with undesired mould colonies	10.3 Cheese combined with flavouring foods (e.g. herbs, spices and fruits)	Suitable if the specific assessment determines that any additional mould species can be controlled by the measures already in place to ensure that the possibility of mycotoxin formation is minimised See 4.10.4							
	Cheese not complying with 10.1, 10.2 or 10.3 above	Disposal and use as ABP			According to animal by-products legislation				Disposal
11. Line recoveries	11.1 Cheese edges off-cuts	Suitable for further food processing. See 4.11.	Unless frozen, the material should be vacuum packaged or packed in modified atmosphere as quickly as possible and without unnecessary delay in sufficiently strong bags and with effective sealing. See 5.4.8 (b).	None required.	No specific information required. Traceability back to the original manufacturer See 5.1.3	Keep refrigerated and below temperatures of 6 °C until the material has been received at its final destination. Handle with care to avoid breakage of vacuum packaging.	Handle with care to avoid breakage of vacuum packaging. Unless frozen, do not store broken vacuum packaging. Keep refrigerated and below 6 °C. Adequate stock rotation. See 5.3.2. Cheese curd that is more than 4 days old should be heat treated prior to or as part of the processing.	Suitable.	None required.
	11.2 Cheese curd								
	11.3 Floor sweepings	Disposal and use as ABP See 4.11.3.			According to animal by-products legislation.				

Type of raw material	Sub-group & type of deviation/ defect	Measures applicable prior to release				Measures applicable during storage & transport	Measures applicable prior to use		
		Assessment of suitable destiny/ usage	Handling		Accompanying information		Handling and storage	Assessment of suitability for usage	Specific treatment
			Protection of surfaces	Preventative measures					
12. Cheese exceeding age specifications	12.1 Exceeding pre-established durability date	Further food processing.	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	None required.	Intended usage, e.g. "food for further processing, only". Traceability back to the original manufacturer See 5.1.3	Keep at temperature and within time limits specified by the manufacturer. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Clear marking of storage area where the material is located. See 5.2 & 5.3.2.	Unless frozen, keep dry rind, packaging and coating intact until actual use. Adequate stock rotation. See 5.3.2.	Suitable.	None required.
	12.2 Exceeding pre-established use-by date	Disposal and use as ABP See 4.12.2.			According to animal by-products legislation.				
13. Cheese contaminated with cheese mites		Cleaned cheese is suitable for further food processing.	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1 Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	None required.	Intended usage, e.g. "food for further heat processing, only". Traceability back to the original manufacturer See 5.1.3	Keep at temperature and within time limits specified by the manufacturer. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Clear marking of storage area where the material is located.	Handle with care to avoid breakage of vacuum packaging. Unless frozen, do not store broken vacuum packaging. Keep refrigerated and below 6°C. Adequate stock rotation. See 5.3.2.	Suitable.	Remove contaminated material. Heat treatment at least 75°C for at least 1 minute.
		Infested parts of cheese disposed of as ABP. See 4.13.			According to animal by-products legislation.				

Type of raw material	Sub-group & type of deviation/ defect	Measures applicable prior to release				Measures applicable during storage & transport	Measures applicable prior to use		
		Assessment of suitable destiny/usage	Handling		Accompanying information		Handling and storage	Assessment of suitability for usage	Specific treatment
			Protection of surfaces	Preventative measures					
14. Deteriorated cheese	14.1 Cheese contamination with other pests	Disposal and used as ABP. See 4.14.				According to animal by-products legislation.			
	14.2 Protein or fat decomposition	Suitable for further food processing.	Packaging if not already packaged, frozen and/or protected by an intact dry rind or coating. See 5.1.1. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2.	None required.	Intended usage, e.g. "food for further processing, only" Traceability back to the original manufacturer See 5.1.3	Keep at temperature and within time limits specified by the manufacturer. Avoid physical damage of the protective cheese surface and keep dry rind, packaging and coating intact. See 5.1.2. Clear marking of storage area where the material is located.	Handle with care to avoid breakage of vacuum packaging. Unless frozen, do not store broken vacuum packaging. Keep refrigerated and below 6°C. Adequate stock rotation. See 5.3.2.	Suitable.	
	14.3 Nauseous taste and smell	Disposal and use as ABP. See 4.14.				According to animal by-products legislation.			

ANNEX II TO GUIDANCE FOR CHEESE AS A RAW MATERIAL

Scientific documentation for control of mould and mycotoxins in cheese

The EDA/EUCOLAIT Guide on Cheese as Raw Material provides guidance on the assessment, preparation, handling and use of cheese that is contaminated with undesired mould.

This paper provides the scientific references for the control strategy as well as for additional precautionary measures applied as extra safety margins to minimise any risk associated with unforeseeable presence of mycotoxins at low levels.

1. SUMMARY

Experiments published in scientific literature strongly indicate that prevention of mycotoxin formation on cheese by contaminating moulds can be achieved through controlling the growth of moulds and the conditions impacting mycotoxin formation.

Literature points out the mycotoxins of importance for cheese to be sterigmatocystin, cyclopiazonic acid, ochratoxin A, penicillin A, aflatoxin B₁/G₁ and citrinin.

Among the mould species growing on cheese, literature identifies *A. versicolor*, *A. flavus*, *A. paraciticus*, *P. commune*, *P. nordicum*, *P. crustosum*, *P. citrinin* and *P. verrucosum* as the species that have been shown to be able to produce these toxins.

Note: Most of the experimental work on mycotoxin production has been carried out at room temperatures (20-30°C), under aerobic conditions and by growing mould species isolated from cheese on various types of agar plates (i.e. a different substrate than cheese).

Growth of the relevant mould species can be controlled by the 3 control measures (i) surface protection, (ii) restricted oxygen access and (iii) low temperature.

Whether moulds capable of producing mycotoxins actually do so depends on the substrate (cheese is a poor substrate) and temperatures that typically are higher than minimum temperatures for growth. From the various reports of experimental work on mycotoxin formation on cheese, it can be concluded that mycotoxins are not likely to be formed, when cheese is kept under refrigerated conditions (i.e. temperatures below 9°C).

The EDA/EUCOLAIT Guide therefore focuses on the prevention of mycotoxin formation by the contaminating moulds by controlling growth and conditions impacting mycotoxin formation, i.e. surface protection, restricted oxygen access and refrigerated storage and transport.

Additional precautionary measures are required by the EDA/EUCOLAIT Guide to provide extra safety margins to minimise any risk associated with unforeseeable presence of mycotoxins at low levels. These precautionary measures are

- (i) cutting off established mould/scraping off mould spots,
- (ii) heat treatment and
- (iii) restrictions of shares of moulded surfaces of ingoing cheese.

The guidance provided on cutting off is based on scientific recommendations and existing risk management practices in certain countries.

2. HAZARD IDENTIFICATION

2.1 Most of the contaminating mould species are not capable of producing mycotoxins²⁹

Visible mould is not evidence of the presence of mycotoxins, but an indicator of an increased probability of toxin formation.

Cheese is a good substrate for mould growth but a poor substrate for mycotoxin production³⁰. However, only a small percentage (2-15%) of the moulds commonly found growing on cheese are capable of producing mycotoxins. For instance, **Bullerman (1981)** found that 1.8-12.4% of the species isolated from cheese were capable of producing the commonly studied mycotoxins, when grown on optimized substrates.

In most cases, the mycoflora of non-mould ripened cheese are contaminating moulds of the species used as starter cultures.

The following is to be observed as regards cheese contaminating moulds:

- A limited number of *Penicillium* species typically count for 70-90%;
- A few *Aspergillus* species count for 4-8% (*A. versicolor* being the most frequent); and
- Species of *Cladosporium* (*C. cladosporoides*, *C. herbarum*), *Alternaria*, *Phoma*, *Scopulariopsis* (*S. brevicaulis*) and *Fusarium* (*F. dimerum*, *F. domesticum*, *F. oxysporum*) may occasionally be present.

Among the non-starter species that develop into visible colonies during chilled storage are almost all *Penicillium* species (typically *P. brevicompactum*, *P. caseifulvum*, *P. citrinum*, *P. crysogenum*, *P. commune*, *P. discolor*, *P. nordicum*, *P. expansum*, *P. nalgiovense*, *P. solitum*, *P. verrucosum*, *P. viridicatum*), as they in contrast to other relevant mycoflora, may grow at low temperatures.

Among these, *P. commune* and *P. nalgiovense* are dominating. *P. commune* is the wild type ancestor of *P. camemberti*³¹.

P. commune is well adapted to growth on cheese (has the enzymes necessary). *P. commune* appears typically together with *P. nalgiovense*, which is a starter culture used in salami production³².

2.2 Mycotoxin formation requires growth

It is important to distinguish between fungi that can be isolated from cheese and those that may grow.

Lund et al (1995) showed that the fungal flora in manufacturing environments and the flora on cheese differs, and that several environmental fungi can be isolated from cheese, despite that they do not grow. Similar findings were made by others³³. These species are survivors of fungal spores from various sources (environment, smear, etc.). An example is *A. versicolor* that may dominate the environment in a cheese factory, but rarely grow on cheese³⁴.

Mould is generally visible when above 10³/ml to 10⁴/ml³⁵. Visible mould means that growth has occurred (but stopped) or is still occurring.

It should be noted that most of the experimental work on mycotoxin production has been carried out at room temperatures (20-30°C), under aerobic conditions and by growing mould species isolated from cheese on various types agar plates (i.e. a different substrate than cheese).

²⁹ Sources: Bullerman & Olivigni (1974), Bullerman (1979), Bullerman (1981), Scott (1983), Lund et al (1995), Filtenborg et al (1996), López-Díaz et al (1996), Nielsen et al (1996), Terplan & Kaiser (1996), Larsen et al (2002), Sengun et al (2008).

³⁰ Larsen et al (2002).

³¹ Haasum & Nielsen (1998).

³² Lund et al (1995)

³³ Kure et al (2004)

³⁴ Lund et al (1995)

³⁵ Lund et al (1995)

2.3 Mycotoxins of importance

Cheese is a poor substrate for mycotoxin production³⁶, particularly when stored at 5-7°C³⁷. The explanation is that cheese is rich in protein containing sulphhydryl such as cysteine and glutathione and that the activities of lactic acid bacteria, which are present in most cheese types, impact the ability of mycotoxin formation by many mould species³⁸.

The most common mycotoxins that are stable in cheese are citrinin, cyclopiazonic acid, penicillium A, roquefortine C, sterigmatocystin and aflatoxin³⁹.

Cold storage results in favouring species and strains that are capable of producing less stable toxins such as penicillinic acid, patulin, mycophenolic acid as well as penicillium A and possibly ochratoxin on the expense of producers of aflatoxins and sterigmatocystin. Due to their instability, it is not likely that penicillinic acid, patulin and mycophenolic acid will be present at any significant level⁴⁰.

As stated in a scientific review from 2008, “the significance of patulin, penicillinic acid, and mycophenolic acid in cheese in small amounts is probably not great from a public health standpoint because of their low oral toxicity while sterigmatocystin is of more concern because of its carcinogenicity”⁴¹.

Northolt concluded that in mould contaminated cheese, the most important toxin is sterigmatocystin⁴². This was confirmed by others⁴³.

Taking into account all references available, the important mycotoxins relevant for safety of mould contaminated cheese are:

- Sterigmatocystin, which can be produced by *A. versicolor*⁴⁴. Sterigmatocystin is among the most commonly detected mycotoxin in moulded cheese⁴⁵;
- Cyclopiazonic acid, which can be produced by *P. commune*⁴⁶;
- Ochratoxin A, which can be produced by *P. commune*⁴⁷, *P. nordicum*⁴⁸ and *P. verrucosum*⁴⁹;
- Penicillium A, which can be produced by *P. crustosum*⁵⁰;
- Aflatoxin B₁/G₁ can be produced by *A. flavus* and *A. parviticus*⁵¹;
- Citrinin, which can be produced mainly by *P. citrinin*, but has also been reported to be produced by *P. verrucosum*⁵².

Note: Any aflatoxin M₁ present is most likely due to presence in the milk used to manufacture the cheese.

³⁶ Lopes-Diaz et al (1996), Frisvad (1988), (FDA 1985), Larsen et al (2002)

³⁷ Bullerman (1981)

³⁸ Dalié et al (2010)

³⁹ Taniwaki et al (2001)

⁴⁰ Bullerman (1981), Stott & Bullerman (1976), Lieu & Bullerman (1977)

⁴¹ Sengun et al (2008)

⁴² Northolt et al (1980)

⁴³ Filtenborg et al (1996)

⁴⁴ Lund et al (1995)

⁴⁵ Filtenborg (1996), Northolt et al (1980), Taniwaki et al (2001)

⁴⁶ Taniwaki et al (2001), Lund et al (1995)

⁴⁷ Bullerman (1981)

⁴⁸ Larsen et al (2002), Kokkonen et al (2005)

⁴⁹ Kokkonen et al (2005)

⁵⁰ Kokkonen et al (2005)

⁵¹ Bullerman & Olivigni (1974), Gourama & Bullerman (1995)

⁵² Bailly et al (2002), Sengun et al (2008), Frisvad & Nielsen (2012), Sweeney & Dobson (1998)

2.4 Conclusion

Mould control in cheese can be designed to control the two important species as follows:

- *Penicillium* species, in particular *P. commune* (= *P. cyclopium*) and *P. nagliovese*; and
- *Aspergillus* species, in particular *A. versicolor*.

Other species mentioned in the literature as associated with cheese may be present in small amounts but they will not grow to any significant levels; consequently, any mycotoxins that they may be able to form, will not appear in any significant concentration.

Focus shall be on the important mycotoxins sterigmatocystin, cyclopiazonic acid, ochratoxin A, Aflatoxin B₁/G1, citrinin and penicillic acid. Among the mould species growing on cheese, *A. versicolor*, *A. flavus*, *A. paraciticus*, *P. commune*, *P. nordicum*, *P. crustotum*, *P. citrinin* and *P. verrucosum* have been shown to be able produce them.

Other mycotoxins that in literature are associated with cheese are only likely to be present in amounts that are insignificant to human health.

Based on research findings to date, the level of mycotoxin contamination is likely to be low, even if mould growth does occur on cheese

3. MYCOTOXIN CONTROL

3.1 Factors impacting mycotoxin formation

Mycotoxins are secondary metabolites, i.e. their formation does not play a role in the normal metabolism associated with the growth of colonies.

Prerequisites for the formation of mycotoxins in cheese are:

- The strains shall be genetically capable of producing mycotoxins, AND
- The mould shall be growing⁵³, AND
- The specific conditions for the formation of the toxin during growth shall be met.

Growth/no growth of mould depend on temperature, access to oxygen, CO₂, accessible humidity and other factors. Mould colonies, like bacteria, have a lag phase prior to growth⁵⁴.

For instance, lag time of *P. expansum* was determined to be 182±25 hrs. at 5.2°C⁵⁵.

For those strains that are capable of producing mycotoxins, toxin production does not correlate with mould growth.

The capability of mould to form mycotoxins decreases with water activity and increases with temperature up to the optimum growth temperature – at temperatures above optimum, it decreases again⁵⁶. However, in general, the water activity in cheese is too high to have any impact on mould growth or on the ability to form mycotoxins.

Activities of lactic acid bacteria also impact the ability of toxin formation by many mould species⁵⁷.

⁵³ Lund et al (1995)

⁵⁴ Garcia et al (2009)

⁵⁵ Gougouli & Koutsoumanis (2013)

⁵⁶ WHO (2002), US FDA (2005), Takahashi & Yazaki (2007)

⁵⁷ Dalié et al (2010)

3.2 Oxygen access

Moulds are aerobic organisms that require oxygen to grow. Oxygen content on the surface of cheese can be reduced through vacuum packaging and packaging in modified atmosphere (MAP).

Vacuum packaging is recommended as it reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside and thus prevents/stops growth of most mould species. As carbon dioxide is typically produced within the package by the cheese itself, the main objective of the packaging process is to remove the oxygen.

Smith et al (1986) has previously demonstrated that total inhibition of fungal growth in packaged bakery products is only possible if head space O₂ is reduced and maintained at levels below 0.4%.

The most extensive study on mould growth and mycotoxin production under MAP conditions on cheese surface was carried out by **Taniwaki et al (2001)**. They conclude as follows:

- MAP has a strong inhibitory effect on mycotoxin production.
- CPA produced by *P. commune* at 25°C after 14 days but not at 8-10°C after 1 month, suggesting that CPA is not formed under refrigerated conditions.
- CPA formation can be prevented if adequate modified atmosphere packaging is used. O₂ <0.5% will prevent growth, while 20-40% CO₂ and 1% O₂ will reduce CPA production to very low levels.

Aflatoxin production by *A. flavus* and *A. paraciticus* is inhibited by reduction of available oxygen through MAP, barrier film or oxygen scavengers inside the packaging⁵⁸.

The inhibitory properties of carbon dioxide have been clearly demonstrated by **Eliot et al (1998)** and **Haasum & Nielsen (1998)**.

3.3 Protection of open surfaces

Cheese rind, cheese coating, packaging materials, in particular ripening film and vacuum packaging, protect the more moist parts of the cheese and thus assist in preventing mould growth.

Broken packages, broken coatings and broken rind increase the risk of mould growth.

3.4 Temperature

3.4.1 Penetrim A

Penetrim A is, if present in cheese, most likely to origin from *P. crustosum*.

The minimum conditions for toxin formation are reported as 10°C and a_w 0.92⁵⁹.

It can be concluded, that Penetrim A is not likely to be formed in cheese kept <10°C.

3.4.2 Ochratoxin A (OTA)

OTA is, if present in cheese, most likely to origin from *P. commune*. Growth of *P. verrucosum* may also be the cause.

P. commune (= *P. cyclopium*) requires min. 20°C to form OTA on cheese⁶⁰, which is above the normal temperatures used for the ripening of firm cheeses. Despite that *P. commune* is likely to grow during refrigerated conditions (see 1.1 above), the risk of OTA formation is considered insignificant, provided that the cheese is kept under refrigerated conditions.

P. nordicum is genetically very close to *P. verrocusum* and behave like that species.

⁵⁸ Sweeney & Dobson (1998)

⁵⁹ ICMSF (1996)

⁶⁰ Scott (1983)

On the right substrate, *P. verrucosum* can form OTA at all growth temperatures, i.e. from 0-31°C, with optimum at approx. 20°C. The amount formed correlates with growth rates⁶¹, which depend on substrate and temperature. OTA levels that may be formed on cheese and under refrigerated conditions, respectively, are low⁶². Cheese substrate seems to be unsuitable for *P. verrucosum* to produce OTA⁶³.

P. verrucosum is mostly found in the early phases of cheese ripening, and mainly in cold storages⁶⁴ and seldom on finished cheese. It is very sensitive to elevated CO₂ concentrations and do not grow at concentrations from 25%⁶⁵.

It has been reported that lactic acid bacteria metabolize OTA to various extents (8-28%)⁶⁶. Others reported that OTA content in hard cheese is halved after 48 hrs. at 25°C⁶⁷.

It can be concluded, that OTA is not likely to be formed in finished cheese kept under refrigerated conditions.

3.4.3 Sterigmatocystin

Sterigmatocystin is, if present in cheese, most likely to origin from *A. versicolor*.

Investigations have shown that *A. versicolor* does not produce sterigmatocystin on cheese at 25°C (tilsit, edam, gouda). This is in contrast to other studies, where this toxin is formed from naturally contaminating *A. versicolor*⁶⁸.

However, at refrigeration temperatures growth does hardly occur and toxins are not formed. The following conclusions from various publications support this:

- *A. versicolor* can grow at 4°C and can dominate ripening rooms, but the species rarely grow on cheese⁶⁹;
- Minimum growth temperature of 9°C has been reported⁷⁰. Although growth occurs, no toxins have been found at refrigeration temperatures⁷¹;
- Experiments on various cheese types could not detect sterigmatocystin after growth of otherwise toxin producing *A. versicolor* on cheese for 6 months at 10°C⁷²;
- Refrigeration prevent toxin formation from *Aspergillus*⁷³;
- Low temperatures (5°C) prevent growth of *A. versicolor* and production of sterigmatocystin⁷⁴.

The toxin appears to be highly stable in cheese⁷⁵.

It can be concluded, that sterigmatocystin is not likely to be formed in cheese kept <9°C.

⁶¹ Takahashi & Yazaki (2007)

⁶² Takahashi & Yazaki (2007)

⁶³ Kokkonen et al (2005)

⁶⁴ Lund et al (1995)

⁶⁵ Haasum & Nielsen (1998)

⁶⁶ Dalié et al (2010)

⁶⁷ Bullerman (1981)

⁶⁸ Scott (1983), Northolt et al (1980)

⁶⁹ Lund et al (1995)

⁷⁰ ICMSF (1996)

⁷¹ Bullerman & Olivigni (1974), Lund et al (1995)

⁷² Terplan & Kaiser (1996)

⁷³ Bullerman (1979)

⁷⁴ Bullerman (1981)

⁷⁵ Metwally et al (1997)

3.4.4 Cyclopiazonic acid (CPA)

Cyclopiazonic acid (CPA) is, if present in cheese, most likely to origin from *P. commune*.

This organism can produce the toxin at 25°C, but not under refrigerated conditions⁷⁶, <12°C.

It can be concluded, that CPA is not likely to be formed in cheese kept <12°C.

3.4.5 Aflatoxin B₁/G₁

Aflatoxin B₁/G₁ is, if present in cheese, most likely to origin from *A. flavus* or *A. paraciticus*.

pH values below pH favour the formation of aflatoxin B₁ rather than aflatoxin G₁⁷⁷.

These organisms can produce low levels of aflatoxins in cheese at room temperatures, but not <10°C⁷⁸ or <12°C⁷⁹.

Aflatoxins are relatively stable in cheese.

It can be concluded, that aflatoxin G₁ is not likely to be formed in cheese, and that aflatoxin B₁ is not likely to be formed in cheese kept <10°C.

3.4.6 Citrinin

Citrinin is, if present in cheese, most likely to origin from *P. citrinin* or *P. verrocusum*.

P. citrinin can grow between 5 and 40°C *(optimum 26-30°C), but citrinin is only produced in the temperature range 15-37°C⁸⁰. This is also confirmed in experimental work on various cheese types⁸¹.

Experiments have shown that *P. verrocusum* strains capable of producing citrinin on meat did not form any when grown on cheese⁸². The lack of the ability to produce citrinin in cheese has been confirmed by others⁸³.

It can be concluded, that citrinin is not likely to be formed in cheese kept <15°C.

Note: Presence of propionic acid destroys citrinin⁸⁴. Propionic acid is present in Emmental, Jarlsberg and similar cheeses.

3.5 Conclusion

Growth of the important contaminating mould species is controlled through

- Surface protection
- Oxygen access
- Temperature control

Mycotoxin formation is prevented through temperature control.

Whether moulds capable of producing mycotoxins actually do so depends on the substrate (cheese is a poor substrate) and on temperatures; typically, higher temperatures than minimum temperatures for growth are needed.

⁷⁶ Taniwaki et al (2001)

⁷⁷ Bullerman & Olivigni (1974), Gourama & Bullerman (1995)

⁷⁸ Bullerman & Olivigni (1974), Bullerman (1981)

⁷⁹ Sweeney & Dobson (1998)

⁸⁰ Sweeney & Dobson (1998)

⁸¹ Terplan & Kaiser (1996)

⁸² Takahashi & Yazaki (2007)

⁸³ Lund et al (1995), Kokkonen et al (2005)

⁸⁴ EMAN (2013)

From the various reports of experimental work on mycotoxin formation on cheese it can be concluded that mycotoxins are not likely to be formed, when cheese is kept under refrigerated conditions (i.e. temperatures below 9°C).

4. SUPPLEMENTARY PRECAUTIONARY MEASURES

The EDA/EUCOLAIT Guide relies on measures that prevent mycotoxin formation.

When these measures are implemented and followed, the risk of mycotoxins being present is very low.

However, as the correct implementation of these measures is associated with some uncertainty, additional precautionary measures are recommended. These additional measures are intended to minimise risk associated with the potential presence of mycotoxins in the recovered cheese due to this uncertainty.

4.1 Cutting off established mould/scraping off mould spots

Mycotoxins, if developed at all, are formed by the mould filaments and will therefore be present near the surface⁸⁵. The peak production occurs in the centre of the colony⁸⁶. In some firm (< 60% MFFB11) and all hard and extra hard cheeses, any mycotoxins formed near the surface will not diffuse into the interior of the cheese. There is a likelihood of diffusion in the case of cheese with higher moisture contents.

A number of experiments have been carried out to determine how far mycotoxins penetrate into cheese. These are mainly concerning the aflatoxins, although some experiments have involved sterigmatocystin, ochratoxin A, citrinin, patulin and penicillic acid. These experiments have demonstrated that toxins generally stay within 0.5-2 cm from the cheese surface⁸⁷.

Literature generally advice that 1-2 cm is cut off to ensure that mycotoxins that may have been formed will be practically removed.

The EDA/EUCOLAIT Guide recommends minimum 1.3 cm (=1 inch), which is based on the UK FSA Cheese Recovery Guidance (2007), US FDA guidance (2005) and scientific references⁸⁸. In practice, 2-3 cm will be cut off in order to achieve effective removal of 1.3 cm.

4.2 Heat treatment

Mycotoxins are relative heat stable, whereas moulds are readily killed by heat. Any concentrations of mycotoxins may be reduced by heat treatment, but they will not be eliminated. Scientific information on heat destruction of mycotoxins is extremely limited. This only allows for a default approach to heat treatment.

The processing must include steps that ensure a heat treatment that effectively destroy all mould filaments so as to prevent transfer of living cells from raw material to end products. In the absence of scientific evidence of the adequacy of lower process criteria, the default criteria of at least 75°C for a minimum of 1 minute is used.

Citrinin decomposes under semi-moist conditions at a temperature of about 140°C⁸⁹.

4.3 Restrictions of shares of moulded surfaces of ingoing recovered cheese

For practical reasons, a maximum tolerance relating to the share of mould contaminated cheese surface to be used, either prior to cutting off or after cutting off is recommended. The chosen numerical limit of 10% based on the UK FSA Cheese Recovery Guidance (2007).

The EDA/EUCOLAIT Guide includes restrictions on the share of moulded cheese used, as follows:

1. Firm and soft cheese. Visible mould shall be cut off (spots can be scraped off). The cleaned material can then be used, but at a maximum of 10% of the raw materials used. This additional precaution has

⁸⁵ FDA (2005)

⁸⁶ Garcia et al (2009)

⁸⁷ Bullerman (1981), Scott (1983), Ostry et al (2004)

⁸⁸ Bullerman (1981), Terplan & Kaiser (1996), Sengun et al (2008)

⁸⁹ EMAN (2013)

been introduced due to an increased risk that mycotoxins present on the surface may penetrate to the core of the cheese.

2. Hard and extra hard cheese: Visible mould covering less than 10% of the surface can be used
 - directly, but the share of the raw materials used shall be less than 10%. This additional precaution has been introduced for practical reasons and as any mycotoxins present will be in very low concentrations. The amount of moulded material used in this case will be <1% of the raw material used (1% only, all the material consists of surfaces (e.g. trimmings, slices).

The above precautionary measure has not been addressed in the scientific literature.

4.4 Conclusion

Additional safeguards are applied by removing filaments and the major part of the mycelium where mould become visible above tolerances, by heat treatment and by restricting use of mould contaminated material.

If a minimum of 1.3 cm is established, 2-3 cm will be cut off in practice. This would be sufficient to remove any mycotoxins that might be present at this stage, despite the other controls.

Implementing the above strategy will result in insignificant risk from the further processed foods.

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