

When approval is required the competent authority will make an on-site visit. According to Regulation 854/2004 the competent authority may grant conditional approval if the on-site visit shows that the establishment meets all the infrastructure and equipment requirements. Full approval is granted if it appears from a new on-site visit (within three months after granting conditional approval) that the establishment meets the requirements on hygiene as provided in Regulations 852/2004 and 853/2004. In case the establishment does not meet the requirements, but clear progress is made in this context, the competent authority may prolong conditional approval. Conditional approval is not allowed to exceed a total of 6 months.

An approved establishment, including conditionally approved, will receive an approval number from the competent authority, to which codes may be added to indicate the types of products of animal origin manufactured.

### 2.3 Official controls for cheese production establishments

'Official control' is defined as any form of control that the competent authority performs for the verification of compliance with food law, including animal health and animal welfare rules.

It is important that official controls cover all aspects that are important for protecting public health, animal health and animal welfare. Nature and intensity of the official control is based on an assessment of public health risks, animal health and welfare, the type and throughput of the processed carried out and the food business operator concerned.

The competent authority will keep the approval of cheese production units under review when carrying out official controls. If serious deficiencies are identified or the production at a unit is stopped repeatedly by the competent authority and the cheese producer cannot provide adequate guarantees regarding future production, the competent authority will initiate procedures to withdraw the approval. However, if adequate guarantees can be provided and deficiencies are resolved within reasonable time, the competent authority may only suspend the approval. It is noted that these procedures or measures also apply to production units already placing cheeses on the market of which there was previously no requirement for approval. The authority's on-site visit (required for approval) will take place as soon as possible.

Member States will ensure that cheese producers offer all assistance needed to ensure that official controls by competent authorities can be performed effectively. Access should be given to all buildings, premises, installations or other infrastructures and to any documentation and record required legally required (*article 4 (1) of (EC) No 854/2004*). Also samples for laboratory analysis whenever necessary might be collected by the competent authority (*article 4 (8) of (EC) No 854/2004*). Official controls for cheese production establishments may include (*article 4(3) and article 8 of (EC) No 854/2004*) audits of good hygiene practices and HACCP based procedures or other specific controls.

Audits of good hygiene practices will verify that cheese production units apply such procedures continuously and properly and will concern at least (*article 4(4) of (EC) No 854/2004*):

(a) Checks on food-chain information;

- (b) The design and maintenance of premises and equipment;
- (c) Pre-operational, operational and post-operational hygiene;
- (d) Personal hygiene;
- (e) Training in hygiene and in work procedures;
- (f) Pest control;
- (g) Water quality;
- (h) Temperature control;
- (i) Controls on food entering and leaving the establishment and any accompanying documentation.

Audits of HACCP based principles will verify that cheese production units apply such procedures continuously and properly. Official controls in this context should determine whether procedures guarantee that cheeses (*article 4(5) of (EC) No 854/2004*):

- Comply with microbiological criteria laid down under Community legislation
- Comply with Community legislation on residues, contaminants and prohibited substances
- Do not contain physical hazards, such as foreign bodies

If procedures as set out in guides to the application of HACCP principles rather than specifically designed procedures are used, the audit will cover the correct use of these guides.

Considering the food traceability concept, it is regulated that producers responsible for production units should ensure that all products of animal origin placed on the market bear either a health mark or an identification mark (*article 5(1) of 853/2004*). For production units producing cheese, this means that a verification of the application of identification marks and compliance with other traceability requirements may take place (*article 4(6) of (EC) No 854/2004*).

## 2.4 Requirements for cheese production

The following products of animal origin are not allowed unless the competent authority has approved them (*article 2 of (EC) No 853/2004*):

- Meat of domestic ungulates
- Meat from poultry and lagomorphs
- Meat of farmed game
- Wild game meat
- Minced meat, meat preparations and mechanically separated meat (MSM)
- Meat products
- Live bivalve molluscs
- Fishery products
- **Raw milk and dairy products**
- Eggs and egg products
- Frog's legs and snails
- Rendered animal fats and greaves
- Treated stomachs, bladders and intestines
- Gelatine
- Collagen

Dairy products are defined as processed products resulting from the processing of raw milk or from the further processing of such processed products (*Annex I to (EC) No 853/2004*). As cheese production falls under the definition of 'dairy products',

approval of a cheese production establishment by the competent authority is required.

Requirements for production of foods of animal origin including cheese production are put in place to establish and secure food safety. Relevant legislation has laid down:

- Minimum hygiene requirements
- Rules regarding official control to check food business operator's compliance
- Requirements to encourage food business operators to establish and operate programs and procedures based on HACCP principles.

General hygiene requirements may be applicable to cheese production and include (*annex II of 852/2004*):

- The general requirements for (mobile and/or temporary) food premises
- Specific requirements in rooms where foodstuffs are prepared, treated or processed
- transport requirements
- Equipment requirements
- Requirements on food waste, water supply and personal hygiene
- Provisions applicable to foodstuffs, the wrapping and packaging of foodstuffs
- Requirements on heat treatment
- Training requirements

For more detailed requirements see Annex II of (EC) No. 852/2004.

For cheese, the following specific requirements are obliged:

- Temperature requirements: upon acceptance at a processing establishment, milk should be quickly cooled to not more than 6°C and kept at this temperature until processed. However, milk may be kept at higher temperatures if (a) the processing begins immediately after milking or within 4 hours of acceptance at the processing establishment requirements for heat treatment and (b) it is allowed by the competent authority for technological reasons;
- Requirements for heat treatment: where this step occurs in the process, this step should satisfy the following requirements (*Annex II, Chapter XI of (EC) No 852/2004*):
  - (a) Heat treatment process is to raise every party of the product to a given temperature for a given time and to prevent product from becoming contaminated during the process
  - (b) Ensure achievement of desired objectives of the process by regularly checking main parameters (particularly temperature, pressure, sealing and microbiology), including the use of automatic devices
  - (c) Ensure that the process conforms to internationally recognized standards (e.g. pasteurization, ultra high temperature or sterilization);
- Criteria for raw cow's milk: immediately before processing the raw cow's milk used to prepare dairy products should have a plate count of < 300,000 per ml at 30°C and processed milk used to prepare dairy products should have a plate count of < 200,000 per ml at 30°C. It is noted that Member States are enabled to maintain or establish national rules permitting food producers, with the authorization of the competent authority, the use of raw milk not meeting the criteria laid down as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days, and dairy products obtained in connection with the manufacture of such cheeses.

## 2.5 Microbiological hazard control in cheese production

### 2.5.1 Introduction

Foodstuffs of animal origin may present intrinsic hazards, due to microbiological contamination. To protect consumers from microbiological risks in food products, Community legislation sets out numerous hygienic measures (such as HACCP based principles, etc). In particular, microbiological criteria have been laid down for specific foodstuffs. These criteria are applicable at the site of food production. Microbiological criteria are tools that can be used in assessing the safety and quality of foods. Due to reasons related to sampling, methodology and uneven distribution of micro-organisms microbiological testing of finished food products done alone is however insufficient to guarantee the safety of a foodstuff tested. The safety of the foodstuffs must principally be ensured by a more preventative approach, such as product and process design and the application of Good Hygiene and Manufacturing Practices (GHP, GMP) and the Hazard Analysis Critical Control Point (HACCP) principles.

### 2.5.2 Zoonoses and zoonotic agents

To help control the occurrence of food borne diseases in the EU along the food chain and within the context of the food law, Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC was introduced. In addition, a Commission Recommendation 2005/175/EC concerning a coordinated programme for the official control of foodstuffs was adopted.

Directive 2003/99/EC was put in place to ensure that zoonoses, zoonotic agents and related antimicrobial resistance are properly monitored, and that food-borne outbreaks receive proper epidemiological investigation, to enable the collection of the necessary information in the EU to evaluate relevant trends and sources. Among others it applies to specific Community provisions on food hygiene and health and safety in the workplace. Therefore, this Directive also applies to the production of cheese within the EU.

Trends of sources of zoonoses were followed by the European Commission with the assistance of the Community reference laboratory for the epidemiology of zoonoses. Data on the monitoring of Member States were collected and published yearly since 1995. However, as the epidemiological data collection of the individual Member States were not harmonized and sometimes incomplete, the Committee recommended improved monitoring arrangements and identified risk-management options. In particular the following zoonoses were identified as public health priorities:

- *Salmonella* spp.
- *Campylobacter* spp.
- *Verotoxigenic Escherichia coli* (VTEC)
- *Listeria monocytogenes*
- *Cryptosporidium* spp.
- *Echinococcus granulosus*
- *Trichinella spiralis*

Member States will monitor these zoonoses and zoonotic agents at all stages of the food chain. In this context, the role of the food producers is to carry out examinations for the

presence of zoonoses and zoonotic agents. They should keep results and arrange for the preservation of any relevant isolate for a period to be specified by the competent authority and communicate results or provide isolates to the competent authority on request. The European Food Safety Authority has been entrusted to prepare a yearly EU summary report on sources and trends of zoonoses and zoonotic agents, on the basis of national reports supplied by Member States. Its first EU summary report is due by November 2005 and will cover the data from the national reports of Member States from 2004.

Furthermore, in 2004 a survey on the safety of cheeses was started under a coordinated programme. In Commission Recommendation 2005/175/EC certain recommendations for the assessment of the bacteriological safety of cheeses made from raw or thermised milk was set out. The competent authorities of the Member States will take representative samples of soft and semi-hard cheeses made from pasteurized milk, both at production and retail levels with a view to testing for the presence of *Salmonella* and *Listeria monocytogenes* and enumeration of *Staphylococcus aureus* and *Escherichia coli*. Results of the testing of these representative samples will be combined with results from the EU summary report (due for November 2005) to get a general overview on the safety of cheeses.

### 2.5.3 *Listeria monocytogenes*

For *Listeria monocytogenes* an attempt is made to determine a criterion for the presence of this pathogen in food. The Scientific Committee on Veterinary Measures relating to public health (SCVPH) was requested by the Scientific Committee on Food (SCF) to assess the risk to human health of *Listeria monocytogenes* at different levels in ready to eat foods (SCVPH, 1999). The SCF agreed with the conclusions of resulting report that all *Listeria monocytogenes* strains should be treated as potentially pathogenic and that levels of this organism in foodstuffs should therefore be kept low in view of the potential for listeriosis (SCF, 2000). Furthermore, the SCF supports the recommendation of SCVPH to significantly reduce the fraction of foods with a concentration of *Listeria monocytogenes* >100 cfu/g (colony forming units/gram) in ready to consume foods. It was also recommended that *Listeria monocytogenes* should not be detected in 25 g of food at the production site (SCVPH, 1999).

Within this context the European Community is currently developing a guideline on the application of general principles of food hygiene to the management of *Listeria monocytogenes* in foods. At this moment a proposed draft version is being discussed within the EU. Important for food producers is that the performance of appropriate studies to assess the growth of *Listeria monocytogenes* in ready to eat foods up to the end shelf life, will become their responsibility. Also time and temperature control, monitoring of effectiveness of control measures for *Listeria monocytogenes*, deriving microbiological limits, etc. is intended to be included in the guideline.

It is noted that currently microbiological criteria for the presence of pathogenic micro-organisms and their toxins in cheese are set out in chapter II, annex C of Directive 92/46/EEC. A distinction in microbiological criteria is made for soft and hard cheese and pasteurised and raw milk based cheese. Specifically with regard to the presence of *Listeria monocytogenes* in cheese, other than hard cheese, this pathogen should not be present in 25 grams of product. As Directive 92/46/EEC will be repealed in January 2006 this standard will officially not be applicable from thereon. However, considering the recommendations of the SCVPH, which is supported by the SCF, it is expected that

this standard for *Listeria monocytogenes* (not detect *Listeria monocytogenes* in 25 g of product at the production site) will be adopted under the new food hygiene legislative framework.

## 2.6 Chemical hazard control in cheese production

Animals are exposed during their lifetime to different chemicals that could lead to the presence of undesirable substances in food of animal origin likely to be harmful to human health. A further exposure to such substances may occur while processing in the food production chain. These substances are generally defined as residues. The concept of residue and the measures to control the presence of chemical residues in food of animal origin are established in Council Directive 96/23/EC (“on measures to monitor certain substances and residues thereof in live animals and animal products”).

Community legislation identifies the following three possible origins of undesirable chemical residues in food of animal origin:

- Residues of substances used for therapeutic purposes (e.g. antibiotics);
- Residues of substances used illegally (e.g. hormones);
- Residues of environmental contaminants (e.g. heavy metals).

Food containing a contaminant to an amount unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market. Furthermore, contaminant levels shall be kept as low as can reasonably be achieved following recommended good working practices. The EU has determined MRL’s (maximum residue limits) to lay down maximum limits for residues or contaminants so as not to pose a risk to human health after consumption of foodstuffs. As contamination and residues may occur during cheese manufacturing, the legislation as described above also applies to cheese production.

## 3 Applicable national legislation for raw milk cheese

### 3.1 Dutch legislation

Dutch legislation on food is laid down in the 'Warenwet'. Cheese which is placed on the market should comply with the 'Warenwet'. The production and processing of food is regulated in the 'Warenwetbesluit bereiding en behandeling van levensmiddelen' and the 'Warenwetregeling Hygiene van levensmiddelen'.

In The Netherlands cheese production is currently subject to the 'Warenwetbesluit Zuivel', the 'Warenwetregeling Zuivelbereiding', the 'Warenwetregeling Bereiding van melk en zuivel' and 'Zuivelverordening 2003, inrichtingseisen zuivelbereiding'. As these regulations are based on Directive 92/46/EEC, which will be repealed in January 2006, they are not discussed in detail. In general these regulations lay down rules and requirements for dairy foods and on requirements for dairy food production units in order to ensure hygienic food production.

The European and so the Dutch legislation concerning hygiene prescribe that food business operators shall identify any step in their activities which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed used to develop the system of HACCP (Hazard analysis and critical control points). If a hygienic code is present then it is possible to implement the rules laid down in such a code in stead of the making of an own HACCP system. There are many branch organizations that developed hygiene codes describing how their products can be produced in a hygienic way. These codes are revised every three years to keep up-to-date. It is noted that for cheese there is a hygiene code available for the production of cheese for small business operators. For instance, the hygienic code for cheese states that the use of rennet made by using gene technology is not allowed to be used for the cheese production, because cheese is considered to be a natural product.

Inspection on whether food business operators comply with these rules is performed by the Dutch 'Voedsel en Waren Autoriteit' (The Food and Consumer Product Safety Authority) and the 'Algemene Inspectie Dienst'. Production units are also verified on HACCP compliance. Thereby the fat, protein and bacterium percentage is measured and it is checked whether the correct temperatures are used for pasteurization. The COKZ (Centraal Orgaan voor Kwaliteitsaangelegenheden in de Zuivel, Netherlands Controlling Authority for Milk and Milk Products) is the controlling authority for milk and milk products and falls under the supervision of the 'Voedsel Waren Autoriteit'. COKZ carries out inspections for both the Dutch and the European authorities, as well as for the dairy industry, and supervises compliance with national and international legislation. These controls concern the various final products and production hygiene. The COKZ has adopted an inspection regulation for cheese production, the 'Keuringsreglement COKZ kaas'. In this regulation method for sampling and analysis at cheese production sites is included for the rennet, contaminants, etc. In addition, checks are performed by the COKZ on:

Physical/chemical analyses

These concern the moisture, fat, protein and other composition regulations. By specializing, the laboratory is able to analyse large quantities of samples per day. For instance, results are reported within 24 hours of the cheese being sampled at the

factory. With this service, COKZ can partly replace the activities of a factory laboratory, or if desired, support the factory.

Instrumental and other analyses

These concern, amongst others, chemical analyses of vitamins, minerals, metals, salts, protein, lactose, aflatoxin M1, PCBs, organochlorine pesticides, environmental contaminants, antibiotics and various other analyses of dairy products.

Microbiological analyses

These concern a large number of analyses specific to the microbiology of dairy products, such as the bacterial count, antibiotics, coliforms, *Salmonella*, *Listeria*, lactobacilli and thermophilic micro-organisms.

It is noted that Dutch legislation, based on Directive 92/46/EEC, requires that *Listeria monocytogenes* is not allowed to be present in 25 g of product for soft and hard cheese.

In 1981 a Dutch law on requirements for cheese was introduced called the 'Kaasbesluit'. In 1995 however, a lot of articles were deleted. Only articles on the definition of cheese and the ingredients allowed to be used in the coating of cheese is maintained. Applicable Dutch legislation for the cheese production (may) include:

- Legislation about the quality of cheese are laid down in 'the Landbouwkwaliteitsregeling kaas',
- Legislation on contamination: applicable EU legislation on residues and 'the Warenwetregeling verontreinigingen in levensmiddelen'.  
The 'Warenwetregeling verontreinigingen in levensmiddelen' is intended to be a comprehensive regulation regarding the contamination of foods with mycotoxins, bacterial toxins and other chemical substances.
- Legislation on substances allowed in cheese coatings: applicable EU legislation on cheese coatings and the 'Warenwetregeling Kaaskorstbedekkingsmiddelen' which has rules with regard to cheese coatings.
- Legislation on food additives: applicable EU legislation, the "Warenwetregeling gebruik van additieven met uitzondering van kleurstoffen en zoetstoffen in levensmiddelen", and the 'Warenwetregeling zuiverheidseisen levensmiddelen additieven m.u.v. kleurstoffen en zoetstoffen'.

### 3.2 French legislation

In France the legislation on foodstuffs is based on French national legislation and EU harmonized legislation. There are specific French laws with regard to dairy products. The French foodstuffs legislation is called '*Reglementation des produits, qualite et repression des frauds*'. It is published only in French and consists of 3 book parts that are regularly updated (<http://www.lamy.fr>). The Agricultural board of Paris provides more information at the website <http://www.amb-pay-bas.fr/fr/ambassade/lba/index.htm>.

### 3.3 Italian legislation

The legislation on foodstuffs in Italy is based on Italian legislation and EU harmonized legislation. Once in three years the '*Tutela Igienico Sanitaria degli Alimenti e Bevande e dei Consumatori*' is published in which the updated food- and stimulants legislation is included. However, the book is available in Italian. Italy has its own legislation on cheese and publishes this in the Italian's *Gazette Ufficiale*. More information is available at the website of the Agricultural board of Rome <http://www.olanda.it/>.



## 4 Discussion on restrictions for raw milk cheese production in the EU

Since pasteurization is generally accepted as a good practice to obtain safe foods it is an obvious routine for the industrialized way of cheese making nowadays. In some countries, like the US pasteurization of milk prior to cheese making is legally required. In the EU where a lot of cheese has been produced in a traditional way, pasteurization was not obligatory. Nevertheless, there is a debate on the raw milk issue. Information in relation to the discussion pro/contra dairy products from raw milk in the EU was gathered from the internet.

The debate regarding the preservation of raw milk cheese production became a topic within the EU in the early 1990's. In the beginning of the nineties the safety of raw milk cheeses was discussed between the EU and the Codex Alimentarius. The Codex Alimentarius which provides standards for the international trade of cheese was considering the mandatory pasteurization of all dairy products. Within Europe there is a clear difference in view between the northern and southern countries. In general the north questioned the continuation of the use of raw milk for cheese production within the context of food safety. The north prefers pasteurization of the milk prior to cheese making. Since raw milk cheese products comprises an important part of the southern Europe countries changing from raw to pasteurised milk is difficult for local cheese makers in these countries. Furthermore, the traditional practice (use of raw milk) is preferred mainly from an organoleptic point of view. Thus far, no compromise was reached on the use of only pasteurised milk for cheese production.

A strategy suggested to assure the safety of raw milk cheese was to implement safety controls and stricter standards in the EU for guaranteeing the safety of these products rather than banning the use of raw milk for cheese production (<http://www.vtcheese.com/vtcheese/rawmilk3.html>). It also noted that using pasteurised milk for cheese production does not fully guarantee the safety as contamination may occur during the production process and pasteurisation may not kill all bacteria or toxins in the milk. The discussion is an actuality in the EU and within the Codex Alimentarius Committee.

The current EU's position (mainly lead by France, Italy, Switzerland and Denmark) is that consumer safety is protected for ready-to-eat raw milk dairy products including cheese, when strict veterinary and sanitary practices are followed from production to consumption. These sanitary practices include:

- Using raw milk from herds that are in good health, have regular veterinary inspections and are subject to regular sanitary controls
- Using milk that is collected, transported, stocked and transformed within a short period of time while applying strict hygienic rules
- Educating consumers about proper storage conditions and shelf life of end products.

The French Delegation maintains that these common hygienic provisions provide adequate health protection without mandatory pasteurization. Their position is reflected in the EU law ([http://www.commercialdiplomacy.org/ma\\_projects/ma\\_dairy\\_hygiene2.htm](http://www.commercialdiplomacy.org/ma_projects/ma_dairy_hygiene2.htm)).

In 2004 the Codex Alimentarius Committee published the '*Code of hygienic practice for milk and milk products*'. This document applies to products in international trade

and focuses on the production, processing and handling of milk and milk products. The use of raw milk (milk not heated beyond 40°C or which has undergone any treatment that has an equivalent effect) is not prohibited. Furthermore, guidance is provided on how to achieve the general requirements contained in the hygienic sections of the Codex commodity standards for milk products.

At this moment it is not expected that raw milk cheese will be prohibited within the EU. It is expected that the EU legislation on food hygiene of foods of animal origin which is applicable from January 1<sup>st</sup> 2006 (see paragraph 2.1) onwards will ensure a high safety to human health.

## 5 Signature

For approval:

Date:

---

Dr. C.A. van den Berg  
Regulatory Affairs Manager Food & Feed

---

Dr. J.H. Brussaard  
Head Food & Chemical Risk Analysis

## 6 References

Codex Alimentarius, Code of hygienic practice for milk and milk products, CAC/RCP 57-2004, 2004.

Commission Recommendation 2005/175/EC of 1 March 2005 concerning a coordinated programme for the official control of foodstuffs for 2005 (*OJ 2005, L59/27*).

Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (*OJ 2003 L18/11*).

Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (*OJ 2003 L325/31*).

Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC (*OJ 2004 L195/12*).

European Commission Health & Consumer Protection Directorate-General, Opinion of the Scientific Committee on Food in respect of *Listeria monocytogenes*, June 22<sup>nd</sup> 2000.

European Commission Health & Consumer Protection Directorate-General, Opinion of the Scientific Committee on veterinary measures relating to public health on *Listeria monocytogenes*, September 23<sup>rd</sup>, 1999.

Kaasbesluit (Warenwet) 1981, Besluit van 4 maart 1982, houdende vaststelling van het Kaasbesluit (Warenwet) 1981.

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 (*OJ 2002, L31/1*).

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (*OJ 2004 L226*).

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygienic rules for food of animal origin (*OJ 2004 L226/21*).

Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (*OJ 2004 L226/83*).

Warenwet, Wet van 28 december 1935, houdende voorschriften betreffende de hoedanigheid en aanduiding van waren.