

**EUROPEAN SYSTEMS FOR THE
SAFE PRODUCTION OF RAW MILK CHEESE**

A report presented to the

Vermont Cheese Council

by Peter H. Dixon

November 28, 2000

ACKNOWLEDGEMENT

I would like to thank the following people and organizations for providing the information, which formed the basis for this report: Réjane Forte of the Federation Nationale des Eleveurs de Chevres, Sophie Villers of the Insitut des Appellations d'Origine, D. Lincet of the Syndicat Interprofessionnel de Defense de l'Appellation d'Origine Brie de Melun, representatives of the Syndicat des Producteurs de Fromages de Pouligny, Carol Delaney of the University of Vermont Extension, Jacky Mege of the Centre de Recherches de l'Elevage Ovine des Montagnes, Philipp Hammer of the Federal Dairy Research Centre of Germany, Dr. George Haenlein of the University of Delaware, Mother Noella Marcellino of the Abbey of Regina Laudis, and the executive director and other representatives of the Communicable Diseases Information Resource Centre of the World Health Organization. I would also like to thank Daphne Zepos, George Steinmeyer, and Rebecca Nixon for their excellent translating services.

INTRODUCTION

In researching the methods used in France to regulate raw milk cheese it was necessary to think of France as a member of an alliance of countries in close proximity to each other, with open borders, and sharing in the common goals of assuring food safety and free trade. This led to the realization that these goals are being pursued by harmonizing divergent approaches at European Union and national levels and providing a high level of protection of consumer health.

This report is structured in a way that allows the reader to follow the development of regulating raw milk cheese in France. The process started with the debate in the EU over the safety of raw milk and products made from raw milk. The outcome was the formation of a set of rules for the manufacture and trade of dairy products in the EU, which laid the ground work for the member states to construct their own laws and regulations. Essential to any regulation system in a EU member state is the use of self controls, based on the principles of HACCP (Hazard Analysis and Critical Control Points).

The Raw Milk Debate In The European Union

The effort to preserve raw milk cheese production in certain countries of the European Union began in the early 1990's. From 1990-92, the European Union debated the safety of raw milk cheese and the Codex Alimentarius, which provides standards for the international trade of cheese, was considering the mandatory pasteurization of all dairy products. Some of the northern European countries wanted to forbid the production of raw milk cheeses for sanitary reasons, pointing toward the reduced health risk from pasteurized milk cheeses.

An indication of the pro pasteurization position at that time comes Mr. Claus Heggum of the Danish National Committee of the International Dairy Federation who reported that the health risk from milk products in Denmark was negligible. He stated that, "this was mainly due to practically no consumption of raw milk, to extensive preventive measures for minimizing the presence of pathogens in raw milk used for manufacturing, and to mandatory pasteurization of milk prior to processing." [1]

In the same report, Dr. Hans Asperger, from the Institut for Milcherzeugung in Austria, pointed out that a major problem in raw milk cheese seems to be *Staphylococcus aureus*. [2] In Austria, where more than 10% of the milk produced is consumed as raw milk and raw milk products with out any heat treatment, Dr. Asperger recommended a different strategy to mandatory pasteurization, "to ensure the hygienic production of raw milk products, the need for appropriate education programs for the producers must be addressed. This is managed by learning, training, and motivation conducted in seminars for raw milk product manufacturers with teaching aids provided. A quality management system concerning the improvement of hygiene in the milk production will also be introduced comprising checklists, producing instructions and production protocols." [3]

Researchers at the Institut National de la Recherche Agronomique (I.N.R.A.), Station de Recherches en Technologie et Analyses Laitieres in Pouligny, France have been studying the properties of traditional cheeses made from raw milk for many years. Around the same time as the WHO report was published, Remy Grappin and Eric Beuvier were finishing a review of the effects of pasteurization on the quality of traditional raw milk cheese. They felt that raw milk cheeses represented a significant proportion of ripened cheeses produced in Europe, particularly in Italy, France and Switzerland, and were concerned about the economic impact from changes in quality due to pasteurization. [4]

They wrote, "in the context of international trade and regulation, where hygienic aspects are predominant, it was important to know the consequences and possible implications of pasteurization on the ripening process, and ultimately on the sensory characteristics of cheese." They found that the interaction between indigenous raw milk microflora and starter bacteria appeared to be extremely important in the ripening process and subsequent flavor and texture of the cheese. Raw milk cheeses (Swiss, Cheddar, Manchego, Raclette and St. Paulin) developed characteristic flavor sooner and the flavor was stronger, richer and more diverse (less uniform) than the same cheeses made from

pasteurized milk. After comparing the same cheeses made from raw and pasteurized milk, they concluded that, "pasteurization modifies the biochemistry and microbiology of ripening, and the flavor and texture of cheese." [5]

They stressed the fact that the approach used in making traditional raw milk cheese has limited or no standardization of the milk, thereby keeping the natural characteristics of the milk that originated from the specific area of production. The cheese is usually made in small to medium sized operations and the make process is adjusted according to the characteristics of the milk. Even with this, the cheese will have variation in quality. This diversity in sensory properties is a direct consequence of variation in the conditions of milk harvesting and transformation. Furthermore, "this diversity is sought by both the producers and the consumers, because it is a special feature of traditional cheeses." [6]

Patrick Rance, one of the great champions of raw milk cheese, was hard at work in England during the late 1980's investigating the relationship between Listeriosis (and Salmonellosis) and raw and pasteurized milk cheeses. He spearheaded the campaign to save raw milk cheese in Great Britain and used the findings of careful research to refute the argument that raw milk cheese was responsible for cases of Listeriosis. Mr. Rance felt that the evidence clearly showed that pasteurized milk cheese is most at risk. [7] He stated that, "pasteurization, far from being the remedy, leaves an open field for *Listeria monocytogenes* to invade and conquer. In all international investigations, no raw milk cheese has been impugned." [8] Mr. Rance was in agreement with Dr. Asperger that risk management strategies were needed to safeguard the quality of the raw milk production: (1) animals should be fed on hay and not silage or root crops, (2) milk parlors should have uncompromising standards of hygienic dairy practice, (3) water supplies should be pure, and (4) the introduction of soil into the milk processing environment should be avoided at all costs. He also alluded to the concept of "competitive exclusion" of pathogens in raw milk by using techniques to bolster the activity of bacteria which can discourage the growth of *Listeria*. [9] This is currently thought of as an effective means to reduce the health risk from pathogens in raw milk.

In Germany, farms were able to produce certified raw milk (Vorzugsmilch). This certified raw milk could be traded on larger scale and consumption was permitted. Since the government was involved in the certification, it was also responsible for the product. The German Milk Ordinance requires that certified raw milk be regulated by strict hygienic standards on the farm and strict surveillance by officials. At least one farm is ISO 9000 certified. [10] Philipp Hammer, a researcher at the Federal Dairy Research Centre, noted that, while the hazard of yersiniosis and campylobacteriosis was present in Germany, the risk for healthy individuals to come in contact with the disease was very low. Persons at risk (mainly school children visiting farms) were advised not to consume non certified raw milk without heat treatment (pasteurization). The practice of certifying farms to produce Vorzugsmilch continues today, with a system of hazard-reducing control points and strict microbiological standards. [11]

These examples of different positions on the public health issue of raw milk and raw milk products indicate the extent of the debate in the EU at the time when the production of raw milk cheese was in jeopardy. No matter how well the proponents of mandatory pasteurization stated their position with regard to public health, there was still the issue of trade to deal with. Statistics from the Direction General de l'Alimentation (Agency of Foods of the Republic of France) showed that 700 million kilos of raw milk cheese were produced in the European Union in 1995; Italy with 240 million kilos, France with 210 million kilos, and Switzerland with 100 million kilos were the largest producers. In France, where raw milk cheese amounted to one quarter of their total cheese production, and in other countries,

particularly Southern European ones, raw milk cheese represented a significant and important contribution to the agricultural economy.

Given the importance of raw milk cheese products to the economies of these countries and the difficulty for cheese makers in these countries and others, like Spain and Portugal, to convert to pasteurization, it was inevitable that a compromise was reached. The approach taken by the Austrian and German dairy industries to implement safety controls and stricter standards demonstrated an effective strategy that the EU countries could use to improve the safety record of raw milk cheese and other raw milk products. In framing a different approach from mandating pasteurization as a safety net for milk products, the traditional raw milk cheese making countries proposed to guarantee the safety of the cheeses instead. To do this, they worked to create a new system for regulating the production and trade of dairy products in the EU, which was based on microbiological risk assessment.

The first step was to develop a new set of regulations for the production and trade of milk and dairy products in the EU. Two "Directives," which contain the regulations were composed with mutual agreement of all member states; these came fully into force on January 1, 1998. "The health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products intended for human consumption," are contained in Council Directive 92/46/EEC. [12] A second text, Council Directive 93/43/EEC of June 14, 1993, governs "the hygiene of foodstuffs," and refers to the use of HACCP protocols, developing guides for member states based on the Codex Alimentarius, and other measures for protecting public health.

These Directives are important because they lay the foundation for the regulatory systems, which member states developed to safeguard the production and sale of dairy products, including raw milk cheese. The concept of HACCP (Hazard Analysis and Critical Control Points) is a dominant part of the regulations and competent authorities are instructed to carry out controls to assess whether the necessary monitoring and verification procedures are being used by producers at critical control points in their processes. The Directives instructed the EU member states to develop their own laws, regulations, and administrative provisions to comply with the new regulations. For EU trade, the EEC Directives are the rule books of reference. Each measure adopted by the member states to fulfill the requirements of a Directive must contain a reference to that Directive and these must also be noted in official publications.

THE EUROPEAN UNION DIRECTIVES

The purpose of this section is to present a synopsis of the important rules that affect the production, sale and trade of raw milk cheese. Within these rules lies the essence of the provisions for the safety of raw milk cheese in the member states of the EU. The Directives 92/46/EEC and 93/43/EEC will be discussed in detail as they form the basis for the national laws and regulations of the member states. They also mandate the systems of self-control and risk reduction in raw milk production and the manufacture of raw milk cheeses which are necessary for the trade of dairy products at a national level and within the EU. The importance of these Directives cannot be underestimated for they represent a collective agreement and methodology for assuring the safety of dairy products and the health of consumers. It is important to clarify some terms before explaining the Directives as they are different from the ones we use in the US. These are taken from Article 2 of Directive 92/46/EEC:

1. "raw milk": milk produced by the secretion of the mammary glands of one or more cows, ewes, goats, or buffaloes, which has not been heated beyond 40 °C (104 °F) or undergone any treatment that has an equivalent effect.
2. "heat treatment": any treatment involving heating that causes, immediately after it has been applied, a negative reaction to the phosphatase test (which is the definition of "pasteurization" in the US regulations).
3. "thermization": the heating of raw milk for at least 15 seconds at a temperature between 57 °C and 68 °C (135 °F and 154 °F) such that after treatment the milk shows a positive reaction to the phosphatase test (which is called "heat treatment" or "sub pasteurization" in the US regulations).
4. "production holding": an establishment at which one or more milk-producing cows, ewes, goats, or buffaloes are kept.
5. "competent authority": the central authority of a Member State responsible for carrying out health and public health checks or any authority to which it has delegated that responsibility.
6. "placing on the market": the stocking or display with a view to sale, offering for sale, sale, delivery or any other manner of disposal in the Community with the exception of retail sale, which must be subject to the checks laid down by national rules for retail business.

DIRECTIVE 92/46/EEC:

The deadline for the transposition of this Directive was January 1, 1994, however, the Council recognized that certain rules were likely to affect both products with traditional characteristics and establishments with limited production. The Directive allowed member states to apply for changes ("individual and general derogation") to some of the rules by October 1, 1994. The work on these changes appears to have been complex. This is probably why the Directive was not fully enforced until January 1, 1998.

The actual conditions for compliance and measures taken for checking compliance with the rules of the Directive may be amended or supplemented. In this case, these procedures are "referred to the Standing Veterinary Committee (or "the Committee"), which consults with the Management Committee for Milk and Milk Products, where matters of chemistry or technology are involved." The changes are to be resolved within a period of three months. This mechanism is used frequently to determine appropriate steps to take in case of non compliance, including defining the types and frequency of sampling and analysis for investigation.

One very important part of the regulations concerns the situation with the direct sale of raw milk and raw milk products made on the farm. The EU Council does not regulate this type of operation as long as the farmstead complies with national health rules. The regulation of the direct-selling producer in France will be discussed later. It is stated in Chapter I - General Rules: Article 1 that:

"This Directive does not affect national rules applicable to the direct sale to the consumer by a producer of raw milk obtained from a herd officially free of tuberculosis and officially free or free of brucellosis, or of milk-based products made on his holding with such raw milk, provided the hygiene conditions of the holding comply with the minimum health rules laid down by the competent authority."

Raw Milk Production and Handling

The requirements for raw milk used for the manufacture of cheese ("milk-based products or heat-treated drinking milk") in member states is set down in Chapter II - Rules governing Community production: Article 3.

This article is very important because it refers to many rules and measures that form the risk assessment approach to safe raw milk production and handling. The main points of Article 3 are as follows:

1. Member States shall ensure that raw milk meets the following requirements:

(a) The milk comes from animals and production holdings which are checked at regular intervals by competent authorities to ensure that animal health and hygiene requirements are being met as follows:

↳ regular veterinary inspections of animals on production holdings

↳ additional inspections if animal requirements are not being met

↳ regular checks of production holdings to ensure compliance with hygiene requirements

↳ if the hygiene is inadequate the competent authority shall take appropriate steps to achieve compliance

(b.1) The milk is checked at the treatment or processing establishment by competent authorities as follows:

↳ hygiene requirements relating to the premises, equipment and staff are met, which include:

· cross-contamination between operations by equipment, ventilation or staff must be avoided

· rooms intended for production purposes shall be divided into wet and dry areas, each having its own operating conditions

· the operator of the establishment shall draw up a cleaning program based on risk analysis to ensure that there is no health risk to products as a result of inadequate cleaning methods

↳ there is permanent supervision by the permanent or periodic presence of the competent authority

↳ the competent authority shall take appropriate measures, up to and including suspension of approval, if there is non compliance with the rules of the Directive

(b.2) The operator or manager of the processing establishment must constantly carry out his own checks to ensure that, at all stages of production, the rules of the Directive are complied with (see article 14, page 13).

(b.3) There will examination of the milk for foreign substances including:

▫ residues of substances having a pharmacological or hormonal action

▫ antibiotics, sulfanomides and similar anti-microbial substances

▫ pesticides, detergents, and other substances which might alter the organoleptic characteristics of the milk or milk-based products and make their consumption dangerous to human health

(b.4) Standards to be met for the collection of raw milk from the production holding or for acceptance at treatment or processing establishments (refer to Table 1, page 19).

(c) Animal health requirements for raw milk:

▫ for cows and buffaloes, officially tuberculosis-free and officially brucellosis-free or brucellosis-free;

for goats and sheep, officially brucellosis-free or brucellosis-free (Brucellosis melitensis)

▫ do not show any symptoms of infectious diseases communicable to humans through milk

▫ in the case of cows, yield at least 2 liters of milk per day

▫ when different animal species are kept together on the holding, each species must satisfy health conditions which would be required if it were alone.

▫ if goats are kept with cows they must undergo a tuberculosis check.

▫ other rules are similar to those in the US, e.g., incapable of giving the milk abnormal organoleptic characteristics.

(d) Requirements for hygiene of the holding:

▫ rules are similar to those in the US, e.g., premises where milking is performed or milk is stored, handled or cooled must be so situated and constructed as to avoid all risk of contamination of the milk

(e) Requirements for hygiene in milking, the collection of raw milk and its transport from the production holding to the collection or standardization center or to the treatment establishment or processing establishment:

▫ if the milk is not collected within two hours of milking, it must be cooled to 8 °C (46.4 °F) or lower in the case of daily collection or 6 °C (42.8 °F) or lower if the collection is not daily

⌘ while milk is being transported to the treatment and/or processing center its temperature must not exceed 10 °C (50 °F)

⌘ absolute cleanliness and healthiness is required of the staff

⌘ other rules are similar to those in the US, e.g., a monitoring system shall be established under the supervision of a competent authority to prevent water from being added to raw milk

Milk Processing and Milk-based Products

The rules for manufacturing raw milk cheeses fall under Article 6 and requirements for the products themselves are contained in Article 7. In the US, cheese which is called “raw milk cheese” is also made from thermized milk (as defined in the Directive) but this is not the case in the EU as “raw milk cheese” is only made from “raw milk,” which is not heated above 104 °F as defined in the Directive.

Under Article 6:

⌘ The raw milk must comply with the previously stated rules (Article 3)

⌘ raw milk must be used within 36 hours of acceptance, if the milk is kept at 6 °C (42.8 °F) or lower, or within 48 hours of acceptance if the milk is kept at 4 °C (39.2 °F) or lower

⌘ thermized milk must have been obtained from raw milk which, if it is not treated within 36 hours of acceptance, has a standard plate count at 30 °C prior to thermization of 300,000 or less per ml

Under Article 7, milk-based products must be prepared in processing establishment that meets the Directive standards and specifications. These rules are similar to those in the US but there are the following exceptions:

(a) General conditions of hygiene for premises, equipment and tools:

⌘ workroom and lavatory taps must not be hand operable

⌘ grandfather clause for wooden walls built before 1 January 1993

(b) General conditions of staff hygiene

⌘ staff assigned to the handling of raw materials must be required to wash their hands at least each time work has resumed and/or where contamination has occurred

⌘ clean headgear which completely encloses the hair shall be used

⌘ when recruited, any person handling products shall be required to prove that there is no medical impediment to such employment

(c) Standards for milk-based products (refer to Table 2, pages 20 and 21)

(d) Conditions governing health marking and labeling:

↳ products must carry a health mark (refer to the example on page 22)

↳ marking must be done during or immediately after manufacture in the establishment, in an easily visible place

↳ the mark shall be legible and indelible

↳ the mark may be applied to the product or to the wrapping or, if the product is individually wrapped and packaged, to the packaging

↳ the health mark must give the following particulars in an oval surround

- above, the name of the consigning country in capitals
- in the center, the approval number of the establishment
- below, one of the following sets of initials: CEE - EOF - EWG - EOK - EEC - EEG

↳ the health mark may be applied by an ink stamp or by branding or it may be applied to or printed on the label

↳ products from such establishments that do not bear the health mark cannot be the subject of trade

↳ the labeling must show 'made with raw milk' for milk-based products manufactured from raw milk whose manufacturing process does not include any heat treatment, including thermization

↳ there shall be a use-by or minimum durability date on labeling for milk-based products in which growth of micro-organisms may occur

Article 14: The Risk Assessment Plan

Article 14 is referred in Article 3 (raw milk production) and Article 7 (milk-based products). The rules define, in simple terms, a risk reduction strategy similar to a HACCP plan. This adds a mechanism for risk assessment, monitoring, and corrective action of the manufacturing processes in each production facility covered by the Directive. The inclusion of this section is the most striking difference between the EU and the US dairy regulations. The rules are as follows:

1. Member States shall ensure that the operator or manager of the processing establishment takes all necessary measures to ensure compliance at all stages of production.

↳ To that end, the operator or manager must constantly carry out his own checks based on the following principles:

- identification of critical points in the processes used in the establishment
- monitoring and checking of such critical points

- taking samples for analysis in a laboratory recognized by a competent authority for the purpose of checking sanitation and compliance with Directive standards
 - keeping a written or registered record of the information required with a view to submitting it to a competent authority for a period of at least two years, except for products which cannot be stored at ambient temperature, the period shall be at least two months after the use-by date
 - inform the competent authority when information reveals that there is a serious health risk
 - in the event of an immediate human health risk, withdraw from the market the quantity of products obtained in technologically similar conditions and likely present the same risk
- ⌞ the operator or manager must guarantee the correct administration of the health marking
- ⌞ the competent authority must regularly monitor compliance with identification, monitoring and checking of critical control points
- ⌞ the operator or manager must organize a staff training program enabling workers to comply with conditions of sanitary production, unless the staff already have adequate qualifications. The competent authority for the establishment must be involved in the planning and implementation and monitoring of the program

Derogation

Member states may be authorized to grant individual or general amendments to the rules for cheese that is made with an aging period of at least 60 days. These changes pertain to the following conditions and standards:

- ⌞ microbiological limits for raw milk may be changed if the finished product meets the requirements for *Staphylococcus aureus*
- ⌞ conditions of the processing establishment
- ⌞ wrapping and packaging
- ⌞ labeling clearly showing 'made with raw milk' is not always required for milk-based products made from raw milk whose manufacturing process does not include any heat treatment, including thermization
- ⌞ general and particular requirements may be adopted as necessary in accordance with the procedure for making amendments and supplements to the rules of the Directive (Article 31)

Member states may be authorized to make amendments to certain rules if they affect the manufacture of cheeses with traditional characteristics as long as the milk used to make the cheeses meets the animal health requirements for raw milk. These changes pertain to:

- ↳ conditions for milk collection, storage and transportation

- ↳ standards for the products

- ↳ conditions of the processing establishment

- ↳ wrapping and packaging

Member states may also be authorized to make changes to the rules for general conditions for approval of processing establishments manufacturing milk-based products whose production is limited if the establishments are checked by a competent authority and comply with Article 14 (risk assessment and reduction plan). These limited production establishments can also be exempted from organizing worker training programs for hygienic production. Uniform criteria for approving these establishments was finalized by January 1, 1998. Until these establishments were classified, their products could not bear the health mark and could only be marketed at national level.

Compliance

The procedures for compliance are laid out in Article 10 and Article 13. These provisions include registration, inspection and certification as follows:

1. Each Member state shall draw up a list of processing and treatment establishments approved by it.

- ↳ each such establishment shall have an approval number

- ↳ approval by a competent authority shall not be given unless they comply with the rules of the Directive

- ↳ this approval may be withdrawn if there is failure to comply

2. Inspection and supervision shall be carried out.

- ↳ the competent authority from a member state shall make spot checks on production holdings, and processing and treatment establishments to verify that they comply with the rules of the Directive

- ↳ the competent authority must analyze the results of the checks in Article 14

- ↳ on the basis of these analyses, conduct further examinations at all stages of production, including microbiological analyses

- ↳ the results of the analyses shall be written up into a report, with conclusions and recommendations to the operator of the establishment

- ↳ the operator shall rectify the shortcomings noted with a view towards improving hygiene

⌋ in the event of repeated shortcomings, checks shall be increased and, where appropriate, labels or seals bearing the health mark shall be removed

Finally, the EU Commission is given the authority to make checks of establishments to ensure that approved establishments are complying with the Directive. This is to ensure that the competent authorities are doing their job.

Experts from the Commission may, insofar as is necessary for the uniform application of this Directive and in cooperation with competent authorities, make on-site checks.

⌋ they may verify by checking a representative percentage of establishments

⌋ the Commission shall inform the member states of the results of the checks

⌋ a member state in whose territory a check is being carried out shall give all necessary assistance to the experts

An important aspect of Directive 92/46/EEC to note is that its rules do not apply to producers who make dairy products on their small farms and sell them directly to consumers, as long as these producers comply with the minimum health rules laid down by a competent authority in their country.

The regulations governing all food businesses, including these direct-selling food producers are standardized within the EU and are laid down in Directive 93/43/EEC.

DIRECTIVE 93/43/EEC [13]

This Directive harmonizes the general rules of hygiene for foodstuffs to be observed at the time of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer in order to protect human health.

The following terms are defined in the Directive:

1. 'hygiene': all measures necessary to ensure the safety and wholesomeness of foodstuffs. The measures shall cover all stages after primary production (the latter including, for example, harvesting, slaughter and milking), during preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer.
2. 'food business': any undertaking, whether for profit or not and whether public or private, carrying out any or all of the following: preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of foodstuffs.
3. 'wholesome food': food fit for human consumption as far as hygiene is concerned.

There are four important cornerstones that lay the foundation for this Directive. These embrace the concepts of HACCP, good hygienic practice, standardization, and education/training. They are as follows:

1. 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 on the basis of the following principles, used to develop the system of HACCP:

- ↳ analyzing the potential food hazards in a food business operation,

- ↳ identifying the points in the operation where the hazards may occur,

- ↳ deciding which of the points identified are critical to food safety - the 'critical points',

- ↳ identifying and implementing effective control and monitoring procedures at those critical points, and

- ↳ reviewing the analysis of food hazards, the critical control points and the control and monitoring procedures periodically and whenever food operations change.

2. The preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of foodstuffs shall be done in a hygienic way.

- ↳ food business operators shall comply with the rules of hygiene; these are listed in the Annex and are similar to those in the US concerning facilities, personnel, etc..

3. Microbiological criteria and temperature control criteria for certain classes of foodstuffs may be adopted.

4. Member States shall encourage the development of guides to good hygiene practice, which may be used voluntarily by food businesses as a guide to compliance with the rules of hygiene.

- ↳ by food business sectors and representatives of other interested parties, such as appropriate authorities and consumer groups

- ↳ in consultation with interests substantially affected, including the competent authorities

- ↳ where appropriate, having regard to the Recommended International Code of Practice, General Principles of Food Hygiene of the Codex Alimentarius

- ↳ the guides may be developed under the direction of a national standards institute

- ↳ Member States shall forward to the Commission those guides they presume to comply with the rules of hygiene

The Commission recognized that, "there may be a need for guides to good hygiene practice to be developed on a European basis." There are provisions in the Directive for creating "European guides to good hygiene practice" with the intention of harmonizing procedures throughout the EU.

The mechanisms for making amendments to this Directive are similar to those in Directive 92/46/EEC, which is also the case for ensuring compliance with the rules.

If the competent authorities find a case of failure to comply, where it might result in risks to the safety or wholesomeness of foodstuffs, they shall take appropriate measures as follows:

▷ withdrawal and/or destruction of the foodstuff

▷ closure of all or part of the business for an appropriate period of time

▷ and determine the risk to food safety or wholesomeness, with regard to the nature of the food, the manner in which it is handled and packed, and any process to which the food is subjected before supply to the consumer and the conditions under which it is displayed and/or stored

Any person affected by the control has the right to appeal the measures taken by the competent authority.

After adoption of Directive 93/43/EEC, member states were given 30 months to bring the rules into force. It is clear from this review of the Directives that all food producers and sellers in the EU are required to have some form of a risk assessment and reduction plan in place at their establishment, based on HACCP principles or otherwise. This risk reduction plan, combined with rules for stricter microbiological standards for raw milk used in raw milk cheese production and raw milk cheese, characterizes the approach taken by the EU to assure the safety of raw milk cheese. There is flexibility built into the Directives for addressing the manner in which “milk-based products with traditional characteristics” and limited-production establishments are regulated. The member states were instructed to start the process of granting derogation in order that they identify dairy products, whose character would be affected by the rules of the Directive. This allowed authorities to review milk collection, storage, manufacturing, and packaging methods and find agreeable ways to maintain tradition.

Table 1. Standards for raw milk intended for the manufacture of milk-based products (maximum limits per ml of milk) from Directive 92/46/EEC.

(Table Missing)

(a) Geometric average over a period of two months, with at least two samples per month

(b) Geometric average over a period of three months, with at least one sample per month, or where production levels vary considerable according to season, method of calculating results can be adjusted in accordance with procedures for amending the Directive

(1) Where: n = number of units comprising the sample; m = threshold value for the number of bacteria; the result is considered satisfactory if the number of bacteria in all sample units does not exceed ‘ m ’; M = maximum value for the number of bacteria; the result is unsatisfactory if the number of bacteria in one or more sample units is ‘ M ’, or more; c = number of sample units where the bacteria count may be between ‘ m ’ and ‘ M ’, the sample considered acceptable if the bacteria count of the other sample units is ‘ m ’ or less.

Table 2: Microbiological criteria for certain milk-based products on removal from the processing establishment from Directive 92/46/EEC.

Table 2a: Pathogenic micro-organisms

(Table Missing)

In all cases where these standards are exceeded there must be a review of the implementation of the methods of monitoring and checking critical control points applied in the processing establishment pursuant to Article 14 of Directive 92/46/EEC. The competent authority shall be informed of the corrective procedures included in the production monitoring system to prevent any repetition of the occurrence.

In addition, whenever the standard M is exceeded in the case of cheese made from raw milk and from thermized milk or soft cheese, testing must be carried out for the possible presence of toxins in such products.

If strains of enterotoxinogenic *Staphylococcus aureus* or strains of *Escherichia coli* that are presumed to be pathogenic are identified, all the batches involved shall be withdrawn from the market. In this case the competent authority shall be informed of the findings and of the action taken to withdraw the suspect batches and the corrective procedures introduced into the production monitoring system.

THE FRENCH SYSTEM

Stricter regulations for the French dairy industry were implemented in 1981. These concerned hygiene and the equipment and facilities used by cheesemakers. Between December 30, 1993 and August 2, 1996, seven laws were passed in France to enforce the rules of the EU Directives. Some of these laws were modified as recently as September 5, 1997. These laws concern the following issues:

- ↳ conditions of the facilities, equipment, and the operations of milk processing establishments
- ↳ hygiene of milk production and the collection of milk
- ↳ microbiological criteria for milk for consumption and milk-based products at the time they are put on the market
- ↳ the agrément sanitaire communautaire (EU community sanitary approval) and health mark
- ↳ exemptions to the community sanitary approval
- ↳ derogation for limited capacity producers

The French rules for the hygiene of dairy farms, health of animals, milk production and storage, milk collection and treatment, hygiene of milk processing establishments, microbiological quality of milk and milk-based products, and labeling of products are in accordance with those of the EU Directives. These

laws are contained in the Journal of the French Republic but are in a form which does not lend itself readily to application in the field. To shape the meaning of these laws into a form that a farmer or cheesemaker could actually follow, another major step was required. The French approached this problem philosophically. Since the EU Directives instructed producers to perform many self-controls in their operations, the dairy industry needed a “rule book” which instructed the producers to comply with the laws without a great deal of help from the authorities. For the French, it was not enough to just have a book of procedures showing producers how to follow rules. Instead, they compiled a manual, which acts as a guide to good practices in farm cheese production and contains all of the regulations concerning this type of production in a practical format.

The second edition of “The National Guide to Good Practices in Farm Cheese Production” was published in December, 1998. It was created under the authority of the Comité de Pilotage National and put together by representatives of National Professional Organizations and the relative government agencies. Because it is important to demonstrate the size and scope of the effort involved in forming “the guide” these persons who worked on the project are listed as follows:

Professional organizations

- Federation Nationale des Eleveurs de Chevres (F.N.E.C.) - MM. K. Bousouar, president, F. Etevenon, P. Georgelet, A. Jury, R. Arnaud, M. Lesty, R. Forte
- Federation National des Producteurs de Lait (F.N.P.L.) - Mlle Yvonne Amram
- Syndicat Interprofessionnel du Reblochon - M. A. Lobry
- Syndicat du Fromage de St. Nectaire - M. A. Dufranne. M.L. Lamoine
- Federation National Ovine (F.N.O.) - Mlle. Sophie Pluvinage, M.B. Martin
- Centre National Interprofessionnel de l’Economie Laitiere (C.N.I.E.L.) - Mme. Elizabeth Vindel,
- Federation National des Groupements de Defense Sanitaire du Betail (F.N.D.G.S.B.) - M. Michel Meneau, M. Marc Debaisieux
- Institut de l’Elevage - MM. G. Carrotte, V. Heuchel, J.C. Le Jaouen, Mme. V. David
- FECAP (Languedoc Rousillon) - Mme. L. Gueit, M. Bussat
- FRECAP (Provence Alpes Cotes d’Azur) - Mme. M. Maurel

Administrations

- Direction General de l’Alimentation (D.G.A.L.), (Agency of Foods)
 - division of animal products - MM. G. Ripaud, D. Nairaud
 - division of food hygiene - M.E. Dumoulin, Mme. C. Vincent Race, Mme. C. Pave

- Direction Generale de la Concurrence, de la Consommation et de la Repression des Fraudes (D.G.C.C.R.F.), (Agency of Commerce, Consumption, and Repression of Fraud) - MM. J.M. Hochard, D. Van Baelinghem, M. G. Dupont
- Office National du Lait et des Produits Laitiers (ONILAIT) - M.E. Petel, M.F. Douel, Mme. I. Froment
- Direction Generale de l'Enseignement et de la Recherche (D.G.E.R) - M.B. DA-Dalt

Other regional groups

- GIE Promotion Elevage Midi-Pyrenees - M.I. Cottier

The guide is divided into two parts; one is the "Regulation Book for the Production of Farm Cheese" (ca. 133 pages) and the other is "the Guide to Good Practices" (ca. 233 pages). Jean Claude Le Jaouen explained the concept of "regulation book" in this way, "it is a response to an evident need for a document which is coherent, given the multiplicity of texts applied to farm activities in France and the EU." The regulation book is, "a reference document, which completely covers the diverse facets farm activities and is practical in its use."¹⁴

It is composed of two parts:

1. The entire process of producing farm cheese from animal rearing to the sale of products is set down in eleven chapters, each of which focuses on one theme as follows:

- definitions and denominations of the cheeses
- classification of quality of the cheeses
- labeling of the cheeses
- techniques of fabrication and conservation
- introduction of the rules of hygiene: the different categories of processing establishments and their regulatory framework
- health qualifications of the livestock: cows, sheep and goats
- rules of hygiene for the production of milk
- qualifications for the cheese making establishments: criteria and standards for the milk and the cheeses
- conditions of hygiene in the cheese making facilities
- conditions for maintaining the materials, of equipment and hygiene of personnel
- transportation and sale of cheeses

References to the French laws and regulatory texts that concern the activities involved in producing farm cheese are made in a column on the right side of each page.

2. the Annexes contain:

- text of legislation on matters concerning cheese making
- an inventory of regulatory texts with their references giving the producers the power to report incidents if the case arises
- a list of addresses and telephone numbers of departmental (county) and regional offices of the Departement of Veterinary Service and the DGCCRF giving each producer direct contact if they wish

The regulations for the production of farm cheese follow the rules of the EU Directives and are very similar to the US dairy industry regulations. In describing the system for regulating raw milk cheese any mention of regulations that are redundant shall be excluded and the main focus shall be to show how the French regulations were adapted to different categories of farm cheese producers.

In France, the “competent authority,” so often mentioned in the EU Directives, is the Veterinary Service, which is an arm of the Agency of Foods (DGAL) in the Ministry of Agriculture. The Veterinary Service (DSV) regulates the products of animal origin and is in charge of providing certificates of health for herds and flocks, inspecting facilities for milk and cheese production, and assuring safety of the products. In the French system, the producers of raw milk cheese are charged to implement their own system of self controls in their production processes. The DSV approves these systems, known as “auto controls,” and checks the records of controls on a regular basis. The DSV also performs its own “official controls.”

The expression, “Farm cheese” describes cheeses that are not always made on the farm but rather have the characteristics of farmstead and artisanal cheeses. They are produced by family, small-scale (known as “limited production”), and larger sized businesses. The operational structures vary from private to cooperative and can include farmsteads where the entire production is made and ripened on the farm, individual cheese producers who own centralized ripening facilities for their cheese or groups of farmers who own and supply milk to centralized cheese making and ripening facilities. Cheese making businesses, which are not farmstead, are called “artisan” if they have ten employees or less. Farm cheeses are, for the most part, made from raw milk. The regulation book sets down all the necessary directions which raw milk cheese producers need to facilitate compliance with French and EU rules regardless of the type and size of their operations.

For commercializing their products, producers should have the community sanitary approval, which is issued by the DSV subject to the following conditions:

1. The cheese business shall be registered with the DSV.
2. The dairy farm shall conform to sanitary regulations required by law.
3. The cheese making facility and conditions of fabrication shall conform to prescribed laws (confirmed by having an approval number which is also the identification number of the establishment).
4. The milk is used in cheese making such that the cheese placed on the market shall conform to the hygienic and microbiological standards.

5. The cheese shall be packaged and labeled in accordance with the current regulations.

Certain adaptations apply to producers who sell all their product directly and to producers who sell a small part of their production to an intermediary according to certain conditions.

Producer Classification

Cheese making businesses are classified in different ways, which influence the kinds of regulations they must follow to place their products on the market. There are six categories of farm cheese producers, with the characteristics of each, listed as follows:

1. Direct-selling producer:

↳ 100% of cheeses shall be sold directly to the final consumer (at the farm, farmer's market or fair, and by mobile sale or delivery to the consumer's residence) by the producer or immediate family members

↳ requires written Declaration of activity with the DSV

↳ livestock health is certified by the DSV

↳ must comply with regulations for facilities and equipment

↳ must comply with hygiene regulations

↳ identification, surveillance and control of critical steps in the cheese making process (based on HACCP principles)

↳ carry out auto controls on raw milk and cheese not of the frequency defined in the EU Directives (see section on "Controls" later on)

↳ identification of cheeses for sale by signage; labeling of individual cheeses not required

↳ Potable water (fit for human consumption) is sufficient for use; for private water supplies, a certification document is required.

2. Direct-selling producer also using an intermediary:

↳ A minimum of 70% of cheeses shall be sold directly to the final consumer.

↳ A maximum of 30% of cheeses shall be sold through retailers or restaurants within a distance of less than 80 km, with a limit of 250 kg of cheese sold during any single week of the year, and only sold in France.

↳ producers exempt from having a community sanitary approval

↳ requires a "patente sanitaire" from the DSV

▷ requires a document listing the each intermediary seller, address, and quantities and types of cheese sold filed with the DSV

▷ livestock health is certified by the DSV

▷ must comply with regulations for facilities and equipment

▷ must comply with hygiene regulations

▷ identification, surveillance and control of critical steps in the cheese making process (based on HACCP principles)

▷ carry out auto controls on raw milk and cheese not of the frequency defined in the EU Directives

▷ identification of cheeses for sale by signage; labeling of individual cheeses not required

▷ registration number is given by the DSV to use on invoices and bills of lading

▷ is unique to France and is being phased out because it is not recognized by the EU as there is not always a direct exchange between the producer and final consumer

▷ Potable water (fit for human consumption) is sufficient for use; for private water supplies, a certification document is required.

3. Producer with limited production: using a maximum of 500,000 liters (1,135,000 lb.) milk/ year:

▷ having new or existing facilities

▷ producers must have a community sanitary approval

▷ livestock health is certified by the DSV

▷ must comply with regulations for facilities and equipment

▷ must comply with hygiene regulations

▷ There are exemptions from certain regulations concerning the hygiene of facilities and conditions of production (see section on “Exemptions” later on).

▷ The case for exemptions must be presented to the DSV in a letter accompanying the petition (dossier) for community sanitary approval.

▷ identification, surveillance and control of critical steps in the cheese making process using methods compatible with the means of the establishment

▷ carry out auto controls on raw milk and cheese not of the frequency defined in the EU Directives

▷ Labeling includes information required by law and the “health mark” required by the community sanitary approval.

⌞ The health mark is used on all labeling, packaging, invoices, and bills of lading.

⌞ Potable water (fit for human consumption) is sufficient for use; for private water supplies, a certification document is required.

4. Producer with limited production: using a maximum of 2,000,000 liters (4,540,000 lb.) milk/ year:

⌞ The configuration of the existing facility must limit all possibility of expansion if exemptions are desired.

⌞ The case for exemptions must be presented to the DSV in a letter accompanying the petition (dossier) for community sanitary approval.

⌞ must have an employee training program for hygienic production of foods

⌞ All other conditions are similar to the previous limited production category except that the exemptions from regulations are not as extensive.

5. Producers of cheeses with traditional characteristics and cheeses with more than 60 days of ripening:

⌞ these cheeses are defined and listed by the government. The list is able to evolve as demanded by professional organizations

⌞ the cheese is:

- one with historical precedent and has been in existence for at least 50 years
- protected by a national law, e.g., Appellation d'Origine Controlée (A.O.C.)
- made by techniques required by a professional organization or producer association

⌞ exemptions from regulations that are not compatible with conditions of production, e.g., using wooden tools; (see section on "Exemptions")

⌞ All other conditions are similar to limited and unlimited production establishments, depending on level of milk usage.

6. Unlimited producer:

⌞ Producers must have a complete community sanitary approval (no exemptions).

⌞ Livestock health is certified by the DSV.

⌞ must comply with regulations for facilities and equipment

⌞ must comply with hygiene regulations

⌞ identification, surveillance and control of critical steps in the cheese making process using methods compatible with the means of the establishment

↳ carry out auto controls on raw milk and cheese (see section on “Controls” later on)

↳ Labeling includes information required by law and the “health mark” required by the community sanitary approval.

↳ The health mark is used on all labeling, packaging, invoices, and bills of lading.

↳ Potable water (fit for human consumption) is sufficient for use; for private water supplies, a certification document is required.

The Sanitary License (Patente Sanitaire)

This license does not concern the sale and fabrication of products from goat and sheep milk. It is required for all users of bovine milk given the following conditions:

- who sell raw milk directly to the consumer
- who sell raw milk to a dealer
- who make raw butter
- who are exempted from the community sanitary approval following a request to the DSV

The farmer is directly responsible to carry out the necessary actions to control disease. The farm must not have shown clinical signs of Q fever over the previous twelve months. The requirements for having the license follow the EU Directive 92/46/EEC concerning the rules for the hygiene of the holding. The sanitary license is obtained from the DSV and must be renewed each year.

The Community Sanitary Approval -

L’Agrément Sanitaire (Communautaire)

The authorization to sell cheese in the EU requires a completed “Dossier d’Agrément Sanitaire Communautaire.” The dossier concerns the facilities for fabrication of cheese and for storage of milk and cheese. The producer must file the dossier with the DSV. The completed document is sent, with a letter to the director of the DSV indicating the types of derogation requested:

- producer making cheeses ripened more than 60 days
- producer making cheeses with traditional characteristics
- producer using less than 2,000,000 liters/year
- producer using less than 500,000 liters/year

The dossier is composed of:

↳ the name and address of the petitioner

↳ the address of the establishment

▷ the nature of the business

▷ the list of products made

▷ a diagram of the location (scale of 1:1000), indicating the ways going to and from the establishment, the property boundaries, the sources of potable water and, in case non potable water is used, the circuit for evacuation of residual water.

▷ a diagram of the lay out of the establishment (scale of 1:100 to 1:300), indicating the arrangement of the different places for work and for personal use and:

- the circuit of fabrication, showing all steps from the entry of the raw milk until the exit of the cheeses
- the circuit of waste disposal: solid and septic
- the circuit of water pipes
- the mechanics of ventilation
- the principal pieces of equipment
- the changing and wash rooms
- the circuit of floor drains and drainage pipes

▷ the detailed description of the facilities used for:

- the reception and storage of raw materials,
- storage of packaging materials,
- fabrication of products,
- packaging, storage and delivery of finished products

▷ the capacity of the storage of raw materials and finished products showing quantities used and produced on a daily basis

▷ the description of the equipment and materials used

▷ the sanitation plan for the establishment

▷ the plan for the training of personnel

▷ the analysis of critical control points

▷ an attestation of using a public water supply or, in the case of using private water sources, a copy of the authorization to use the water

▷ the diagrams of the fabrication of all products in the establishment

↳ the copy of the latest results of auto controls on the raw milk and the finished cheeses before sale

If the dossier is in order and the establishment is in compliance, the producer is approved. Then, the producer is issued an approval number and the “health mark,” which is required on all products sold in France and the EU (refer to the example on page 22). Cheeses that are sold “green” to an affineur are exempt from carrying the health mark. For farm cheeses without individual packaging, the health mark shall be placed on the outside packaging, the box, etc.. The sanitary approval must be renewed whenever a new product is added or a modification is made to any part of the establishment.

New establishments must petition for the sanitary approval before they open. In this case, if the conditions do not permit authorities to inspect the hygiene under normal operating conditions, the establishment can receive a provisory approval, which is renewable in three months. It is possible for a producer, who has a principal establishment and one or more additional places for cheese making in the mountains, to use the same health mark on his products. In this case, the producer must provide a precise description of the facilities and fabrication processes used at each place. It is necessary to note the differences between each place as they exist in the format of the dossier.

Exemptions from certain requirements of the Community Sanitary Approval

In cases where the characteristic quality of a producer’s cheeses would be negatively impacted or where his business would be economically burdened, exemptions from certain regulations may be granted. These exemptions pertain to limited production establishments and producers of cheeses with traditional characteristics and/or cheeses that are ripened more than 60 days. The producer must petition the director of the DSV for specific exemptions. The producer may be able to adapt the rules as follows:

↳ The same refrigerated facilities can be used for storing raw materials and finished products provided:

- the capacity of the facility is sufficient for both,
- there is no risk of cross contamination,
- and the facility guarantees adequate conservation of the most perishable product or raw material in storage.

↳ Storage coolers and freezers may be equipped with max./min. thermometers or other procedures to monitor temperature changes.

↳ A separate office for the DSV agent is not required but the entire facility shall be open to the agents for inspection, including documents

↳ in the case of a family business, the bathroom of the establishment may be in the family residence.

↳ Separation of wet and dry areas and their functions is not required if the configuration of the establishment limits all possible expansion.

↳ Natural caves or rooms where walls, floors, and ceilings are not smooth for ripening cheeses are allowed, as long as the facilities are well maintained.

▷ Use of vats, boards for ripening and other wooden tools or cloths (organic) is allowed, if they are maintained in good repair and, if necessary, disinfected.

▷ Specific equipment for handling and protecting unpacked foodstuffs is not required if the operations are carried out to avoid the contamination of foods and microbial proliferation.

The Controls

“Official controls” for the safety of cheeses are done by the Veterinary Service while “auto controls” are the responsibility of the producers. They must have their cheeses tested for pathogens at a certified lab and keep the results on file. If pathogens are found, the producer is obligated to report this to the DSV, which then reports the incident to DGCCRF. The auto control system makes each producer responsible for the quality and safety of their cheeses. The frequency of analysis is determined by risk assessment; it is based on the nature of the product, more precisely to the risks inherent in the technology of production.

The frequency of analysis follows the rules of Directive 92/46/EEC: bimonthly tests for bacteria and monthly tests for somatic cells. In the case of producers using less than 80,000 liters (181,600 lb.) sheep and goat milk or less than 150,000 liters (340,500 lb.) of cow milk per year, the frequency of milk analysis can be reduced for a group of homogeneous producers (fabrication of the same type of cheese, same area of production, identical conditions of animal rearing, etc.). The producers must devise a specific program for analysis, which is approved by the DSV.

Recommendations for the frequency of auto controls are given in the following section on Controls from “the Guide to good practices in farm cheese production.”

OFFICIAL CONTROLS AND AUTO CONTROLS

OVERVIEW

- The regulations require that cheese making establishments and products be controlled in two ways: by official controls and by auto controls.
- Official controls are done by the administration for the producer.
- Auto controls are done by the producer at his cost.
- The frequency of the auto controls varies according to the average daily milk production and the animal species.

DEFINITIONS

Official controls: These are done by agents of the official departmental services: the Veterinary Service (DSV) and the Services of the DGCCRF, who are qualified to:

- verify conformity to regulations for livestock, facilities, and conditions for making and selling cheese.
- take samples of cheese for analysis (at the cost of the administration)
- impound lots of suspect cheese and remove cheese from the market which doesn't conform to regulatory standards

Auto controls:

These are done by the producer at his cost (for analysis) and are:

- obligatory when required by officials for regulations concerning farm cheese. The results are kept for official review.
- voluntary for surveillance of cheese sanitary quality or to provide information about accidents in the production of cheese

The frequency of official and auto controls for both milk and cheese is based on average daily production volumes after considering the annual milk production and species. Recommendations for frequency of analysis are given in the following table.

THE OFFICIAL CONTROLS

These controls apply to all stages of the production of milk, the fabrication of cheese, treatment, packaging, storage, transportation, distribution, and sales. They consist of one or many of the following operations:

- inspection
 - of facilities (buildings and grounds, equipment, means of transportation)
 - raw ingredients and finished products
 - cleaning and maintenance procedures
 - fabrication and milk treatment procedures
 - means of labeling and packaging
- sampling and analysis
- control of personal hygiene
- review of records and documents
- examination of auto control system and results

These controls are identical for all foodstuffs destined for sale in national and EU markets. The Directive 92/46 EEC of June 16, 1993 specifies the nature of these controls for farmstead cheese production. The goal of these controls is guarantee the safety of cheese products.

In farm cheese production the official controls pertain to:

1. The farm:

- the veterinary control of milking animals with respect to their health relative to raw milk (absence of brucellosis, tuberculosis, and contagious diseases transmissible to humans, and the cleanliness of livestock)
- the periodic hygienic control of the farm, essentially the condition of places for milking animals
- the control of raw milk by taking samples for analysis to verify compliance with regulations for microbiological quality, and to try to find drug residues (pharmacological and hormonal, e.g., antibiotics)

2. The cheesemaking facility:

- the state of the buildings and grounds, facilities, and equipment
- the personal hygiene
- the fulfillment and effectiveness of the auto controls
- the conditions of storage and transportation
- the fulfillment of the guarantee of safety (healthiness) of products by taking all necessary samples for laboratory analysis

3. The cheeses:

- the hygienic and microbiological quality by taking all necessary samples for laboratory analysis
- the absence of drug residues (pharmacological and hormonal, e.g., antibiotics)

THE AUTO CONTROLS

These are self controls initiated by the producer with respect to the sanitary and hygienic characteristics of products destined for the market. The auto control is a regulatory obligation except for producers who sell their entire cheese production directly to the final consumer. It is always recommended for producers who sell directly, who are otherwise submitting to official controls, to carry out auto control analyses of cheese to verify that their operations conform to regulations.

The auto control consists of:

- Taking and arranging analysis of samples of milk and cheese in a certified laboratory chosen by the producer at his cost. The results of analyses should be kept to present to the administration if the case arises.

- monitor the conditions of milk and cheese production and sale (critical points of contamination)
- inform the Veterinary Service if results of analyses indicate grave risks to consumer health (if necessary, recalling products from the market)

HOW TO IMPLEMENT AUTO CONTROLS

1. Consult with the Veterinary Service for necessary forms and procedures.
2. Choose a laboratory: generally the departmental veterinary lab but, if possible, choose another certified private lab.
3. Take samples of milk and cheese, respecting the appropriate procedures for sampling and transportation.
4. Keep the results on file to present to officials. In case of exceeding the limits, notably for pathogens: *Listeria monocytogenes* and *Salmonella*, when there is a grave risk to the consumer, notify the Veterinary Service.
5. Respect the regulations for hygiene at every step in the process: from milk production and cheese making to selling the products, particularly to control the critical points of contamination.

TAKING SAMPLES OF MILK AND CHEESE AND SENDING TO THE LABORATORY

Milk Samples

The milk is filtered and the sample is taken before the start of cheese making.

The sample is transported to the laboratory on the same day as it is taken. In case this is not possible due to an emergency, the sample should be stored at 0 to 4 °C for as short a time as possible before it is transported by the producer or by postal service. Samples should arrive at the lab at the beginning of the week.

Identification of the sample:

The identification is a document, which accompanies the sample to the laboratory. It contains the following information:

- name of the producer
- address
- number of agreement (EU communal agreement for sale and trade)
- type of sample and number (in order of all samples taken for the year, e.g., first sample of raw milk taken for the year = RM-01)
- sample date

- animal species
- requested analysis: auto control,
- details of the analysis requested (types of tests)
- date of arrival at the lab
- date of analysis
- date of results
- type(s) of corrective measures put in place, if necessary

The document is returned to the producer with the results of the analysis. It is kept by the producer for at least one year.

Analyses:

1. For raw milk cheese:

- cow milk
 - total bacteria (30 °C)
 - somatic cells
 - Staphylococcus aureus
- sheep and goat milk
 - total bacteria (30 °C)
 - Staphylococcus aureus

Also recommended, but not required, are the following tests in order to monitor the production:

- pH
- fecal coliforms

2. Pasteurized milk:

- cow milk
 - total bacteria (30 °C)
 - somatic cells

- sheep and goat milk
- total bacteria (30 °C)

Regulations:

- In case regulatory limits are exceeded (in two consecutive analyses) it is necessary to inform the Veterinary Service. Measures must be taken to determine the cause(s) of poor results.
- It is required that a risk analysis of critical control points is put in place. This analysis identifies and monitors the risks of contamination (sanitary quality of the production) at each step of the production process. The corrective measures used to prevent contamination are defined in the analysis plan.
- For regulatory limits for milk refer Table 4 (page 41).

Cheese samples

The sample is always taken at the end of the fabrication, in other words at the moment of the shipping or of the sale.

The protocol for auto control differs depending on the type of cheese.

- Cheeses from primarily lactic fermentations and hand ladling (small cheeses) require five cheeses from the same day of production.
- Cheeses from primarily rennet coagulation (large cheeses) require five samples of 100 g each from two cheeses from the same day of production.
- Samples are immediately placed in a sterile pouch furnished by the laboratory (on demand).
- Samples are transported to the lab on the same day they are taken. If this is not possible due to an emergency, the cheese samples should be kept at 4 to 6 °C:
 - fresh cheeses: 4 °C, and
 - other cheeses: 6 °C is recommended.
- Transportation procedures are the same as for raw milk.

Identification of the sample:

The identification is a document, which accompanies the sample to the laboratory. It contains the following information:

- name of the producer
- address
- number of agreement (EU communal agreement for sale and trade)

- type of sample and number (in order of all samples taken for the year, e.g., first sample of cheese taken for the year = C-01)
- sample date
- animal species
- age of the product in days (from the day of renneting)
- analysis requested: auto control,
- details of the analysis requested (types of tests)
- date of arrival at the lab
- date of analysis
- date of results
- type(s) of corrective measures put in place, when necessary.

The document is returned to the producer with the results of the analysis. It is kept by the producer for at least one year.

Analyses:

For all types of cheese:

- *Listeria monocytogenes*
- *Salmonella*

These bacteria are the most dangerous to the health of the consumer.

- *Staphylococcus aureus*
- *E. coli*

These bacteria indicate faults in hygiene (sanitation).

Regulations:

- In case regulatory limits are exceeded (in two consecutive analyses) it is necessary to inform the Veterinary Service. Measures must be taken to determine the cause(s) of poor results.
- In the case of *Listeria monocytogenes* or *Salmonella*, the incriminated lot of cheese should be taken off the market.
- In the case of *Staphylococcus aureus* or *E. coli*, if there is evidence of the presence of enterotoxins, the incriminated lot of cheese should be taken off the market.

- It is required that a risk analysis of critical control points is put in place. This analysis identifies and monitors the risks of contamination (sanitary quality of the production) at each step of the production process. The corrective measures used to prevent contamination are defined in the analysis plan.

- Refer to Tables 5a, 5b, and 2b (pages 42 and 20) for microbiological standards.

The Environment

Although the producer is not required to take environmental samples, it is essential to carry out in case of unsatisfactory results.

Sampling is done on:

- milking and cheese making equipment
- water
- facility: floors, walls, ceiling, etc.
- ambient air

Petri films are used, which can be furnished by the lab. It suffices to sample the environment and then place the films in sterile pouches. Conserve the films at 4 °C. Sampling should be done with single service gloves. Water samples should be taken in the same manner as those for raw milk.

Frequency of sampling:

- in case of problems with contamination, one analysis per month for each piece of equipment for three months
- in case of satisfactory results, one analysis per four months
- facilities: two analyses per year
- water: one analysis per year

Types of analyses:

- systematic testing of total bacteria (30 °C)
- two times per year: research of Salmonella, Listeria, and Staphylococcus

Samples are cultured and identified at the lab. This type of auto control aids in evaluating the quality of cleaning and disinfection (sanitation).

Standards:

The standards for pathogens in cheese reflect the health risks associated with different cheese varieties. There is also a standard for general coliforms but this only applies to soft-ripened cheeses from pasteurized milk (Tables Missing)

The standards for indicator micro-organisms are the same as in Directive 92/46/EEC (see Table 2b, page 20).

Labeling and Storage of Cheeses

Conditions:

1. for Direct sale:

↳ labeling is not required for sales at the farm

↳ it is necessary to inform the consumer about the product

↳ a sign, in plain view at the entrance to the establishment, which indicates the nature of the product is sufficient, e.g., "Farm cheeses for sale"

↳ for direct sale and delivery of products handed directly to the consumer there is a maximum storage temperature requirement:

· 4 °C for raw milk, fresh products from raw milk, and cut and sliced cheeses

· 8 °C for other fresh dairy products

· for ripened cheeses, the storage temperature is the responsibility of the producer

2. for Direct sale at the market or other places:

↳ it is necessary to inform the consumer about the product

↳ generally, the cheese is packaged before handing over to the consumer

↳ individual labeling of cheeses is not required, however a sign shall indicate:

· type of cheese, e.g., farm-made goat cheese (non-defined), St. Marcellin (defined)

· fat-in-dry-matter for defined cheeses (e.g. St. Marcellin as opposed to non-defined, "farm-made goat cheese")

· place of fabrication for defined cheeses: name of county or region, name of farm or village

3. Sold by an intermediary:

↳ for cheese in bulk, individual labeling is not required

↳ information may be present at the retail outlet

↳ self-service counters must have cheeses protected with a wrapper or paper

↳ each cheese shall be labeled individually

Labeling requirements:

- name and address
- place (county) of fabrication for defined cheeses
- net weight except for non-defined cheeses sold by the piece
- list of ingredients
- expiration date:
 - for ripened cheeses, <preferably consumed before --/---->
 - for highly perishable (fresh) cheeses, <for consumption until --/---->
- lot number = date of fabrication but is not required if the expiration date can indicate the lot number
- minimum level of fat-in-dry-matter as a percentage except for A.O.C. and non-defined cheeses with the designation “fermier” (farm-made), which must have a “non precise” fat-in-dry-matter
- mixed milk percentages
- denomination of sale, e.g., A.O.C. cheese - Ossau-Iraty A.O.C., defined cheese - St. Marcellin, non-defined cheese - “fermier”
- conditions for storage (recommended temperature)
- “lait cru” (raw milk) cheese if milk used in fabrication is not heated to more than 40 °C (104 °F) but is not required for cheeses ripened for more than 60 days
- health mark (from community sanitary approval)

Transportation of Cheeses

Documentation:

Before transporting foods, the transporter must indicate the following points on an “accompanying document”:

- types of products
- state of the products (refrigerated, frozen,...) and required temperature for transport, when not defined by regulation
- point of departure

· destination

This document must be available for inspection by agents in charge of controls.

Temperature:

The temperature, which is required during transportation, is dependent on the type of product and the conditions and distance of the transit. See Table 5 on the next page.

Auto controls and verification:

The transporter carries out regular controls to assure the following:

▫ that the equipment being used is suitable for transporting foods and is functioning properly

▫ that the required temperatures are maintained

▫ that the methods of cleaning and disinfecting the containment area are effective

The transporter shall identify all aspects of his activities that affect the security of the foods and make sure that proper procedures are used. In order to establish the nature and frequency of the controls, the transporter shall:

▫ refer to a guide of good hygienic practices certified by the public health authorities

▫ use the self control system based on the principles of HACCP.

The Sale of Cheeses

The facilities for selling cheese are constructed, equipped, cleaned and maintained in a way that prevents contamination of the foods. The regulations pertaining to the facilities, hygiene, and personnel in retail stores are similar to those in the US but, as in the case of transportation, the operator must have a risk reduction program. This auto control and verification is developed using the same guidelines as in the previous section.

THE GERMAN SYSTEM

The German dairy industry regulations are established cooperatively by the Ministry of Health, the Ministry of Agriculture, and Dairy Research Institutes, such as the Federal Dairy Research Center at the University of Kiel. industry organizations and consumer representation groups are involved in the process through public hearings. The regulations are synchronized with those of the EU and are set down in the German Milk Ordinance (latest version from July, 2000). [14] The process of updating German laws to align with the EU Directives has been going on since July, 1998.

Raw milk cheese is not made in Germany in any appreciable quantity. It may be legally produced from any milk as long as the milk meets the EU standards for total bacteria at 30 °C, somatic cells, and *Staphylococcus aureus* and the standard of the German Milk Ordinance for *Salmonella* (refer to Table 7, page 5).

There is a separate category of milk called “Vorzugsmilch,” which is certified for consumption as raw milk. This milk, which is referred to as “certified Grade A milk,” can be sold commercially as a retail product. There are only sixty farms, which produce Vorzugsmilch; one of them has been certified according to ISO 9000 standards. The government takes responsibility for regulating these farms and securing the safety of the milk. The standards are stricter than for regular raw milk. Direct producer marketing of Vorzugsmilch is not very frequent yet, but there is an increasing trend.

Vorzugsmilch

This milk is produced in accordance with all the requirements of the German Milk Ordinance for raw milk destined for sale and further use, which follow the EU Directive rules for animal health, milk microbiological and physical standards, and the hygiene of production facilities, equipment and personnel. In order for it to be sold as “Konsummilch” (milk for consumption) in its raw state there are some additional requirements as well.

For production and packaging of milk:

↳ it meets stricter microbiological standards (see Table 8, page 6)

↳ from the time of packaging to the time of sale, the temperature does not exceed 8 °C (46.4 °F)

↳ the package is marked “Raw Milk <to be consumed by --/-->” while the latest date of consumption can be no more than 96 hours after harvesting

For cows being held for milk production:

↳ production facilities have to keep records within a framework of internal controls on cows as follows:

- inclusion or purchase or sale, providing information on time, name and address of seller or recipient;
- time, type and length of illness and any noticeable disruption of general health condition;
- time and type of medicine dispensed; and
- records of medical examinations.

The documenting records are to be kept chronologically for two years and must be presented to authorities on request.

Milk sold directly from the farm

It is also legal for farmers to sell raw milk directly to consumers at their farms. This milk is referred to as “ex-farm milk.” As in the case of Vorzugsmilch, the rules of the EU Directives must be upheld in the production of this milk, however the microbiological standards are not stricter. Milk can be sold by the producer directly to the consumer at the farm if certain conditions are met.

The production and sale of raw milk:

- ↳ the milk is produced on the day of sale or one day before the sale
- ↳ at the sales location, clearly visible notations are posted “boil before consumption”
- ↳ the sale of raw milk has been reported by the producer to the appropriate authority in advance

The delivery of raw milk to consumers is permissible in the following circumstances:

- ↳ to family members of the producer and lessors of the facility
- ↳ to people who are employed in the milk producing facility and their family members
- ↳ through alpine pasture facilities to hikers and mountain hut operators

A recent study by researchers in Kiel, Germany showed that the incidence of pathogens (*L. monocytogenes*, *E. coli*, *S. aureus*, *B. cereus*, *Salmonella* spp. and *C. jejuni*) in Vorzugsmilch was significantly lower than in ex-farm milk. The researchers felt that ex-farm milk, when consumed or used in its raw state in insufficiently heated foods represented a serious health risk. However, if the manufacturer and the consumer correctly follow the current hygienic regulations, there was no need of changing them. [15]

The Self Control System

Milk producers and processors are required to regulate themselves through the system of “Self Control, which is supervised by the Veterinary Health Agency. The principles of HACCP or similar risk reduction systems are applied to develop the Self Control system, which is used more at the processor level rather than direct-selling producers of raw milk. [16]

The requirements for the Self Control system are set down in Article 16 of the German Milk Ordinance.

Facility Internal Controls and Documentation:

1. Whoever produces or treats milk or milk-based products is required to establish a system of internal controls to:

- determine the critical points applicable to the production process;
- determine and carry out methods for watching and controlling these critical points depending on the quantity of the milk to be processed and on the milk-based products;
- check the result of the tests for the adherence of the norms identified in this ordinance;

- develop a plan for cleaning and disinfection of space, equipment and tools, and check the results of the sanitation processes applied;

- reassure that milk and milk-based products are not affected by pharmacological or hormonal influence as well as by antibiotics, pesticides, cleaning materials and other materials which are harmful to or which can damage organoleptic properties and which are dangerous to human health; and

- document the process and results of tests.

2. Documentation is to be kept chronologically for two years and is to be shown to the appropriate government agency upon request. This does not apply to milk-based products which cannot be stored at temperatures of the surrounding environment. These documents must be kept for two months beginning with the code date or “best used by” date of the product.

3. Production and treatment facilities have to carry out the internal controls or have them carried out by a certified laboratory either within the facility or outside the facility.

Inspections of facilities and documents to check compliance with the rules of the ordinance are performed by Official Veterinarians, who are appointed by the appropriate government authority. The German Agriculture Association and the German Veterinary Association are in charge of approving materials for chemical disinfection of equipment.

Transportation

Whoever transports, or has transported by others, heat treated milk and milk-based products, which are not packaged in ready-made packages, has to provide an accompanying document, which can also be a sales document. This record must contain the following:

1. information about the fitness for consumption of the product, such as the EU health mark
2. type of last heat treatment

CONCLUSION

It is important to realize that the work in France, Germany, and other member states of the EU is not complete. The President of the Comité de Pilotage du Guide had these remarks about future endeavours in France,

“our wish is henceforth to engage the profession to construct a ‘Guide of Good Hygienic Practices’ for dairy products and farm cheeses, according to Directive 93/43. The guide will be directly operational in all types of farm cheese production. It will give each producer the concrete elements to put in place a self-control approach for the sanitary quality of their products. In addition, it will constitute a

formalization and reconnaissance of the 'savoir faire' of farm cheese producers. The guide will also act as a reference for officials and be equally well utilized in their agencies for their controls."¹⁵

The member states were required to encourage and participate in the development of these guides within 30 months of the adoption of Directive 93/43/EEC, which happened in France on September 5, 1995. Producers who have total or partial exemption from the requirements of the community sanitary approval will need to comply with the provisions of the new guide when it is completed.

The task of implementing systems of self-regulation at all levels of production, transport, and sale of foods, let alone dairy products, is enormous. The European Commission has recently adopted a proposal whose primary objective is to provide the basis for assuring a high level of protection of human health while ensuring the effective functioning of the internal market.¹⁶ The proposal sets down fundamental principles and requirements of food law and establishes a European Food Authority. This appears to be part of the ongoing effort in the EU to harmonize approaches to food safety assurance.

The code of hygienic practice for milk and milk products being drafted by the Codex Alimentarius Committee on Food Hygiene is still at step 3 of the eight-step process. The code is used as a reference for member states in creating the guides of hygienic practice. The assessment of the risks from different dairy products is a key issue in the drafting process. At this stage, the draft code allows individual countries to manufacture dairy products in whatever manner they desire and to establish their own level of public health protection.¹⁷

An ongoing debate in the Codex Committee on Food Hygiene concerns effective ways of carrying out risk assessments on microbiological hazards to create standards that are achievable by producers of traditional products and producers in developing countries. [17] In its report from 1997, the Codex Committee agreed to stress the importance of control measures at all stages of the food processing chain, from primary production to consumption.¹⁹ In the EU, the strength of the approach to place safe dairy products on the market lies in the use of self-controls by the producers of raw milk and other dairy foods with additional controls and verification of compliance performed by officials. In each member state of the EU, risk assessment has been used to provide a sufficient level of protection for consumer health. The evaluation of the risks associated with raw milk and products made from raw, thermized, and pasteurized milk resulted in the formation of standards and protocols for analyzing the safety of these products.

In France, the standards for raw milk and cheese and the frequency of analysis, which is linked to production levels, reflect the inherent health risks from microbiological hazards in farm cheese made by all producers, from the smallest to the largest. Therefore, it can be said that, the regulatory system in France directly reflects the French cultural interpretation of risk from the consumption of raw milk and cheese. The German regulations for raw milk and cheese are similar to those in France but stricter standards for *Vorzugsmilch*, which is raw milk intended for direct consumption and sold as a retail product, indicate a slightly different interpretation of risk from the French.

[1] Mr. Claus Heggum, Risk management in Denmark to minimize risks associated with raw milk, in the Report of a WHO Consultation on Public Health Implications of Raw Milk and Meat and their Products, Kiel, Germany, 17-20 December 1995, page 9, World Health Organization [2] Dr. Hans Asperger, Austrian trends in the production and consumption of raw milk products with special emphasis on the problem of *Staphylococcus aureus* in cheese, *ibid.*, page 5.

[3] *Ibid.*

[4] Remy Grappin and Eric Beuvier, Possible implications of milk pasteurization on the manufacture and sensory quality of ripened cheese, *Int. Dairy Journal* 7: 751-776, 1997, Elsevier Science Limited, Great Britain.

[5] Ibid.

[6] Ibid.

[7] Patrick Rance, *The French Cheese Book*, 1989, Macmillan London Limited, appendix 1.

[8] Ibid.

[9] Ibid.

[10] Philipp Hammer, *Campylobacter and Yersinia in raw milk - organisms of minor importance?*, in the Report of a WHO Consultation on Public Health Implications of Raw Milk and Meat and their Products, Kiel, Germany, 17-20 December 1995, page 9, World Health Organization

[11] Bekanntmachung der Neufassung der Milchverordnung, Vom 20. July 2000. *Bundesgesetzblatt Jahrgang 2000*.

[12] Council Directive 92/46/EEC of June 16, 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products, *Official Journal of the European Communities*, L 268: volume 35, 14 September 1992.

[13] Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs. *Official Journal of the European Communities*, L 175, 19/07/1993 p. 0001-0011.

14 J.C. Le Jaouen from "Le Guide de Bonnes Pratiques - Production Fromagère Fermière - Recueil réglementaire," avec la collaboration de la Direction Générale de l'Alimentation et la Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes, second edition, 1998.

[14] Bekanntmachung der Neufassung der Milchverordnung. Vom 20. July 2000.

[15] Hahn, G., Walte, H.-G., Coenen, C., Teufel, P.. Direct marketing of raw milk: findings and risk consideration. *Kieler Milchwirtschaftliche Forschungsberichte* 51 (2): 105-115 (1999).

[16] Personal communication with Philipp Hammer of the Federal Dairy Research Center in Kiel, Germany.

15 K. Boussouar from Ibid.

16 European Commission adopts proposal to establish new European Food Authority. November 17, 2000. *Cheese Reporter*, page 9.

17 Proposed Codex Milk Hygiene Code returned to step 3 for redrafting. November 10, 2000. *Cheese Reporter*, page 16.

[18] Report of the Thirtieth Session of the Codex Committee on Food Hygiene, Washington, D.C., 20 - 24 October 1977. page 3.
19 Ibid. page 6.