

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 Center for Dairy Research 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).¹ 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

¹ Bekanntmachung der Neufassung der Milchverordnung. Vom 20. July 2000.

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.²

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.³

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 can not be stored at temperatures of the

² 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).

³ Personal communication with Philipp Hammer of the Federal Dairy Research Center in Kiel, Germany.

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

Microbiological standards for cheese

The standards are in Table 9, pages 7 and 8.

Table 7. German standards for raw milk used in the manufacture of milk-based products.

	Cow milk		Sheep and Goat milk		Buffalo milk	
	for products made with 'heat-treated milk'	for products 'made with raw milk'	for products made with 'heat-treated milk'	for products 'made with raw milk'	for products made with 'heat-treated milk'	for products 'made with raw milk'
Standard plate count (a)	100,000	100,000	1,500,000	500,000	1,000,000	500,000
Somatic cell count (b)	400,000	400,000			500,000	400,000
<i>Salmonella</i> in 25 g n=5		0		0		0
<i>Staphylococcus aureus</i> (1) n=5, c=2 m M		500 2,000		500 2,000		500 2,000
In addition, pathogenic micro-organisms and their toxins must not be present in quantities such as to affect the health of consumers						

(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 8. German standards for Vorzugsmilch (certified Grade A milk).

Category	m	M	n	c
1. Total bacteria/ml 30 °C	30,000	50,000	5	2
2. Coliform bacteria/ml 30 °C	20	100	5	1
3. <i>Staphylococcus aureus</i> /ml	100	500	5	2
4. <i>Streptococcus agalactiae</i> /ml	0	10	5	2
5. Somatic cells/ml	300,000	400,000	5	2
6. <i>Salmonella</i> in 25 ml	0	0	5	0
7. Pathogenic micro-organisms and their toxins must not be present in quantities such as to affect the health of consumers.				
8. Sensory evaluation: without signs of abnormality				
9. Phosphatase: positive				

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 9: Obligatory microbiological criteria for certain milk-based products (German Milk Ordinance).

◆ Table 9a: Pathogenic micro-organisms

Type of micro-organism	Hard cheeses	Other cheeses
<i>Listeria monocytogenes</i>	Absence in 1 g n=5, c=0	Absence in 25 g (a) n=5, c=0
<i>Salmonella spp</i>	Absence in 25 g, n=5, c=0	
In addition, pathogenic micro-organisms and their toxins must not be present in quantities such as to affect the health of consumers		

(a) the 25 g sample consists of 5 specimens of 5 g taken from different parts of the same product

◆ Table 9b: Indicator organisms

	Soft cheeses made from heat-treated (pasteurized) milk
Coliforms (plate count at 30 °C) per g (1)	m = 10,000 M = 100,000 n = 5, c = 2

(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 9c: Micro-organisms indicating faults of hygiene

Type of micro-organism	Cheeses made from raw milk and from thermized milk	Soft cheese made from heat-treated (pasteurized) milk	Fresh cheeses made from heat-treated (pasteurized) milk
<i>Staphylococcus aureus</i> per g (1)	m = 1 000 M = 10,000 n = 5, c = 2	m = 100 M = 1,000 n = 5, c = 2	m = 10 M = 100 n = 5, c = 2
<i>Escherichia coli</i> per g	m = 10,000 M = 100,000 n = 5, c = 2	m = 100 M = 1,000 n = 5, c = 2	-

(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.