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# **Food Quality Management Systems in the Dairy Industry: A Case Study on the Application of Predictive Microbiology in the Microbial Quality of Milk**

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## **Abstract**

Agri-food industries must guarantee the safety of the produced foods through the application of the existing regulations, by correctly implementing quality control systems. In relation to the quality of drinking milk, it is extremely important to monitor the industrial treatments to which it is subjected to avoid the multiplication of spoilage and pathogenic microorganisms. Raw milk must undergo strict quality controls at the primary production level based on the knowledge of the main factors that influence their quality and microbiological safety: hygienic practices, health status of cows, frequency and moment of collection, storage temperature and time of transportation. To improve food safety and estimate food shelf life, predictive microbiology is a widely used tool for the estimation of microbial behavior as a function of intrinsic and extrinsic by using mathematical models. Throughout this chapter, a description of the current food quality management systems (FQMS) carried out by dairy industries will be provided by reflecting the current challenges, the guidelines, and available tools. A case study based on the application of predictive microbiology considering the importance of controlling certain factors in the primary production dairy chain will be developed.

**Keywords:** quality management system, dairy industry, MicroHibro, HACCP, predictive microbiology

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## **1. Introduction**

Food industries are responsible of assuring the quality and food safety by means of the implementation of quality management systems (QMS). Industrial QMS allows to accomplish with the specifications between the food companies and customers, claiming the quality along

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the time [1]. The food production chain connects different actors and stages. In the case of dairy production, the chain includes some steps as milking, milk collection, milk reception, industrial treatment and dairy transformation, packaging, storage, distribution, and consumption [1, 2]. Each stage should offer added value to the product with minimal cost [3] and apply the European Union legislation such as: Regulation (EC) 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, Regulation (EC) 852/2004 on the hygiene of foodstuffs, Regulation (EC) 853/2004 laying down specific hygiene rules for on the hygiene of foodstuffs, and Regulation (EC) 854/2004 on the organization of official checks on products of animal origin intended for human consumption.

Milk is a nutritious food, which allows the growth of microorganisms. Its composition includes proteins, fats, carbohydrates, vitamins, minerals, and essential amino acids, which provide an adequate environment for the microorganisms' proliferation because of a neutral pH and a high-water activity on milk. Some microorganisms use these nutrients directly, and others unleash the metabolism of them. Their proliferation is determined by temperature, time, and nutrient availability [3, 4]. For this reason, good manufacturing and good hygiene practices (GMP and GHP) applied at all the stages of the chain must to be adopted.

QMSs are focused in the control of the main hazard sources that can occur in the food industry. The dairy chain implies several limitation and potential hazard that can reduce the quality and safety of milk. The intrinsic characteristic of milk, as an ideal environment for microorganisms, [4] combined with its direct contact with equipment and facilities during the different stages of milk production make the implementation of QMS in the dairy production chain a challenge [5]. Two types of hazards have been considered the most relevant: chemical hazards are more associated to feed and farm and microbiological hazards more related with farm and dairy processing [6]. Application of validated predictive models is recognized as a valuable tool able to estimate behavior of potential microbiological hazards or spoilage microorganisms on raw milk during production chain. The obtained outcome can provide an estimation of the impact of relevant factors within the milk production chain and corrective measures to be applied.

## **2. Quality management system of the dairy production chain**

### **2.1. General consideration of the self-control and quality management systems (QMSs)**

The self-control systems are based on the Hazard Analysis of Critical Control Point System (HACCP). This is a systematic procedure focused to identify microbiological, chemical, and physical hazards as early as food manufacturing and to eliminate these hazards by taking the suitable measures [7, 8]. Correct practices and conditions described on the Codex Alimentarius [9] and Regulation (EC) 853/2004 define prerequisites to be deemed before the development of HACCP.

The International Organization for Standardization (ISO) created the international standards which give specifications for products, services, and systems, to ensure quality, safety, and

efficiency. They comprise standards for the development of a quality system of any type of organization and any part of the world. They were directed for the assurance of the process quality and the establishing of an international normative frame for the management and quality control [2, 10]. The requirements applied by the food industry can be tougher than the compliance of legal rules. The ISO certification has become a very important strategy for the companies because it provides the confidence to customers and other stakeholders to control food safety hazards. In addition, international standards enhance transparency in the development of food quality and safety procedures, thus helping to improve and update food safety systems [11]. The implementation of these standards is fixed with the ISO 9000:2000—Quality management systems—fundamentals and vocabulary, which takes part of others onto NMX ISO 9000:2000 with guidance, technical reports, and specifications [2, 10].

## **2.2. QMS applied in farms and transport**

Although HACCP are systems implemented in the industries, the primary production has no duty of developing them. On this case guidance and advices for the correct management are followed in relation with animal health, food, traceability, hygiene, and cleaning [12].

The milk collection by the trucks in farms must to be done in hygienic conditions to prevent microbial contamination. For the correct handling of raw milk, the truck driver must be trained to use suitable clothes and to avoid the entrance to stables. Milk samples will be collected for quality control, verifying the temperature of storage (8°C for daily collection and 6°C for each 48 h collection), and trucks must maintain the milk temperature on tanks below 10°C according to EC Regulation 853/2004 [13].

Current transportation unit designing must have an efficient cleaning and drainage system to prevent corrosion and the transference of foreign substances to milk [14]. Complete cleaning and disinfection of truck are made after use and for 48 h. Trucks must have available the Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage (ATP), which is a treaty of United Nations laying down rules about international transport of perishable food like milk between states members of the treaty [15].

Finally, the round-trip sheet of the truck must include information of the address industry, of the driver, of the suppliers of milk or farms, and of the date, hour, deposit, or liters collected.

## **2.3. QMS applied to the dairy industry**

There are seven principles on the development of the HACCP on a dairy industry [16]. They are conducting a hazard analysis, identifying the critical points in the process, establishing critical limits, critical control point monitoring requirements, corrective actions verification, as well as record-keeping procedures and documentation of the system. The principles of HACCP are mainly oriented to achieve the following objectives—identifying, assessing, and controlling health hazards—to increase the level of product quality and safety and to low product liability risks and to enhance consumers' protection and confidence [9, 17].

The process and product description lead to describe the different production stages, and it helps to detect and define the hazard and critical points in the industry. Onto the different stages of the dairy industry, there are some where milk is not heat-treated (so it is raw) and others where milk receives a heat treatment. Regarding raw milk, time and temperature conditions are some of the main factors affecting milk quality. Bacterial counts can be highly influenced by the time since the milk is collected in tanks until it is thermally treated in the industry [18, 19]. Despite that the most spoilage and pathogenic microorganisms are inactivated by the thermal treatment, the previous stages in which milk remains untreated are very important from the assurance of quality point of view, to minimize undesirable effect of microbiology in the treated and packaged product [7]. These stages are tank truck reception and storage on silos. Truck's reception involves the stage in which milk go from tank of truck to silo of industry. Silo is a big container for the storage of milk in isothermal conditions. The temperature of milk must to be below 6°C until its transformation except when milk will be transformed immediately after or over the next 4 h. The truck reception is an important quality control point where quality control technicians collect milk samples for analyses before content passes to silo. Because raw milk is stored on tanker trucks and silos under isothermal conditions, if refrigeration temperature of tanks is not working properly, initial microorganisms could grow until reaching unacceptable levels. Thus, cooling and storage temperature of milk in farms should be controlled to prevent microbial contamination.

For safety assurance, antibiotic waste, mycotoxins, somatic cells, and bacterial counts in milk of trucks before discharging from cisterns to silos should be analyzed. Besides, from a quality point of view, additional physicochemical parameters of milk such as color, odor, appearance, acidity, alcohol stability, cryoscopic point, and milk temperature at arrival to industry are usually monitored. Likewise, chemical composition (mainly fat, proteins, and dry matter) is also analyzed [20].

Hazards must be identified to be eliminated or reduced to acceptable safety levels. The hazard occurrence probability and importance (i.e., severity of foodborne illness) allow to define different tolerance levels for hazard (**Table 1**). The source of hazards can be produced by biological, chemical, or physical agents. The incidences can be determined by the presence of any of these agents or favorable conditions for the effect of them on the human health. Incidences by biological agents can be caused by the reception of milk with higher somatic cells or bacteria than legal limits accepted. Biological agents can be originated by mastitis cows, poor management practices during the milking, cooling, and storage or through damaged equipment. All these factors

Probability	Importance		
	Low	Medium	High
Unlikely	Tolerable	Tolerable	Medium
Temporary	Tolerable	Medium	Not admitted
Likely	Medium	Not admitted	Not admitted

**Table 1.** Classification of hazards according to their level of tolerance based on their occurrence probability and importance.

involve tissue damages on udder or proliferation of pathogenic microorganisms related to mastitis process. Incidences by chemical hazard can occur because the presence of disinfectant waste associated to milk blended with water cleaning. Incidences by physical hazard can be caused by the presence of foreign material when the maintenance of tank, truck, or silo does not have been verified consistently [8].

### **3. Case study on the application of predictive microbiology tools to determine the effect of production chain conditions on the microbial quality of milk**

The optimization of the milk production chain to reduce spoilage before the heat treatments at industry greatly relies on the knowledge of storage temperature and times at the different steps in the primary production chain [21].

The temperature of milk below 7°C for a long storage period is associated with the proliferation of certain psychrotrophic bacterial species. The glycolytic, proteolytic, and lipolytic activity of these types of bacteria can produce deterioration of milk quality after heat treatment [22]. The most common species of psychrotrophic bacteria are *Pseudomonas* spp., *Alcaligenes* spp., *Bacillus cereus*, *Lactobacillus*, *Micrococcus*, *Streptococcus*, and *Enterobacteriaceae* family [4]. *B. cereus*, *Streptococcus*, and *Pseudomonas* spp. are known as the most persistent bacteria able to survive forming biofilms on equipment in dairy industries [23]. The main concern of these psychrotrophic species is related to the survival capacity of their enzymes and spores to typical heat treatments applied to milk. Species as *Pseudomonas fluorescens* produce extracellular enzymes when bacterial population reaches or exceeds 10<sup>6</sup> CFU/ml in food [21]. They can contribute to casein and lipid degradation, causing product alteration during distribution and home storage [24]. In addition, an increase in the number of milking times from two milking per collection and truck (only 1-day milking) to four milking per collection and truck (2-day milking) can result in a larger hydrolysis of fat globules and higher production of oxidation and browning phenomena because of temperature rises during different milkings [25].

Predictive microbiology is a scientist branch within food microbiology aimed at predicting microbial behavior in foods at different processing and storage conditions. Predictive microbiology is gaining relevance in the establishment of HACCP systems in food industries as tool to identify microbial hazards, set control limits, and/or define corrective measures to be implemented. One of the most relevant applications is focused on the study of the bacterial behavior on foods under different environmental conditions. The kinetic parameters (i.e., maximum growth rate, lag time, inactivation rate, etc.) are estimated by means of mathematical equations. The use of predictive microbiology is very interesting in order to optimize food processes and to provide assistance in decision-making in a short time frame to food industries. To this sense, the use of mathematical models by the food industry will depend on the development of appropriate and easy-to-use software tools, which encompass predictive models and allow different users to retrieve information from them in a rapid and convenient way.

On this case study, microbial growth was assessed at different time and temperature conditions during the milk production chain, from farm to industry, by the application of predictive microbiology. Further, corrective measures and recommendations to industrials are provided on the storage and handling practices to avoid milk spoilage before application of thermal treatments.

### 3.1. Selection of a predictive microbiology model

*Pseudomonas* spp. was selected as the reference spoilage microorganism group given its relevance as psychrotrophic bacteria and its influence on milk stability [23].

The model for *Pseudomonas* spp. corresponded to the one developed by Lin et al. [21] for *P. fluorescens* in UHT milk, considering storage temperature as the prediction variable:

$$\sqrt{\mu} = c(T - T_0) \quad (1)$$

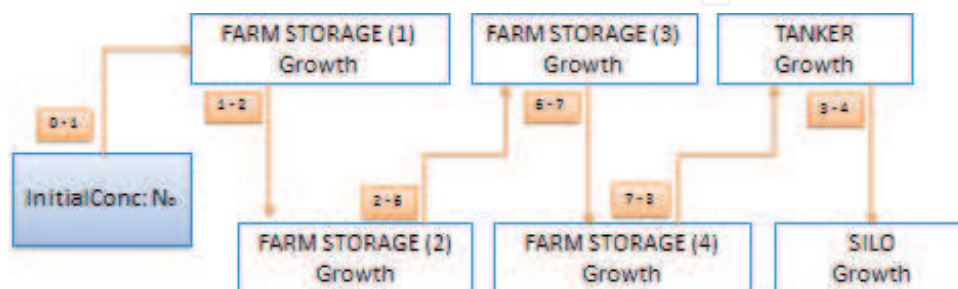
where  $\mu$  is the growth rate,  $c$  is the slope of regression line,  $T$  is the storage temperature, and  $T_0$  is the hypothetical minimum growth temperature where the extrapolation of the regression line intersects the  $T$  axis.

### 3.2. Definition of the stages and variables for dairy chain

The different stages considered in the present study are represented in **Figure 1**. At *Farm*, milk is stored up to its collection by tank trucks, and it can be split into four different steps: (1) the cooling process after the first milking, (2) storage at low temperature, (3) the cooling process after the second milking, and (4) storage at low temperature up to collection. The stage *Tanker* in **Figure 1** represents for milk storage during tank truck transport from farm to industry. Finally, *Silo* stands for the milk storage in the containers at industry.

Since the purpose was to determine *Pseudomonas* spp. growth along the different represented steps by applying the selected predictive model, growth factors along the different considered steps and initial bacterial concentration at farm had to be defined beforehand.

To this end, an expert knowledge elicitation was carried out using the Delphi method [26, 27] where five experts were identified in base of their experience (**Table 2**) and asked for their



**Figure 1.** Flow diagram showing the stages considered for the exposure assessment model.

No.	Responsibilities, education, and specialization			
	Job position	Qualification	Experience	Experience (years)
1	Cistern reception control	Technician	Responsible for ensuring specifications of raw milk during reception of cistern trucks by means of analyzing milk quality and composition	4
2	Cistern reception control	Technician	Responsible for ensuring specifications of raw milk during reception of cistern trucks by means of analyzing milk quality and composition	3
3	Milk quality control chief	Graduate	Manager responsible for the quality of the milk, dairy products, and industrial processes	15
4	Cistern truck driver	Operator	Responsible for the hygienic collection of milk from tanks to cistern of truck and collection of quality control samples from farms	25
5	R + D responsible	Graduate	Responsible for the Research and Development Department	3

**Table 2.** Description of the profile of selected experts.

estimation for time and storage temperature of raw milk at the different stages studied: during storage at farm, in tankers and silos at industry facilities.

The values obtained from the Delphi method are presented in **Table 3** together with the initial concentration of psychrotrophic bacteria on raw milk at farm based on the study of Cempírková [28]. These values were used to define probability distributions that were then used to input the selected growth predictive models to predict *Pseudomonas* growth from farm to industry.

### 3.3. Case study assumptions

It should be mentioned that model by Lin et al. [21] has certain limitations concerning its application in the present case study. While the targeted product in the present study was raw milk as the study scope encompasses from farm to industry (i.e., before processing), the predictive model used was performed in UHT and low-fat milk. Therefore, predictions from the model could overestimate the actual growth in raw milk, in which competing microbiota and higher fat content are expected to reduce bacterial growth in comparison with treated milk. Nonetheless, estimates are still useful to represent for a worse-case scenario in which

Parameters	T (°C)			Time (h)			<i>Pseudomonas</i> spp. (log CFU/ml)		
	Max	Min	Med	Max	Min	Med	Max	Min	Med
1. Tank	3.9	3.5	3.7	18	1	12	4.81	2.84	3.66
2. Tanker	6	3.5	4.5	8	1	5	—	—	—
3. Silo	6.5	3.5	4.0	24	4	14	—	—	—

**Table 3.** Representative values for temperature (°C) and time (h) along the different steps from farm to industry for the milk production chain and initial concentration of *Pseudomonas* spp. at farm (log CFU/ml) [28].



bacterial growth is not influenced by the accompanying microbial population. Besides, the model domain of Lin et al. [21] was between 4 and 29°C so that temperatures below 4°C have not been considered for the exposure assessment model.

To enable to assess the suitability of the milk production chain in terms of microbial quality, a cut-off value was set determining spoilage associated with microbial protease activity after heat treatment. This reference value corresponded to  $10^6$  CFU/ml in food as discussed previously [21].

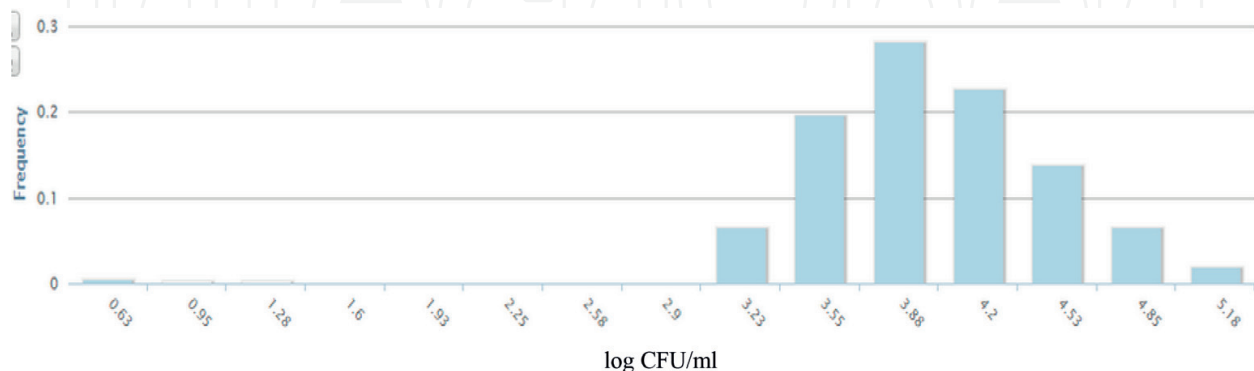
### 3.4. Exposure assessment model

An exposure assessment model was implemented in MicroHibro software v 1.7.7. (www.microhibro.com) including the stages abovementioned and based on the application of the selected predictive microbiology model. Storage time and temperature of milk at each stage were introduced by defining triangular distributions based on data presented in **Table 3**. Since distributions were used, a Monte Carlo simulation was performed in MicroHibro with 10,000 iterations. The Monte Carlo method implemented in MicroHibro enables to run the *Pseudomonas* growth model with a total of 10,000 random combinations of time and temperature for each step in the milk production chain and returns a probability distribution reflecting variability in the output which, in our case, corresponded to the concentration of *Pseudomonas* after storage in Silo.

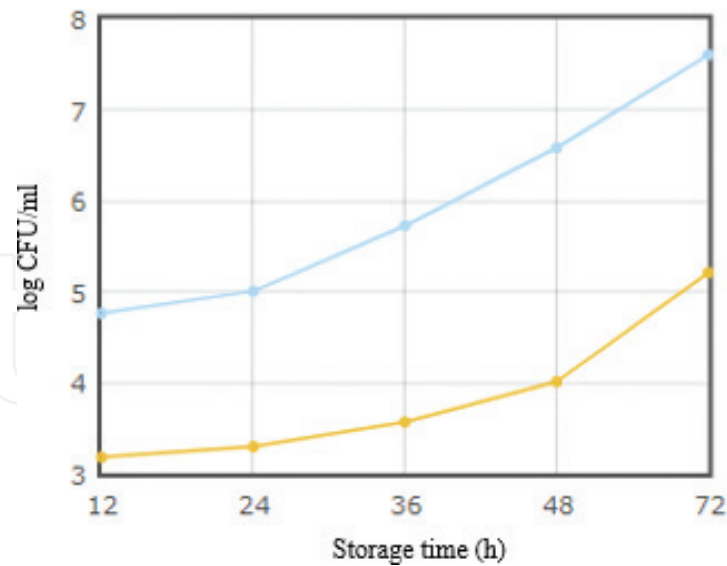
The output from the model simulation provided the final concentration distribution for *Pseudomonas* after silo storage and just before heat treatment at industry as shown in **Figure 2**.

The simulated data in MicroHibro software yielded a mean concentration corresponded to 3.8 log CFU/ml, which means an increase in 0.2 log CFU/ml with respect to the initial concentration defined at farm second expert specifications in **Table 3**. The maximum value also resulted in a slightly higher increase of 0.4 log CFU/ml than that at farm. These results evidence that the milk production chain as defined in this study was adequate to significantly reduce milk spoilage due to psychrotrophic bacteria growth.

A scenario analysis was also performed in which different constant values for time and temperature during storage in silo were tested. According to the simulated data, the 5th and 99th

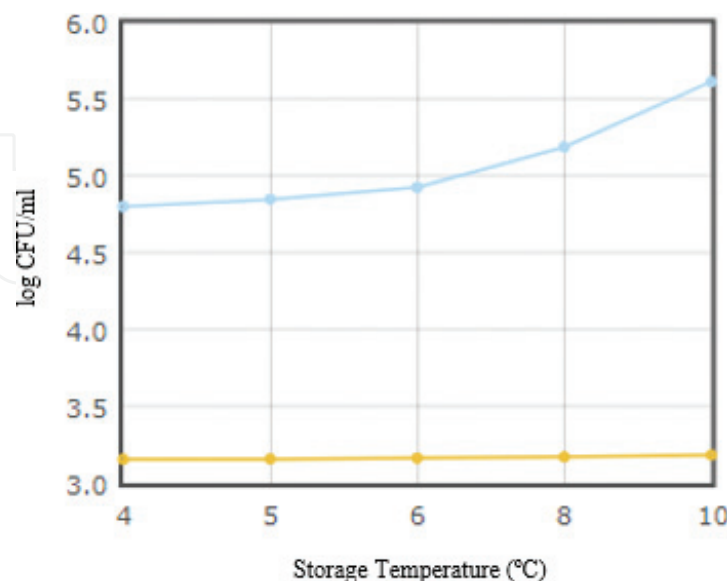


**Figure 2.** Simulated output distribution for final concentration of *Pseudomonas* after silo storage and before heat treatment at industry obtained using MicroHibro software.



**Figure 3.** Simulated percentiles for the concentration of *Pseudomonas* versus storage time (h). The blue and yellow lines represent for the 99th and 5th percentiles, respectively.

percentiles (log CFU/ml) of the final concentration of *Pseudomonas* spp. were calculated. Percentile is a statistic widely used in exposure assessment studies to indicate the values below which a percentage of observations fall. In **Figure 3** the 5th and 99th percentiles are represented for obtained final levels of *Pseudomonas* for different storage time in silo. According to **Figure 3**, both percentiles showed a significant increase as time increased. For times higher than 36 h, the 99th percentile for *P. fluorescens* concentration was above 5.5 log CFU/ml (i.e., 1% of simulated values exceeded this limit). Considering a worst-case scenario (99th percentile), predicted microbial concentration was above 6 log CFU/ml (microbial quality criterion) when the storage time was around 40 h. This fact shows the importance of maintaining a short-time milk storage in silos



**Figure 4.** Simulated percentiles for the concentration of *Pseudomonas* versus storage temperature (°C). The blue and yellow lines represent for the 99th and 5th percentiles, respectively.

before processing. Besides, although considering relatively low counts of *P. fluorescens*, it is recommended that milk should not be stored in tanks for more than 24 h since unloaded milk remaining inside tanks could have a high risk of milk contamination to silos.

**Figure 4** shows the effect of temperature. Results are only significant if considering extreme values (99th percentile) from the exposure assessment model. Even though, storage temperatures did not yield to increase levels of *P. fluorescens* above 6 log CFU/ml when simulated 99th percentile was considered for 10°C of storage temperature. However, extreme combinations of long storage times and high temperatures should be avoided to prevent milk from microbial spoilage. Storage temperature maintenance between 4 and 6°C seems to be enough to prevent the high proliferation of bacteria.

## 4. Conclusions

Quality system of food industries must apply the current regulations and guarantee the compliance of specifications indicated by customer. Industries can be tougher from the quality point of view by means the application of ISO 22000 and 9000:2000 Standards whose compliance provides confidence and positioning with respect to other companies. One of the most relevant parts when developing a HACCP consists in the identification and classification of hazards and analyzes possible incidences and correcting measures. Predictive microbiology is an efficient tool for the prediction of microbial safety and quality associated with specific steps along the milk production and distribution chain. To this respect, the case study presented herein evidenced that the current temperature and time values observed in the milk production chain are suitable to maintain milk microbial quality. In addition, specific critical limits were identified, especially for storage time at silo, where times shorter than 36 h could be a reliable measure to reduce milk spoilage due to microbial protease activity after heat treatment.

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