

“DISEÑO E IMPLEMENTACIÓN DE UN SISTEMA DE ASEGURAMIENTO DE LA CALIDAD BASADO EN LAS BUENAS PRÁCTICAS DE MANUFACTURA PARA GARANTIZAR LA INOCUIDAD EN LOS PRODUCTOS LÁCTEOS BONANZA”

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Abstract:

This article is a study in Good Manufacturing Practices developed as a system of quality assurance to maintain and ensure the safety of dairy products

It is based on Decree No. 3253, Good Manufacturing Practice for Processed Foods (BPM) and INEN standards.

Then a diagnosis of the initial situation is made using a checklist of requirements GMP, to identify shortcomings in, installations, food handlers, raw materials and inputs, in production operations, packaging-labeling, storage-distribution and assurance and quality control and a microbiological analysis is made for the presence of pathogenic microorganisms in dairy products due to poor manufacturing practices.

Finally an assurance system is developed, creating a GMP manual, Programs of: Cleaning and disinfection, waste management, pest control, training, standard operation procedures (SOPs), sanitation standard operating procedures (SSOPs) to apply methods and get a healthy and safe product for the end consumer.

Keywords: quality, programs, procedures, records, safety, assurance.

1. Introduction

Dairy products are an important food group because it creates an important contribution to the ingestion of vitamins, but its nature, composition, processing, handling have a high probability of causing injury to health if not are treated in an appropriate manner.

Currently the handling of food is considered from source until that the product to arrive the consumer, for this

reason each phase of process should have control measures adopted for each activity. (Sanz, 2012, pág. 45)

So develop a system of quality assurance would give confidence that the quality requirements of product be met.

Furthermore the GMP intended to guide in basic principles and general hygiene practices in the manipulation, preparation, processing, packaging and storage of food for human consumption, in order to ensure that the food manufactured is in good sanitary conditions. (Decreto Ejecutivo 3253, 2002)

2. Materials and methods

The factory is evaluated with a checklist of requirements of Good Manufacturing Practices from Ministerio de Salud Pública in accordance with the Agencia Nacional de Regulación, Control y Vigilancia Sanitaria-ARCSA. This list evaluates segments like: installations, food handlers, raw materials and inputs, in production operations, packaging-labeling, storage-distribution and finally assurance and quality control; contains 144 items about the requirements mentioned.

A microbiological analysis of the products is performed and compared with the requirements of Standard INEN each product.

Proposing an improvement plan for giving solutions to the shortcomings found in the factory.

Developing the system of assurance and quality control contain:

Manual GMP is the principal document from system of quality it shown in way generally the operational control inside of factory to facilitate the production of safe food, the manual includes procedures, sanitary conditions of the factory, training and personnel hygiene, cleaning and disinfection, pest control.

Standard operation procedures (SOPs)

Are written procedures that describe and explain how to perform a task for a specific purpose, indicate how, when, where and by who, supplying a record that demonstrates the process control to ensure that the work is carried out safely and respecting the same procedure.

Sanitation standard operating procedures (SSOPs)

Engage essential practices for maintaining hygiene this are apply before, during and after processing operations, being a condition to ensure the safety of products at every stage of the food chain. (Administración Nacional de Medicamentos, Alimentos y tecnología Médica., 2011)

Cleaning and disinfection program (C&D)

The object of cleaning and disinfection program is to have a document about the cleaning and disinfecting procedures work areas, equipment and utensils used in food processing, where is the C & D agent (hot water, soap, chlorine etc.), concentration, preparation and instructions for use. (García B., 2007 , págs. 84,85)

To design a cleaning and disinfection program must be establish

- What will you to cleaned and disinfected?
- What tool are you going to use to cleaning and disinfection?
- How often are you going to do the cleaning and disinfection?
- What is the best way to perform the operations of C&D?
- Who does the C&D?

Waste management program

Because of the amount of waste, both solids and liquids generated in a food industry and the danger from that exist contaminate food, it is necessary to establish a program for the disposal of this waste. (Equipo Vértice , 2009, pág. 59)

Pest Control Program

Pests present major threats to the safety and suitability of food. The composition of raw materials and finished products are propitious to the development of pests and they can produce diseases. To eliminate this possibility must be maintained, next to C&D program a pest program. (García B., 2007 , pág. 85)

The pest program provides in detail:

- Name of the product used.
- Type (composition) and dose products used.
- Method and frequency with which these operations are performed.
- Result or effectiveness of the traps and number of incidents detected.
- Personnel who is responsible for these activities.

Training Program

The training program must be designed with themes on Good Manufacturing Practices for the organization has knowledge of how to ensure product safety.

Records

It is a way of demonstrating the system created and programs are met properly.

2.1 Case Study

This system was applied to the dairy plant "Bonanza" that make, yogurt, cheese and manjar.

An initial assessment was conducted leaning checklist of BPM with which it was concluded that the plant only met 41% of the total percentage of BPM requirements, this means that the plant no ensured a product safety; institutions such as the Ministerio de Salud Pública y ARCOSA indicate that a company is able to ensure the development of a healthy product minimum with 80% of BPM requirements.

GMP decree requirements	Percentage		
	complies	no complies	Required partial
installations	14,3%	18,4%	32,8%
Equipment and utensils	2,5%	5,7%	8,2%
staff	5,3%	7,0%	12,3%
Raw materials and inputs	3,3%	1,6%	4,9%
Production Operations	3,3%	5,7%	9%
Packaging and labeling	2,5%	2,5%	4,9%
Transport and storage distribution	4,5%	3,7%	8,2%
Assurance and quality control	5,3%	14,7%	19,7%
TOTAL	41%	59%	100%

Table 2.1: Results of the initial evaluation as required of GMP

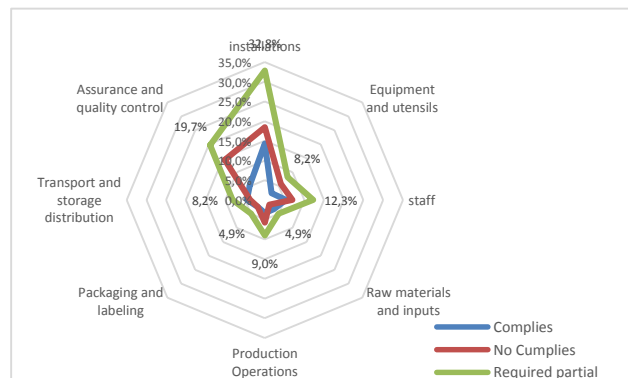


Figure 2.1: Results of the initial evaluation by segments of GMP requirements

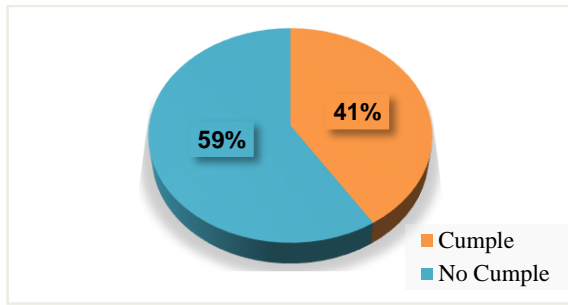


Figure 2.2: Total result of Initial Evaluation

In the initial results of the microbiological analyzes existed a high presence of molds and yeasts compared with the INEN standard of yogurt, cheese and manjar, was observed; molds and yeasts can cause food spoilage, altering its organoleptic characteristics as undesirable flavors, texture and unpleasant aroma for product appearance

The presence of these fungi can be to poor sanitation of equipment and utensils, poor manufacturing practices

m = maximum allowable index to identify level of quality

Product	Count	Unit	UTN Laboratory Initial Results	INEN standard value (m)
Yogurt	molds	UFC/g	600	200
	yeasts	UFC/g	7000	200
Cheese	molds	UFC/g	1500	X
	yeasts	UFC/g	60000	X
Manjar	molds	UFC/g	150	10
	yeasts	UFC/g	400	10

Table 2.2: Initial Results microbiological count of molds and yeasts

Se levantó y aplico lo siguiente:

- Manual GMP
- Standard operation procedures (SOPs)
- Sanitation standard operating procedures (SSOPs)
- Cleaning and disinfection program (C&D)
- Waste management program
- Pest Control Program
- Training Program
- Records

3. Results

With the implementation of programs and procedures the percentage rose by 32% this means that in the final

evaluation existed a fulfillment of 73% requirements of GPM.

GMP decree requirements	Percentage		
	complies	no complies	Required partial
installations	18,03%	14,75%	33,06%
Equipment and utensils	4,51%	3,69%	8,06%
staff	10,25%	2,05%	12,10%
Raw materials and inputs	4,51%	0,41%	4,84%
Production Operations	7,38%	1,64%	9,68%
Packaging and labeling	4,10%	0,82%	4,84%
Transport and storage distribution	6,97%	1,23%	8,06%
Assurance and quality control	16,80%	2,87%	19,35%
Total	72,54%	27,46%	100,00%

Table 3.1: Results of the final evaluation as required by BPM

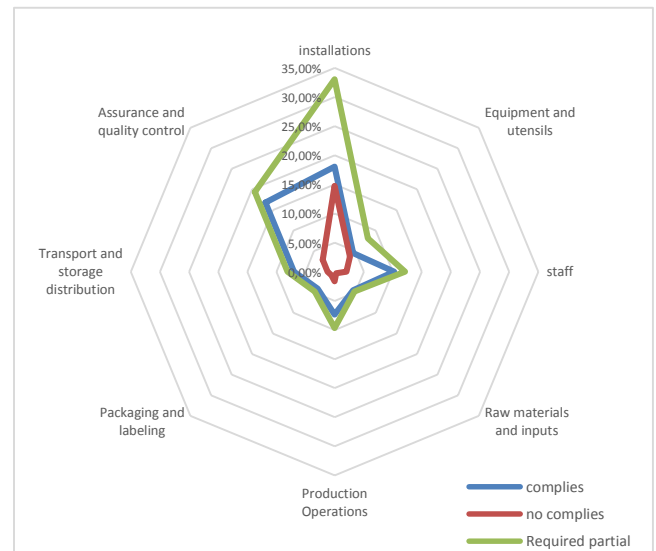


Figure 3.1: Result of final assessment requirements BPM segments

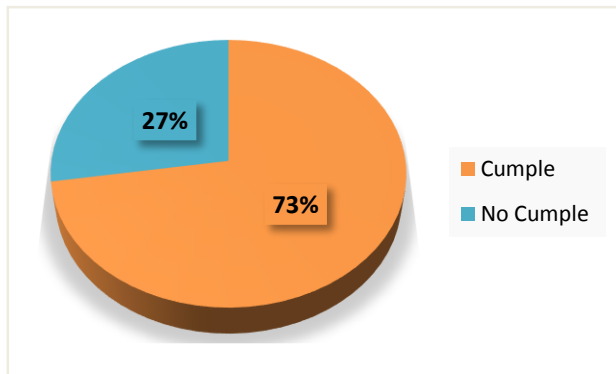


Figure 3.2: Total Result of final evaluation

In the final analysis it was found a large decrease in colony forming units per gram (CFU / g) of molds and yeasts in yogurt, cheese and manjar and compliance with the INEN standard for each product.

Note that in the standard INEN 1528: 2012 Queso fresco no maduros. Requisitos, there is not the maximum values of molds and yeasts for fresh cheese, but equal had an initial and final count of these fungi because causes alterations as product deterioration.

Product	Count	Unid	Initial Results	Final results	Complies INEN Standars	
					SI	NO
Yogurt	molds	UFC/g	600	<10	X	
	yeasts	UFC/g	7000	<10	X	
cheese	molds	UFC/g	1500	<10		
	yeasts	UFC/g	60000	<10		
Manjar	molds	UFC/g	150	<10	X	
	yeasts	UFC/g	400	<10	X	

Table 3.2: Comparison of initial and final molds and yeasts count

4. Conclusions:

- With the development and implementation of the present work was achieved meet 71% of the requirements of Ministerio de Salud Publica and ARCSA

- Product quality was improved by reducing molds and yeasts in yogurt, cheese and manjar, this by implementing the quality management system based on GMP, which helped to produce a safe, healthy and quality for human

consumption product also meets INEN into effect for each product

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