



"IMPLEMENTATION OF A PLAN OF GOOD MANUFACTURING PRACTICES IN THE COMPANY UNIQUESO OF THE CITY OF CAYAMBE"

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Resumen. Este artículo presenta un estudio enfocado en la elaboración e implementación de un Plan de Buenas Prácticas de Manufactura, para una empresa de lácteos de la ciudad de Cayambe "Uniqueso".

El tema se centra en cumplir con la mayoría de requisitos de la reglamentación ecuatoriana referente al Decreto Ejecutivo 3253, que provee de lineamientos necesarios para precautelar que se elaboren alimentos seguros e inoctrinos para el consumo del ser humano, a través de prácticas de higiene y cuidados durante la elaboración de los mismos.

Mediante este estudio se pudo realizar una auditoría interna de la empresa, para verificar el cumplimiento de los ítems requeridos para la aprobación de esta reglamentación, obteniéndose una calificación debajo del nivel aceptable, para lo cual se proponen medidas correctivas en relación a :Infraestructura, equipos y utensilios, personal manipulador, materias primas e insumos, operaciones de producción, envasado, etiquetado y empaquetado, almacenamiento distribución y transporte y aseguramiento de la calidad.

El plan de medidas correctivas fue desarrollado mediante el levantamiento de procesos productivos y la estandarización de los mismos, capacitaciones constantes para los trabajadores acerca de prácticas de higiene, orden, limpieza y búsqueda en equipo de soluciones para problemas de calidad e inocuidad.

Gracias al compromiso adquirido por los miembros de la empresa, a la continua motivación junto con un arduo trabajo y una visión enfocada en la satisfacción constante y salud del cliente, se logró que Uniqueso implementara la mayoría de las soluciones propuestas, alcanzando un nivel de cumplimiento óptimo para entregar al cliente un producto de mejorado y apto para su consumo.

Palabras Claves

Buenas Prácticas de Manufactura, Inocuidad, Limpieza, Higiene, Manipulador de Alimentos, Desinfección.

Abstract. This article presents a study focused on the development and implementation of a Plan of Good Manufacturing Practices for dairy company of the city Cayambe "Uniqueso".

The theme is focused in compliance of the most requirements about of Executive Decree 3253 of Ecuador, which provides necessary guidelines to obtain foods safe and harmless for human consumption, through hygiene practices and care during the preparation of them.

I did an internal audit of the company, to verify compliance with the items required for the adoption of this regulation, and the results were below the acceptable level, for which corrective measures are proposed in relation to: infrastructure, equipment and utensils, food handlers, materials and inputs, production operations, packaging, labeling and packaging, storage, transport and distribution and quality assurance

The corrective actions plan was developed through lifting production processes and standardize lists. Rather of them, through constant training to workers about hygiene practices, order, cleanliness and search of solutions for quality and safety problems.

Thanks to the commitment of the members of the company, continuing motivation coupled with hard work and constant focus on customer satisfaction and health of the customer, Uniqueso fulfilled most of the solutions proposed, reaching an optimal level of compliance to deliver the customer a product improved and suitable for consumption.

Keywords

Good Manufacturing Practices, Safety, cleaning, hygiene, food handler, disinfection.

1. Introduction

Good Manufacturing Practices is a management system that establishes standards and requirements within the production processes, with a view to obtaining a product to ensure its safe use. Focuses on actions, which make it possible to ensure the maximum possible hygiene of food from its development to its consumption. The policies, regulations or activities they pursue that objective should cover the whole processing chain products to quality control is total.

The Ecuadorian State has now established a system of safety as a mandatory requirement for all food businesses, exposed in the regulation of Good Manufacturing Practices for processed foods published in the official register as executive decree 3253 on 4 November 2002, by what its compliance incurs in the closure of operations of the organizations that do not work with this system. (1)

To develop the research will be focused on the National Plan of good living, that focuses on the transformation of the productive matrix and drives to companies through innovation and the introduction of new tools for production and quality, with the purpose to replace imports and develop better productive forces that add value to the Ecuadorian industry, it also establishes promote food sovereignty and ensure permanent access to healthy food and culturally appropriate (2)

UNIQUESO is a company located in the town of Cayambe, dedicated to the development of dairy products (cheese and fresh cheeses Mature), the same does not have a quality control system and its physical resources and materials are not correct. The company currently has an infrastructure are not suitable for food handling and moreover, there is lack of knowledge about the Good Manufacturing Practices, because the company does not meet the basic requirements that demand the regulations posted in the above-mentioned decree, by what customers of UNIQUESO do not consume a product with the required features.

In this situation, the company, has the interest to develop and deploy within its productive scheme processing and Good Manufacturing Practices ; that includes hygiene procedures from the management of their raw materials, products in process, finished goods, storage and subsequent distribution of the same, with the purpose of providing an improved product to your customers and be able to continue to operate before the obligatory regulations imposed by the Ecuadorian state , for which it is necessary the diagnosis, analysis and recommendations to establish the possible changes that must be done for a successful implementation and subsequent certification.

2. Methods

2.1 Internal Audit of the Company

In the canton Cayambe is made a technical visit in the processing plant for dairy products "UNIQUESO", with the purpose of lift information on compliance with Good Manufacturing Practices on the basis of a Check List (Verification Form) in which consist aspects relating to: situation and conditions of the facilities, equipment and utensils, Personnel, raw materials and inputs, production operations, packaging, labelling and packaging, storage, distribution and transport and Quality Assurance.

All these aspects were taken into account and subsequently audited based on the Decree 3253 of Good Manufacturing Practices. The Check List is prepared based on the requirements of the Rules of Good Manufacturing Practices for processed foods.

The rating assigned to each item is of 0-3 points, according to their status of compliance:

0 = Does Not Meet

1= Partially meets

2= Satisfactorily Meets

3= Meets very satisfactorily

N/A = The item does not apply to site conditions. (3)

Evaluated Aspects	No. Items	Maximum Grade	Qualification Obtained	% Of Fulfilment
Facilities	161	483	168	34.78 %
Equipment and Utensils	72	216	122	56.48 %
Staff	58	174	90	51.72 %
Raw materials and inputs	39	117	69	58.97 %
Production Operations	42	126	39	30.95 %
Packaging, labelling and packaging	23	69	31	44.93 %
Storage, distribution and transport	24	72	31	43.06 %
Quality Assurance and Control	85	255	109	42.74 %
TOTAL	504	1512	659	43.58 %

Tab. 1 Initial Assessment of Uniqueso

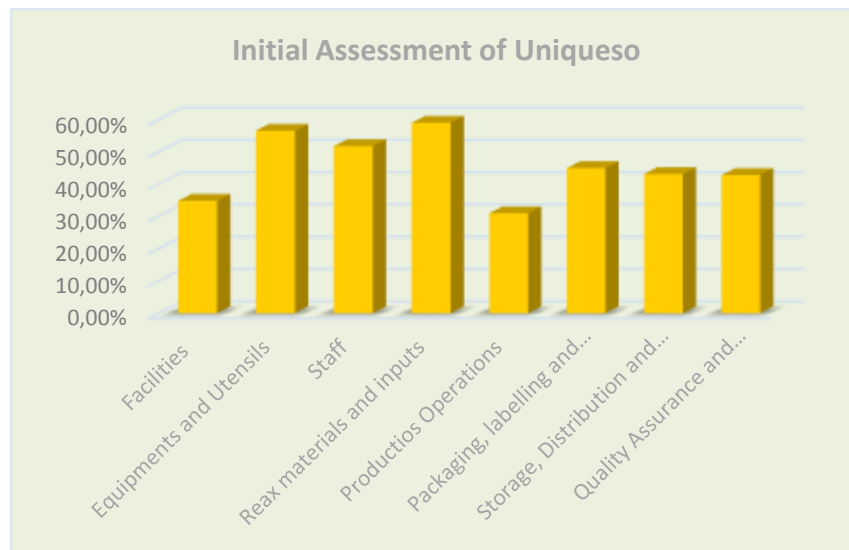


Figure 1. Initial Assessment of Good Manufacturing Practices in Uniqueso

2.2 Microbiological Analysis

The microbiological analysis of food does not have a preventive, rather it is simply an inspection carried out by taking samples of the food to make later methods of testing and verifying the presence of pathogens (external agents housed in the body of an animal, a human being or a vegetable that cause harm in the same) Or germs (microscopic life forms) in the product. To ensure the safety of the food, and an increase in the microbiological quality is necessary to determine in the industry the risk points of contamination or microbial growth and avoid them by following a strict code of good manufacturing practices and distribution of the food (4)

The analysis of products manufactured by UNIQUESO, were made at the Technical University of the North by the laboratory analysis of physical, chemical and microbiological of the Faculty of Engineering in Agricultural and Environmental Sciences.

We analyzed the main microbiological aspects for dairy products among which we have:

In Standard Plate Count (aerobic mesophiles): In this count is estimated the total microflora without specifying types of microorganisms. Reflects the quality of a health

Food, the conditions of handling and the hygienic conditions of the raw material. (5)

Total coliform count (Enterobacteriaceae): Are those that come from the intestinal contents human or animal. Coliform bacteria are particularly useful as components of microbiological criteria to indicate pollution thermal processing. (6)

Escherichia coli Count: This organism is found in the intestine of vertebrate animals. The pollution of a food with Escherichia Coli involves a risk to health, it can easily be removed by thermal processes. (7)

Count of molds and yeasts: It is the determination of the number of typical colonies of yeasts and molds that develop from a gram or cubic centimeter sample. Molds are certain multicellular fungi, which are formed on certain foods and produce toxins. The yeasts are unicellular fungi, which as well as the molds, cause alterations in the foodstuffs. (8)

Requisitos microbiológicos NTE INEN 2604 – NTE INEN 2613			
Requisito	n	m	M
Aerobios Mesófilos (UFC/g)	5	10 ³	10 ⁴
Enterobacteriaceas (UFC/g)	5	2 x 10 ²	10 ³
Escherichia coli (UFC/g)	5	<10	10
Requisitos microbiológicos NOM-242-SSA1-2009			
Requisito	m	M	
Mohos y levaduras (UFM/g y UFL/g)	---	500	

Table 2. Microbiological Requirements for mature cheeses

Where:

N = Number of samples to be tested.

M = maximum allowable Index to identify level of good quality.

M = maximum allowable Index to identify acceptable level of quality.

C = Number of samples with results permissible between m and M.

Parameter Analyzed	Unit	Results	Test Method
Standard plate count in	CFU/g	<10	AOAC 989.10
Total coliform count (Enterobacteriaceae)	CFU/g	<10	AOAC 989.10
Escherichia coli Count	CFU/g	<10	AOAC 989.10
Mold count	UFM/g	300	AOAC 997.02
Yeast Count	UFL/g	100	AOAC 997.02

Tab. 3. Initial for microbiological analysis of mature cheese Uniqueso

Requisitos microbiológicos NTE INEN 1528 - NTE INEN 2613			
Requisito	n	m	M
Aerobios Mesófilos (UFC/g)	5	10 ³	10 ⁴
Enterobacteriaceas (UFC/g)	5	2 x 10 ²	10 ³
Escherichia coli (UFC/g)	5	<10	10
Requisitos microbiológicos NOM-242-SSA1-2009			
Requisito	m	M	
Mohos y levaduras (UFM/g y UFL/g)	---	500	

The Tab. 4. Microbiological Requirements for fresh cheeses

Parameter Analyzed	Unit	Results	Test Method
In Standard plate count	CFU/g	870000	AOAC 989.10
Total coliform count (Enterobacteriaceae)	CFU/g	14400	AOAC 989.10
Escherichia coli Count	CFU/g	3200	AOAC 989.10
Mold count	UFM/g	200	AOAC 997.02
Yeast Count	UFL/g	100	AOAC 997.02

Tab. 5. Initial Analysis for microbiological cheese Uniqueso

2.3 Action Plan for the implementation of Good Manufacturing Practices

The Plan of Good Manufacturing Practices developed for UNIQUESO seeks to establish solutions before the populace that were detected in the initial diagnosis with the aim of improving the quality and safety of all the products that the company offers, as well as enable the company to achieve certification later in Good Manufacturing Practices through the implementation of the basic solutions raised, prioritizing the immediate changes to provide a better product.

The Plan is focused on establishing basic guidelines through a Manual showing the principles for the development of products using manufacturing standards for handling, storage, distribution and consumption later.

For the standardization of all the processes of manufacture of the products it is necessary to develop POE (Standard Operating Procedures) and to maintain a proper cleaning and disinfection of all the elements involved in the productive process is necessary to develop sops (Standard Operating Procedures for sanitation). These documents will be of vital importance for the company since they are guide to obtain a product with safety features.

Below are some basic requirements that must comply with the company to ensure good manufacturing practices:

The Company shall be built away from places that represent hotbeds of unsanitary or contamination.

The building should provide protection against dust, pollutants, leakages, pests, income of pets, etc.

The outer areas of the plant must be kept clean at all times and for which will be cut off the weeds each week or when necessary, will collect the existing trash and debris.

The different areas of production of Uniqueso must be built according to the volume of production of the factory, in accordance with a flow of orderly process with the purpose of that there is a correct transfer of materials and movement of staff and a good maintenance.

The flammable products must be outside the area for processing, with the purpose of not put at risk the safety of workers.

The different areas must be marked according to basic requirements.

You must maintain the standards of hygiene and disinfection in each of the areas.

Meet with the cleaning and disinfection programs described for each of the areas.

It must carry out checks of pests.

The floors, windows, ceilings, doors and other openings must be of a washable and durable material.

The company must dispose of their waste through the use of landfills identified by colors and installed in specific places

Comply with the requirements and responsibilities of hygiene for manipulators and visitors.

The raw materials, products in process and finished products must pass a quality control of its characteristics, to be approved, detained or rejected depending on its condition.

Continuous training of employees on Good Manufacturing Practices.

2.4 Standardized Operating Procedures (POE)

These are the ones written procedures that describe and explain how to perform a task to achieve a specific purpose, in the best possible way. Its application helps to ensure the maintenance of the levels of quality and service and has as purpose, in addition to providing a record that demonstrates the control of the process, minimizing or eliminating errors and risks in the food safety and ensure that the task be carried out in safely. (7)

2.5 Standardized Operating Procedures for Sanitation (POES)

They are practical and of sanitation procedures written that an establishment fortifier of food should develop and implement to prevent direct contamination or adulteration of the food producing, processing, subdivide and/or marketed. (7)

3. Results

3.1 Implementation of the Plan of shares in the Company

Uniqueso made adaptations of floors, walls, ceilings, windows and pest control, in regard to infrastructure, both on the outside and in the interior of the production facility:



Figure. 2. Adequacies of infrastructure in Uniqueso



Figure 3. Adequacies of infrastructure in complementary areas in Uniqueso

Was the lifting of the processes (POE AND POES), with the standard-setting adjusted to standards and registries that allow record the activities carried out in each stage of the production process.



Figure 4. Lifting of processes in Uniqueso

For the control of the raw materials, products in process and finished product has been implemented a tagging system that allows you to identify each product according to their status either retained, approved or retained.



Figure 5. Quality Control in Uniqueso

There were continuous training for the staff of the company on Good Manufacturing Practices.



Figure 6. Trainings in Uniqueso



3.2 Final Evaluation

After the implementation of the plan of actions is proceeded to verify compliance with Good Manufacturing Practices through the Check List mentioned above and the following results were obtained:

Evaluated Aspects	Maximum Grade	Qualification Obtained	% Of Compliance
Facilities	483	356	73.71 %
Equipment and Utensils	216	196	90.74 %
Staff	174	165	94.83 %
Raw materials and inputs	117	99	84.62 %
Production Operations	126	101	80.16 %
Packaging, labelling and packaging	69	56	81.16 %
Storage, distribution and transport	72	53	73.61 %
Quality Assurance and Control	255	192	75.29 %
TOTAL	1512	1218	80.56 %

Tab. 6. Results of the Final Evaluation of Uniqueso

In comparing the results of the initial diagnosis with the final diagnosis, we can observe that the level of compliance with items relating to Good Manufacturing Practices increase considerably, thanks to the corrective actions set in motion. Below is a summary table of comparison:

Evaluated Aspects	% Of Compliance (Initial situation)	% Of Compliance (Final situation)
Facilities	34.78 %	73.71 %
Equipment and Utensils	56.48 %	90.74 %
Staff	51.72 %	94.83 %
Raw materials and inputs	58.97 %	84.62 %
Production Operations	30.95 %	80.16 %
Packaging, labelling and packaging	44.93 %	81.16 %
Storage, distribution and transport	43.06 %	73.61 %
Quality Assurance and Control	42.74 %	75.29 %
TOTAL	43.58 %	80.56 %

Tab. 7. Comparison between the initial assessment and End of Uniqueso

When looking at these results, we see that Uniqueso increased its percentage of compliance in a 36.98 %, thus obtaining 80.56% for their final qualification that would allow it to achieve certification in Good Manufacturing Practices.

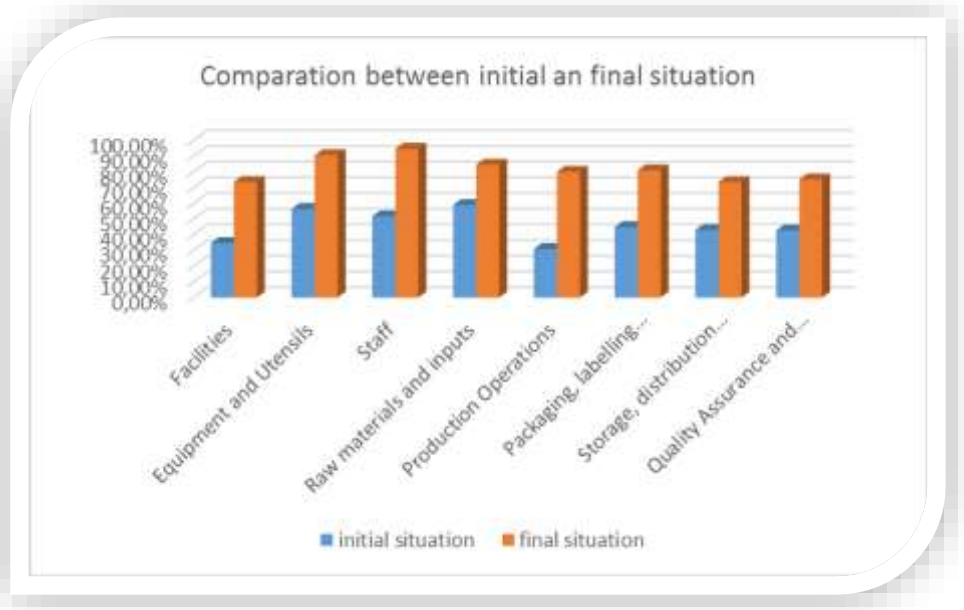


Figure 7. Comparison between initial situation and End of Uniqueso

3.3 Microbiological analysis (Final situation)

Parameter Analyzed	Unit	Results	Test Method
Standard plate count in	CFU/g	80	AOAC 989.10
Total coliform count (Enterobacteriaceae)	CFU/g	<10	AOAC 989.10
Escherichia coli Count	CFU/g	0	AOAC 989.10
Mold count	UFM/g	20	AOAC 997.02
Yeast Count	UFL/g	160	AOAC 997.02
Salmonella	(Presence/Absence 25gr)	Absence	AOAC 967.26

Tab. 8. Final for microbiological analysis of mature cheese Uniqueso

When comparing these results with those initial microbiological analysis we can observe that it continues to maintain the safety of the product and that all the evaluated parameters are within the permissible limits for what is a cheese of good quality and safe

For the health of the consumer. In addition, it was considered pertinent to perform analysis to verify the presence of

Salmonella, a bacteria that is very dangerous for the human body, obtaining results of absence of the same in the product.

These parameters favorable obtained, are thanks to the permanent deployment of Good Manufacturing Practices in Uniqueso and the standardization of all processes

Parameter Analyzed	Unit	Results	Test Method
Standard plate count in	CFU/g	220	AOAC 989.10
Total coliform count (Enterobacteriaceae)	CFU/g	<10	AOAC 989.10
Escherichia coli Count	CFU/g	0	AOAC 989.10
Mold count	UFM/g	40	AOAC 997.02
Yeast Count	UFL/g	250	AOAC 997.02
Salmonella	(Presence/Absence 25gr)	Absence	AOAC 967.26

Tab. 9. For microbiological analysis final, cheese Uniqueso



When comparing these results with those initial microbiological analysis we can observe that the safety of the product has improved considerably and that all the evaluated parameters are within the permissible limits, so it is a cheese of good quality and safe for the health of the consumer.

These parameters favorable obtained, are thanks to the permanent deployment of Good Manufacturing Practices at all stages of the production chain in Uniqueso using the standardization of all processes, constant use of rules of hygiene, identification and control of the critical points and prevention of contamination. Yet we can see that the company took a real commitment, with the purpose of providing quality products at all times.

4. Conclusions

The company made the implementation of the corrective actions in the short and medium term, through which he could improve his initial score information on Good Manufacturing Practices, from a 43.58 % to 80.56 % of compliance, percentage that allows achieve certification in Good Manufacturing Practices.

That achievement is the focus of production operations, which presented major deficiencies in the initial evaluation will increase their level of compliance with 30.63 % to 80.16 %, this was necessary for the implementation of the necessary documentation with which the company should have to perform their standardized processes and pollution-free.

The company deployed the majority of the corrective actions proposed in relation to facilities and step of a percentage of initial compliance of 34.78 % to 73.71 %, thanks to the adaptations and changes to the infrastructure, redesign of the process flow, adaptations of basic areas and maintenance of the same through an order, permanent cleaning and disinfection.

In regard to the quality assurance and control is managed to move out of a percentage of initial compliance with 42.74 per cent to a 75.29 %, through the designation of an area of quality control, with the purpose of which is carried out in strict controls of the raw materials, additives and inputs that receives Uniqueso, verifying compliance with established standards, to safeguard the safety and quality of the product.

The ongoing training provided to all staff of Uniqueso on Good Manufacturing Practices were constant and allowed to increase the percentage of initial compliance of 51.72 % to 94.83 %, thanks to the permanent practice of a culture of hygiene and housekeeping in order in each of the areas of work, as well as the commitment to work for the

benefit of the company and the satisfaction of their customers.

The documents prepared for the company including: Manual of Good Manufacturing Practices, POE and POES, have been implemented and used daily by all employees of Uniqueso, those who plan their productive activities and comply with the procedures, standards and established critical points for the development of cheese, with features of quality and safety, which has made it possible to deliver products on time and decrease the levels of complaints from customers in a 20% to 3 %.

The microbiological analyzes end made for processed cheeses to pulp base yarn (mature cheese and cheese), continued to maintain its characteristics of safety, while for the fresh cheese, significantly improved through the application constant and permanent hygiene practices at all stages of the production chain and the establishment of critical control points crucial to prevent microbial development, in the development of the products, such as: Time, Temperature, Humidity, acidity, etc.

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