

“IMPLEMENTATION OF A SYSTEM OF GOOD MANUFACTURING PRACTICE FOR THE COMPANY LACTINOR IN THE ATUNTAQUI CITY”

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Resumen. *Este artículo presenta el diseño e implementación de un Sistema de Buenas Prácticas de manufactura en la empresa de lácteos “LACTINOR” ubicada en la ciudad de Atuntaqui.*

Para el desarrollo de la investigación se tomó como base al decreto ejecutivo 3253 de buenas prácticas de manufactura para alimentos procesados, para garantizar la calidad e inocuidad de los productos, con la finalidad de ser más competitivo en el mercado y a su vez que le permita mejorar con respecto a industrias similares.

Inicialmente se recopiló las bases teóricas, normas y reglamentos necesarios para el desarrollo del trabajo, luego se realizó un diagnóstico de la situación actual mediante una lista de verificación de los requisitos de las Buenas Prácticas de Manufactura, para identificar las falencias y proponer mejoras en los siguientes aspectos: Infraestructura, equipos y utensilios, personal manipulador, materias primas e insumos, operaciones de producción, envasado, etiquetado y empaçado, almacenamiento, distribución, transporte y aseguramiento de la calidad.

Se elaboró un cronograma de trabajo para la implementación de las mejoras en la empresa y de igual manera se desarrolló un sistema de buenas prácticas de manufactura que Incluye: Manual de Buenas Prácticas de Manufactura, procedimientos operativos estandarizados (POE), instructivos, procedimientos operativos estandarizados de saneamiento (POES), programas de limpieza y desinfección y Registros para toda la empresa.

Al final se realizó un análisis financiero de la inversión en la Implementación del Sistema de Buenas Prácticas de Manufactura. También una nueva auditoría en donde se evalúa la mejora de la situación final con la situación inicial en base a los requisitos de las BPM.

Palabras Claves

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

Abstract. *This article presents the design and implementation of a system of good manufacturing practices in the dairy company "LACTINOR" located in the city of Atuntaqui.*

For the development of the research it was taken as the basis of Executive Order 3253 of good manufacturing practices for processed foods, to ensure the quality and safety of products, in order to be more competitive in the market and in turn that could improve over similar industries.

Initially the theoretical bases, rules and regulations necessary for the development work was compiled, then a diagnosis of the current situation through a checklist of the requirements of Good Manufacturing Practices was carried out to identify shortcomings and propose improvements following aspects: infrastructure, equipment and tools, personal handler, raw materials and inputs, production operations, packaging, labeling and packing, storage, distribution, transportation and quality assurance.

A work schedule is drawn up for the implementation of improvements in the company and likewise a system of good manufacturing practices including developed: Manual of Good Manufacturing Practices Standard Operating Procedures (SOP), instructions, sanitation standard operating procedures (SOPs), cleaning and disinfection programs and records for the entire company.

At the end a financial analysis of the investment in the System Implementation of Good Manufacturing Practices was held. Also a new audit wherein the improvement of the final status is evaluated with the initial situation based on the requirements of GMP.

Keywords:

Good Manufacturing Practices, Safety, Hygiene, Cleaning, Disinfection.

1. Introduction

The Good Manufacturing Practices is a system that sets standards and requirements within the production processes for the production of a product to ensure its safe use. It focuses on actions to ensure the highest possible food hygiene from development to consumption. Policies, regulations and activities aimed at this objective should cover the entire chain of production of products for quality control is total.

According to the provisions of the Rules of Good Manufacturing Practices Food, all activities of production, processing, preparation, wrapping, packaging, storage, transport, distribution and marketing of food in the country must be done under the basic principles and general hygienic practices in order to ensure that foods are produced in adequate and risks inherent production decline sanitary conditions.

The Ecuadorian government has now established a safety system as a mandatory requirement for all food companies, displayed in the regulations of Good Manufacturing Practices for processed foods published in the official record as the executive decree 3253 November 4, 2002, so your breach incurred in closing operations of organizations that do not work with this system.

LACTINOR, being dedicated to the production of dairy products, belongs to the category A as manufactured foods high epidemiological risk (foods that support microbial growth due to its characteristics of composition), which have a high probability of causing harm the health of consumers because they are consumer products.

Currently LACTINOR dairy company, located in the city of Atuntaqui, does not have adequate cleaning and disinfection methods in different areas, a factor that favors the proliferation of bacteria and therefore the contamination of products. Therefore it requires a system of Good Manufacturing Practices, in which processes are properly managed and the ability of the company to issue safe products that fulfill quality requirements is demonstrated.

Once implemented the system of Good Manufacturing Practices and through the correct application of the basic principles and general hygiene practices, along with the new infrastructure being built, the company LACTINOR may obtain certification of GMP, prerequisite for renewal of its operating license and evidence that the consumer is not at risk by consuming its products.

2. Methods

2.1 Internal Audit (Check List BPM)

Location and conditions: a technical visit to the dairy processing plant products LACTINOR, in order to gather information on compliance with Good Manufacturing Practices based on a Check List (Verification Form) which comprise aspects concerning was performed installations, equipment and tools, Personnel, Raw Materials and Supplies, Production Operations, Packaging, Labeling and Packaging, Storage, Transportation and Distribution and Quality Assurance.

All these points were considered and subsequently audited pursuant to Decree 3253 of Good Manufacturing Practices. The Check List is developed based on the requirements of the Rules of Good Manufacturing Practices for processed foods.

The rating assigned to each item is 0-3 points, according to their status of compliance: The diagnosis of the initial situation of the dairy plant LACTINOR have the following rating:

Valued scale	Description
N/A	Does not apply
0	non-compliant
1	Partially met Partially met
2	meets Moderately
3	Satisfactorily (Best)

Table. 1. Classification of items in the Checklist.

In the Checklist a total of 155 items applicable to the company "LACTINOR" is set; with an excellent rating of 465. The score for each of the compliance requirements set is shown in the following table:

INITIAL RESULTS OF INSPECTION		
ITEMS	Score LACTINOR	Score OPTIMO
A. Facilities	64	150
B. of equipment and utensils	26	45
C. Personal	31	63
D. Commodities and Inputs	20	48
E. Production Operations	23	54
F. Packaging, Packaging and Labeling	19	30
G. Storage, distribution, transportation and marketing	22	45
H. Quality Assurance	2	30
TOTAL	207	465
PERCENTAGE	44,52%	100%

Table. 2. Compliance officers percentages BPM Regulation.

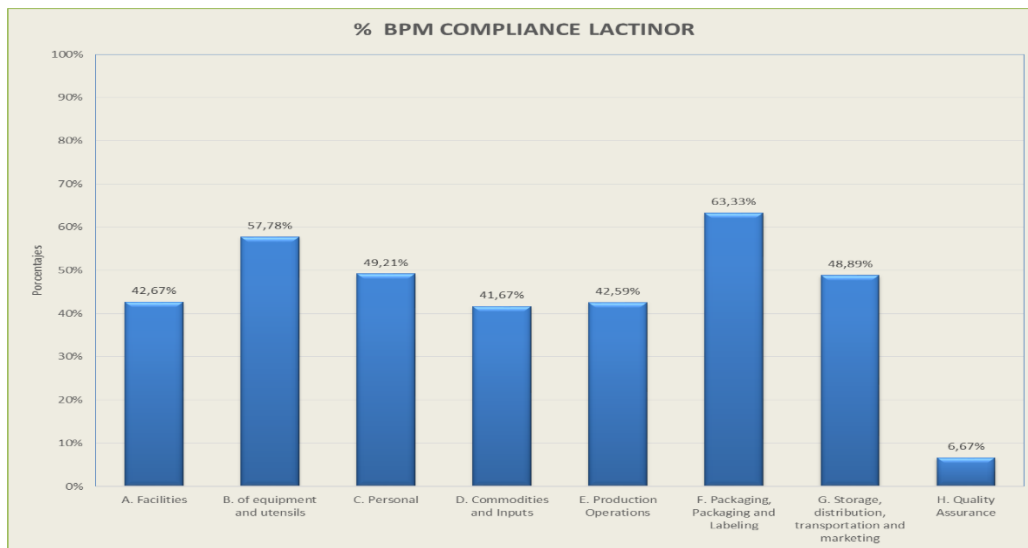


Figure 1. BPM Compliance Regulations

Analyzing the graph is observed to have a low compliance rate in the sections of quality assurance, raw materials and inputs, production operations, and facilities, with percentages of 6.67%; 41.67%; 42.59%; and 42.67% respectively; The remaining sections show greater. Compliance rate with an average of 54.80%; All sections were evaluated based on the requirements of the Rules of Good Manufacturing Practices for Processed Foods Executive Decree 3253.

2.2 Microbiological analysis of the finished product

The microbiological analysis of foods are an effective tool for assessing the safety of a production process. They are based on the cultivation and enumeration of microorganisms in food with trials and laboratory tests; microbiological analysis will evaluate the microbial load and identify potential areas of risk of contamination or microbial growth that can cause foodborne illness to consumers.

Among the major pathogens that may be present in food have coliforms, *Escherichia coli*, staphylococci, molds, yeasts and salmonella.

The objective of these analyzes is performed by the results, identify whether there is any risk to the health of those who consume the products tested and also to determine the elements that are exposed to pollution in order to avoid that in the future this will continue happening.

Microbiological parameters

The analyzed parameters define product acceptability based on the absence or presence or counting the microorganisms in yogurt, finished product for carrying out microbiological analysis.

Total coliform count.

These organisms are easily removed by heat treatment, so their presence in foods subjected to heat suggests further contamination to the heat treatment or that it has been poor. The use of coliforms as an indicator requires extensive knowledge of the process that has suffered food (production, processing, distribution, etc.) and the effect it has had on the count of coliform bacteria.

Enumeration of *Escherichia coli*.

The natural habitat for this organism is the intestines of vertebrates. Microbiological criteria including *E. coli* are useful in cases where one wishes to determine faecal contamination. Contamination of food with *E. coli* implies the risk that they may be in the same enteric pathogens that pose a risk to health. However, the absence of *E. coli* does not guarantee the absence of enteric pathogens.

Salmonella.

Salmonella bacteria are one of the most important pathogenic bacteria and their presence in food is a cause of human salmonellosis, bacterial foodborne infection more frequently. Approximately one third of the foods involved in outbreaks of salmonellosis are meat, meat products and poultry products (eggs and egg products).

Count of molds and yeasts.

It is the typical number determination of yeasts and molds that are developed from one gram or cubic centimeter sample colonies. Molds are multicellular certain fungi, which are formed on certain foods and produce toxins. Yeast are unicellular fungi like molds, cause alterations in foodstuffs.

Analysis of results

Información Nutricional

Parámetro Analizado	Unidad	Resultado	Metodo de ensayo
Recuento de coliformes	UFC/g	0	AOAC 989.10
Recuento de E. coli	UFC/g	0	
Recuento de mohos	UFC/g	120	AOAC 997.02
Recuento de levaduras	UFC/g	80	
Salmonella (presencia/ausencia)	-----	ausencia	AOAC 967.26

Los resultados obtenidos pertenecen exclusivamente para las muestras analizadas

Table. 3. Results of microbiological analysis.

For the evaluation of the values obtained in the microbiological analysis it is necessary to compare the yogurt with the applicable legal regulations which have reference to the following standard.

INEN Ecuadorian Technical Standard - 2395: 2011 - Milk fermentada- requirements.

In which it indicates the microbiological requirements to be met by fermented milks, as seen in the following table:

Requisito	n	m	M	c
Coliformes totales, UFC/g	5	10	100	2
Recuento de E. coli, UFC/g	5	<1	-	0
Recuento de mohos y levaduras, UFC/g	5	200	500	2

En donde:

n = Número de muestras a examinar.

m = Índice máximo permisible para identificar nivel de buena calidad.

M = Índice máximo permisible para identificar nivel aceptable de calidad.

c = Número de muestras permisibles con resultados entre m y M.

Table. 4. Parameters (Yogurt) NTE INEN 2395:2011

The result of microbiological analysis in the laboratory of the UTN, shows that the product meets the requirements of the legislation, once the comparison which means that the products the company offer are of excellent quality.

2.3 Plan for Improvement

The excellence of a company dependent on its ability to continuously improve each and every one of the processes that govern their daily activity. The improvement is when the company learns about herself and others, while taking into account the changing environment that surrounds it.

This plan aims to design a system of Good Manufacturing Practices to improve the quality and safety of products produced in the company LACTINOR; allows processing in accordance with existing regulations and ensure the delivery of healthy foods that meet current needs and food preferences of consumers.

For the standardization of all manufacturing processes of the products it is necessary to develop a manual of good manufacturing practices, SOPs (Standard Operating Procedures) and to maintain proper cleaning and disinfection of all the elements involved in the production

process must be developed SSOP (Sanitation Standard Operating Procedures). These documents are of vital importance to the company as are guides for obtaining a product with safety features.

Then each of the points that you made in the company LACTINOR in the various areas for improvement are described.

2.4 Manual BPM.

The Manual of Good Manufacturing Practices selects all the basic principles and general hygiene practices in handling, processing, storage and distribution of dairy product prepared by the company Dairy North "LACTINOR" which must be met to ensure the production of healthy food, safe, safe to eat and free of contaminants that affect consumer health.

In addition to the BPM it takes into account issues that may affect product safety as the design, construction installation, equipment, utensils used, personal handler, assurance and quality control, storage, distribution, transport and marketing of products.

That's why the company LACTINOR knows that the implementation of GMP regulation is vital to ensure and guarantee the quality of their product to consumers.

2.5 Standard Operating Procedures

In order to ensure uniformity, reproducibility and consistency in making a product must follow a flow of orderly processes is why it is necessary to document every stage of development, in order that those responsible for each activity are trained about what to do according to what is established.

SOPs (standard operating procedures) are those written procedures that describe and explain how to perform a task for a specific purpose, in the best way possible.

2.6 Instructional

These documents describe in a detailed manner the steps to perform successfully certain support activities (sampling, preparation of cleaning solutions) or correct behavior, use of equipment and safety of staff working in the business and visitors, so as to avoid contamination of the products in any area of the production areas.

2.7 Cleaning and disinfection programs

Programs Cleaning and Disinfection describe a general surfaces or elements to be cleaned and disinfected in each of the areas of the company way. These documents show how often they should be carried out these activities, the type of solution to be used and their dosages with the POES reference which specifically describes how to perform the cleaning and disinfection of each element.

The cleaning and disinfection are aimed to provide clean and safe environment, related to the cleanliness and hygiene of all the elements that are used in business processes. This is achieved through compliance with effective procedures to prevent contamination or proliferation of microorganisms that can affect product quality and safety.

2.8 Sanitation Standard Operating Procedures

The poems are written practices and sanitation procedures that a food processing establishment must develop and implement to prevent direct contamination or adulteration of food that there is produced, processed, fractionated and / or market.

If the establishment or the Health Authority detected the POES failed to prevent contamination or adulteration of product, corrective measures must be implemented. These include the proper disposal of the product concerned, the restoration of proper sanitary conditions and take measures to prevent recurrence.

2.9 Records

The establishment must also take daily records sufficient to document the implementation and monitoring of all procedures performed in the company and any corrective action taken. These records must be available when the Health Authority's request.

3. Results

The company invests in the construction of a new building with a view to business growth and this investment includes basic facilities for certification in Good Manufacturing Practices. With the initial diagnosis was made at the company LACTINOR was through a verification form BPM, calling all items, it was possible to identify areas that did not meet the requirements, for which corrective actions were taken, the same that will help to make the company comply with the established standards was mainly worked with the requisite assurance and quality control as this is an essential part that establishes guidelines to ensure the safety of products, as well as worked On-site adjusting to the new requirements of GMP building.

After implementing the improvement actions, a final diagnosis of the company, for this diagnosis the same form of verification of GMP was used, with the same parameters and items qualifying form was made.

INITIAL RESULTS OF INSPECTION		
ITEMS	Score LACTINOR	Score OPTIMO
A. Facilities	64	150
B. of equipment and utensils	26	45
C. Personal	31	63
D. Commodities and Inputs	20	48
E. Production Operations	23	54
F. Packaging, Packaging and Labeling	19	30
G. Storage, distribution, transportation and marketing	22	45
H. Quality Assurance	2	30
TOTAL	207	465
PERCENTAGE	44,52%	100%

Table. 5. Final Inspection Results

After comparing the results of the initial diagnosis with the final diagnosis, we can see that the level of compliance of the items relating to Good Manufacturing Practices greatly increased, thanks to improvements mainly by the construction of the new plant and also corrective actions implemented.

COMPARISON OF RESULTS		
ITEMS	% INITIAL	% FINAL
A. Facilities	42,67%	97,33%
B. of equipment and utensils	57,78%	93,33%
C. Personal	49,21%	93,33%
D. Commodities and Inputs	41,67%	91,67%
E. Production Operations	42,59%	91,11%
F. Packaging, Packaging and Labeling	63,33%	90,74%
G. Storage, distribution, transportation and marketing	48,89%	90,48%
H. Quality Assurance	6,67%	71,11%
PERCENTAGE	44,10%	89,89%

Table. 5. Comparison of results

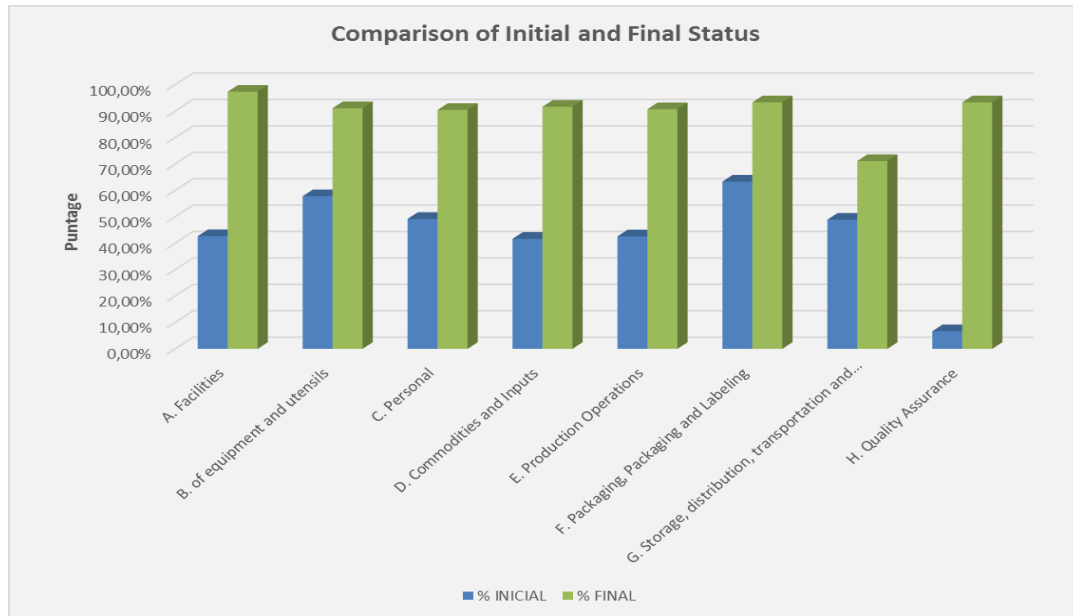


Figure. 2. Comparison between baseline and final

4. Conclusions:

It was possible to determine the theoretical and legal bases underlying the development of the system of Good Manufacturing Practices, which are the definition of terms such as: food safety, food hazards, personal hygiene and rules and regulations that we use in research among others.

An overview of the company was obtained and production operations were identified that represented them by SIPOC flowchart graph and also the diagnosis of the initial situation of the company was developed through a checklist of GMP, bringing the percentage of compliance with each of the items it was determined.

Developed by microbiological analysis for the product made by the company, it was determined that the yogurt is fit for human consumption as it lacks bacteria such as coliforms, *Escherichia coli*, staphylococci, molds, yeasts and salmonella.

It was identified that the requirements for quality assurance, raw materials and inputs, production operations and facilities had a compliance rate below 50% compared to required, ie had no documentation, procedures like SOP and SSOP, instructions for so a plan to work first with those items took place.

The documents prepared for the company LACTINOR including: Manual of Good Manufacturing Practices, POE, instructions, SOPs and records have been developed and implemented since the beginning of January 2016 the company once daily and used by all employees, so it has significantly improved the score of the items under the rules of BPM.

With the construction of a new plant and the adjustments in the other items the company is in condition for GMP certification so it is necessary to have reached 80% of requirements met, according to the Ministry of Public Health, with the help of the \$ 25,000.00 investment could get a modern infrastructure and processes to organize properly.

With the implementation of the System of Good Manufacturing Practices is projected obtain a compliance rate of 89.89%, based on the check list of the current situation, noting considerable improvement compared to the 44.10% initial compliance. What we want to say that the company was in compliance with the requirements of the Rules of Good Manufacturing Practices and with this percentage can achieve GMP certification.

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Bibliographic references

- Caiza, M. (Julio de 2013). *Repositorio de la Universidad Internacional SEK*. Recuperado el Julio de 2013, de Repositorio de la Universidad Internacional SEK:
repositorio.uisek.edu.ec/jspui/handle/123456789/569
- Cárdenas, J. (s.f.). *Evaluación de las condiciones de Trabajo*. Obtenido de Evaluación de las condiciones de Trabajo:
<http://www.slideshare.net/YACARLA/metodos-owas-rula-reba>
- Decreto Ejecutivo 3253. (Noviembre de 2002). *Ministerio de Salud Pública*. Obtenido de <http://www.salud.gob.ec/>
- Equipo Vértice . (2009). *Aplicación de boras y condiciones Higiénico-sanitarias en restauración* . España: Vértice.
- García B., H. R. (2007). *Guía tecnológica para el manejo integral del sistema productivo de la caña de panela* . Bogotá: PRODUMEDIOS.
- NTE INEN 2395: 2011 Leches fermentadas. Requisitos . (2011).
- NTE INEN 9:2008 Leche Cruda. Requisitos. (2008).
- Privados, F. d. (s.f.). *Análisis Riesgos Ergonómicos*. Obtenido de Análisis Riesgos Ergonómicos:
<http://www.serviciosprivados.ccoo.es/>
- Sanz, J. L. (2012). *Seguridad e higiene en la manipulación de alimentos*. . Madrid : Paraninfo.
- Valencia, U. P. (s.f.). *Gestión de la Prevención de Riesgos Laborales*. Obtenido de Gestión de la Prevención de Riesgos Laborales:
<http://www.ergonautas.upv.es/>

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