

Process Design Standard Operating under the philosophy of Good Manufacturing Practices in yogurt production chain to ensure food safety Dairy Company "San Luis"

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Abstract

The objective of this research is to elaborate a Good Manufacturing Practices (GMP) manual, which contains standardized operating procedures and sanitation programs, in order to manage production framed in preserving the safety from the entry of raw materials to The exit of the finished product, in the yogurt production of the San Luis dairy company in Cayambe and under the requirements of the 'Substitute Technique of Good Manufacturing Practices (GMP) for Processed Foods' document emitted on June 03 2015 by the Regulation, Control and Sanitary Surveillance (ARCSA). The development of the work is based on the initial diagnosis made to the company through a Check-list, which assesses the degree of compliance about the application, support and implementation of BPM. A problem-prioritization matrix is then established to evaluate the causal causes of the problem, and to determine the main problem that contributes to ensuring that safety in the yogurt production chain is not efficient. Finally, an improvement plan is suggested in a manual of good manufacturing practices.

Keywords

Processes, Safety, Manufacturing.

Resumen

El presente trabajo de grado, tiene como objetivo elaborar un manual de buenas prácticas de manufactura (BPM), que abarque procedimientos operativos estandarizados y programas de saneamiento, con la finalidad de gestionar una producción enmarcada en preservar la inocuidad desde la entrada de materia prima hasta la salida del producto terminado, en la cadena de producción de yogurt de la empresa de lácteos San Luis en Cayambe y bajo los requerimientos de la 'Norma Técnica Sustitutiva de Buenas Prácticas de Manufactura (BPM) para Alimentos Procesados' documento emitido el 03 de junio del 2015 por la Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA). Para el desarrollo del trabajo se parte del diagnóstico inicial realizado a la empresa mediante un Check-list, donde se valora el grado de cumplimiento en referencia a la aplicación, sustento e implementación de las BPM. A continuación se establece una matriz de priorización de problemas para evaluar las causas circunstanciales de la contrariedad, y poder determinar el problema principal que contribuye a que el aseguramiento de la inocuidad en la cadena de producción del yogurt no sea eficiente. Finalmente, se sugiere un plan de mejoras conformado en un manual de buenas prácticas de manufactura.

Palabras Claves

Procesos, Inocuidad, Manufactura.

1. Introduction

Good Manufacturing Practices (GMP) were introduced in the US in the mid-60s as a regulatory initiative to reduce incidents of adulteration in the manufacture and distribution of food and beverages. These practices have been adopted in more than 100 nations and their contributions to achieve more hygienic and safe agro-food chains are well documented. The rate of incidents salubrious foods and unsafe however, has been increasing since the early 90's (ABT AgroBioTek INTERNATIONAL, 2016)

GMP are basically a set of tools that are implemented in the food industry, which are aimed to obtain hygienically processed products for human consumption. Where the main axis are the methodologies used for the control and management of raw materials, finished product, personal hygiene, pest control, waste management, maintenance of facilities, equipment and utensils among the most important. The implementation of the BMP generates advantages for entrepreneurs which are benefiting in terms of reducing product loss by decomposition or alteration produced by various pollutants and also help to improve the positioning of its products by the brand recognition related its positive attributes of both quality and sanitation. (Food Ecuador, 2016)

A safe and efficient way to perform operations sanitation implementing the Standard Operating Procedures Sanitation (SSOP - SSOP for short) that together with the Good Manufacturing Practices - GMP (acronym GMP - Good Manufacturing Practices and HACCP), by definition are a set of rules that establish the fundamental basis for the conservation of hygiene where remediation work are described by documents where the specific instructions of the activity or function detailed in contemplated GMPs, write what, how, when and where clean and disinfect, as well as records and warnings to be carried out. (Mexico, 2016)

Consumers are becoming increasingly informed and aware of the dangers associated with food consumption, which has made changes generated in the buying habits of consumers who have become more demanding in their selection. So the food industry along the production chain must be based on all their efforts prevention and risk control (Ministry of Agriculture, AGRORURAL, PROSAAMER., 2011)

Making industries, processed, prepared, packaged, stored, transported, distributed and marketed any food have realized the importance

of ensuring product quality following the food chain from the primary production to end consumer. All it based on the implementation of Good Manufacturing Practices and the use of existing rules and decrees that allow the product meets the requirements of both the company and the customer. (MESA, 2011)

Insanitary food has represented a health problem for humans since the dawn of history, and many of the current problems in this area are not new. While governments around the world are making every effort to increase the healthiness of the food supply, the existence of foodborne disease remains a significant health problem in both developed countries and developing countries. (Health, 2007)

The effect of this project aims to diagnose the dairy company "San Luis" in meeting the requirements of the technical standard LIEU OF GOOD MANUFACTURING PRACTICE FOR PROCESSED FOODS presenting corrective drawbacks in the control and registration of its shares operations by implementing Good manufacturing Practice and in turn processes Standard operating facilitate the implementation of its production process to generate a competitive advantage, ensuring its customers and consumers a product produced under strict safety and health and in turn to compliance with the provisions of the Art.- 1 Scope of the substitutive Standard Good Manufacturing Practices (National Regulatory Agency, 2015). The implementation of Good Manufacturing Practices aims to develop various control programs and registration in the different areas that raises the standard. information and documentation will be developed.

Under the guidelines of the goal number 10 of the National Plan for Good Living that mentions "Driving the transformation of the productive matrix" with emphasis on consolidating the productive transformation of industrial priority sectors and manufacturing processes for adding value to maximize the national component and strengthen the capacity for innovation and collective learning. (National Secretariat of Planning and Development, 2013)

2. Materials and Methods

Theoretical and Methodological

It was analyzed and studied documentary information to provide theoretical knowledge and sustain research work based on the replacement Technical Standard for Good Manufacturing Practices ARCSA June 2015.

Initial diagnostic.

He was diagnosed in level of compliance in terms of the explicit requirements of current legislation. Through a list check the level of compliance was determined for each requirement and possible improvements to be implemented if the company agency admitted it

Prioritization Matrix

Prioritization Matrix seeks to determine the criteria of primary importance versus the different alternatives that sustain the legal basis that the solution to search opportunities for improvement in the area of product safety.

- Criteria and Alternatives.

Prioritization matrix is made up of two parts: the evaluation regarding prioritization criteria and evaluation prioritization alternatives. As evaluation criteria is determined as follows:

CRITERIA	
No.	Description
1	SAFETY IN PRODUCTION
2	MAJOR INVESTMENT
3	EXECUTION TIME

As alternatives evaluation sections of the Technical Standard lieu of Good Manufacturing Practices for processed foods it was considered:

ALTERNATIVAS	
Nº	DESCRIPCIÓN
1	De las instalaciones y requisitos de buenas prácticas de manufactura
2	De los equipos y utensilios
3	Requisitos higiénicos de fabricación
4	De las materias primas e insumos
5	Operaciones de producción
6	Envasado, etiquetado y empaquetado
7	Almacenamiento, distribución, transporte y comercialización
8	Del aseguramiento y control de calidad

- Weighting Scale.

By setting importance regarding the evaluation criteria and alternatives weighting the following scale was appointed.

WEIGHING SCALE	
1	Equally important
2	MORE IMPORTANT
3	MUCH MORE IMPORTANT

- Importance of criteria.

Under the interpolation criteria could define that this most important and unique consideration is the criterion of safety in production with

63.83% of importance with respect to the other two mentioned criteria ie processing company yogurt should pay primary attention to the issue in terms of safety and to facilitate consideration meters in the process.

	Inocuidad en la Producción	Mayor Inversión	Tiempo de Ejecución	Suma	Porcentaje
Inocuidad en la Producción		3	2	5	63,83%
Mayor Inversión	1/3		1	1,33	17,02%
Tiempo de Ejecución	1/2	1		1,5	19,15%
			TOTAL	7,83	100,00%

- Evaluation results.

Requisito BPM	Inocuidad en la Producción	Mayor Inversión	Tiempo de Ejecución	Suma	Porcentaje
	63,83%	17,02%	19,15%	1	100,00%
A De las Instalaciones y Requisitos De Buenas Prácticas de Manufactura	6%	16,07%	15,88%	0,38	12,76%
B De los Equipos y Utensilios	14%	15,08%	13,61%	0,43	14,36%
C Requisitos Higiénicos de Fabricación	17%	15,28%	11,75%	0,44	14,67%
D De las Materias Primas e Insumos	10%	4,96%	3,92%	0,19	6,30%
E Operaciones de Producción	14%	6,55%	19,79%	0,41	13,57%
F Envasado, Etiquetado y Empaquetado	10%	10,32%	5,98%	0,26	8,70%
G Almacenamiento, Distribución, Transporte y Comercialización	6%	13,29%	9,90%	0,29	9,69%
H Del Aseguramiento y Control de Calidad	22%	18,45%	19,18%	0,60	19,95%
				3	100,00%

- Order Prioritization.

In the matrix Order of Prioritizing the importance which should take corrective opportunities for improvement actions initiated by section assurance and quality control as the dairy company San Luis in his Yoghurt section does not have the defined documentation necessary assurance of their product that is not defined physical and digital form different processes, controls and records involved in the production of yogurt.

After taking important manufacturing hygienic requirements in terms of product handling and minimum mandatory conditions for employees and the employer must comply with the handling.

REQUISITOS BPM	Porcentaje	Prioridad
H Del Aseguramiento y Control de Calidad	19,95%	1
C Requisitos Higiénicos de Fabricación	14,67%	2
B De los Equipos y Utensilios	14,36%	3
E Operaciones de Producción	13,57%	4
A De las Instalaciones y Requisitos de Buenas Prácticas de Manufactura	12,76%	5
G Almacenamiento, Distribución, Transporte y Comercialización	9,69%	6
F Envasado, Etiquetado y Empaquetado	8,70%	7
D De las Materias Primas e Insumos	6,30%	8

Improvement Plan.

The improvement plan is a document that corrective possible to make in order to improve the production system supported by the yogurt requirements and specifications of the technical regulations in lieu of Good Manufacturing Practices for Processed Foods detailed actions.

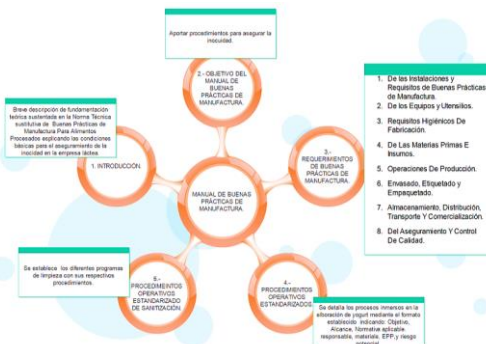
With theoretical foundation of the Technical Standard lieu of Good Manufacturing Practices for processed foods, issued by Official Gazette No. 555 of July 30, 2015, Title I indicates the provisions applicable to establishments where food is processed and requirements Good manufacturing practices.

Manual of Good Manufacturing Practices meets the basic terms and conditions for ensuring hygiene, safety and quality along the production chain of different processed foods that require high standards of care in its preparation and guarantee the customer a product not detrimental to your interest and does not jeopardize their physical integrity and consumption.

Whereas the BPMs focus on different aspects to be evaluated to ensure that the process of developing a range of processed foods high existing in the industry meet the conditions to be healthy, safe and suitable for consumption.

For this reason the dairy industry "San Luis" in his Yoghurt section has presented great interest in the design, use and subsequently the implementation of a system of Good Manufacturing Practices in which assures explicitly its processes, operations and activities through monitoring and recording thereof for such follow up the production plant management and venture into improvements that facilitate the delivery of a healthy and safe product ensuring quality to the customer and end consumer.

Manual of Good Manufacturing Practices. Manual of Good Manufacturing Practices is a document in which the procedures, programs, respective considerations and recommendations regarding safety and production management in the preparation of yogurt is expressed. Manual of Good Manufacturing Practices is structured.



Standard Operating Procedures.

Uniformity, flow to follow, a parameter shows that allows the production of a particular good or service is performed in the same way a thousand times as necessary; establishing a

sequence of activities that triggers a systematic and organized order of reference and validation process by documenting each stage emerges a certain production process which aims to establish the balance of the product to the customer and in turn staff operating desvinculase operational empiricism.

POE (standard operating procedure); is the logical sequence of activities set compulsorily company or the area of production and operations which specifies the best way to perform such an operation or process deforms defined and certain mandatory cases to generate process uniformity and people it performed. As an example.

		PROCEDIMIENTO OPERATIVO ESTANDARIZADO	CÓDIGO: POE-001
		RECEPCIÓN DE MATERIA PRIMA	VERSIÓN: 001
			FECHA: 14/08/2016
			PÁGINA: 1
OBJETIVO:	ALCANCE:	NORMATIVA DE REFERENCIA:	
Estandarizar, inspeccionar y controlar el proceso de recepción de materia prima-Leche cruda.	El POE-001 comprende las actividades necesarias para la recepción de materia prima a procesar durante el día.	NTE INEN 3:2008 Leche Cruda. Requisitos, 2008.	
RESPONSABLE: Operario	AREA: Producción	INICIA: Recibe Vehículo	
	PRODUCTO: Leche Cruda	TERMINA: Bombeo a Planta	
	FRECUENCIA: Diario	MÉTODO: Manual-Mecánico	
MATERIALES	DIAGRAMA DE FLUJO	DESCRIPCIÓN	
<ul style="list-style-type: none"> Cubeta Agua Potable Apilador Jana Manguera Bomba Hidráulica EPP <ul style="list-style-type: none"> Cota Mascarilla Delantal Plástico Botas de látex. Uniforme establecido por la empresa RIESGO POTENCIAL <ul style="list-style-type: none"> RIESGO FISICO: Caída al inspeccionar el contenido. 		<p>Para la recepción de la materia prima se debe empezar por inspeccionar si el vehículo que transporta la materia prima se encuentra limpio sin la presencia de polvo, lodo, yerba o cualquier material o u objeto extraño al proceso caso contrario procesada con la limpieza.</p> <p>Luego la verificación de la guía de envío en la cual se debe verificar la cantidad de leche y el proveedor al igual que la factura de la compra de dicha materia prima. Si existe alguna inconformidad en cantidad de litros reportados u en la factura del mismo se procede a solucionar caso contrario se rechaza. Para la inspección organoléptica se procede con la apertura del tanque contenedor por las tapas de inspección si no presenta inconformidad procede con las pruebas básicas de control.</p> <p>Si las características de la leche se encuentran dentro de los parámetros se recibe la materia prima y se efectúa el bombeo hacia los marmitos contenedores para su posterior operación.</p>	
Elaborado por: Alex Patricio Pozo M.	Revisado por:	Aprobado por:	
Fecha:	Fecha:	Fecha:	

3. Results

the results of the initial audit and comparative Final detailed below.

Initial diagnostic.

For the initial diagnosis of Good Manufacturing Practices in Business "DAIRY COMPANY San Luis SECTION YOGURT" was developed a checklist based on the Technical Standard lieu of Good Manufacturing Practices for Processed Foods.

RESUMEN GENERAL DE CHECK LIST		
	ITEMS	Puntuación San Luis
1	De Las Instalaciones Y Requisitos De Buenas Prácticas De Manu- factura	64,05
2	De Los Equipos Y Utensilios	50,00
3	Requisitos Higiénicos De Fabricación	31,48
4	De Las Materias Primas E Insumos	43,33
5	Operaciones De Producción	56,67
6	Envasado, Etiquetado Y Empaquetado	72,73
7	Almacenamiento, Distribución, Transporte Y Comercialización	72,92
8	Del Aseguramiento Y Control De Calidad	37,78
TOTAL		365
PORCENTAJE		45,61

Resumen General de Check List					
Nº	REQUERIMIENTO	Check-List Inicial %	Check-List Final %	Porcentaje Requerido	Incremento
Área del gráfico					
1	De las Instalaciones y Requisitos de Buenas Prácticas de Manufactura	64,05	69,28	100	5,23
2	De los Equipos y Utensilios	50,00	55,56	100	5,56
3	Requisitos Higiénicos de Fabricación	31,48	46,30	100	14,81
4	De las Materias Primas e Insumos	43,33	48,48	100	5,15
5	Operaciones de Producción	56,67	70,00	100	13,33
6	Envasado, Etiquetado y Empaquetado	72,73	78,79	100	6,06
7	Almacenamiento Distribución, Transporte y Comercialización	72,92	77,08	100	4,17
8	Del Aseguramiento y Control de Calidad	37,78	55,56	100	17,78
TOTAL DE CUMPLIMIENTO		45,61	53,97		8,36

The dairy "San Luis" in his Yoghurt section has a percentage of compliance of 45.61% at a general level in terms of indicators replacement Technical standard of Good Manufacturing Practices for processed foods, denoting for initial internal audit as a company in which the use of the system of good Manufacturing Practices is not well defined and its use is of a low level means whereby the assurance of safety in its supply chain is not optimal and presents difficulties in handling operations and process to ensure that your product and comply with principles and standards of hygiene and safety.

Final diagnosis.

After having met the design of standardized operating processes and in turn their respective controls and records aimed at each program BPMs that detailed in the Manual of Good Manufacturing Practices for processed foods, it should be emphasized that both the initial diagnosis as the end was used just as the Check - List underpinned by the substitutive technical standard for food the same as it was written by the author of this project, the results of the final diagnosis in the dairy Yogurt "San Luis" are presented then.

RESUMEN GENERAL DE CHECK LIST			
	ITEMS	Puntuación San Luis	Puntuación Requerida
1	De las Instalaciones y Requisitos de Buenas Prácticas de Manufactura	69,28	100
2	De los Equipos y Utensilios	55,56	100
3	Requisitos Higiénicos de Fabricación	46,30	100
4	De las Materias Primas e Insumos	48,48	100
5	Operaciones de Producción	70,00	100
6	Envasado, Etiquetado Y Empaquetado	78,79	100
7	Almacenamiento, Distribución, Transporte y Comercialización	77,08	100
8	Del Aseguramiento y Control De Calidad	55,56	100
TOTAL		431,76	800
PORCENTAJE		53,97	100%

Initial vs End.

After evaluating the initial results versus the end we mention the Yogurt Dairy Company "San Luis" in the percentage of compliance increased by 8.36% to abide by the technical and easy to implement recommendations in the processing plant. Taking an increase of 45.61% to 53.97% being maintained at an acceptable level of performance, but not satisfactory and in compliance with regulations.

Conclusions

- Bibliographical collection through theoretical and legal guidelines which underpins the philosophy of Good Manufacturing Practices, diagnosis, monitoring and control which support the methodology applied in the development of this paper grade was established.
- the level of compliance was identified by the dairy company "San Luis" -Section Yoghurt in the management of Good Manufacturing Practices along the production chain, evaluating from receiving operations handling raw material to be sent the finished product to the customer and consumer, through a check list supported by the requirements of Technical Standard lieu of Good Manufacturing Practices.
- In general the degree of initial compliance with the dairy company "San Luis" in his Yoghurt section is a 45.61% having the lowest level in the section for manufacturing hygienic requirements did not have the description and records of their cleaning and disinfection processes in facilities, utensils, and equipment and similarly a plan for cleaning and disinfection to ensure safety in production. Therefore an improvement plan was established, priority actions identified as meeting the requirements described in the Technical Standard proxy for processed foods which degree work was based.
- Under the diagnosed the company did not have the relevant documentation and operating procedures sanitation necessary procedure to not operate accompanied empiricism so a manual of Good Manufacturing Practices ready to be implemented which contains provisions concerning designed to each one of the silver criteria in regulations and likewise the respective programs standard Operating Procedures and sanitization with its respective process specifications and registration.
- Although this paper grade was based on the design as an increase overall objective was

handled in the degree of compliance with the requirements of the Technical Standard substitutive, going from 45.61% to 53.97% with an increase of 8.36% at a general level by establishing a greater degree of improvement requirements: hygiene requirements Manufacturing Production Operations and assurance and Quality Control.

About the author

Alex Pozo was born on December 24, 1993 in the City of San Gabriel Carchi Province attended primary school in the school tax Mixed Abdón Calderón, secondary in the National School José Julián Andrade then turning to the Technical University of the North to train in the industrial engineering area.

His training has been supplemented by training in the following areas:

- Good manufacturing practices
- Chlorine Gas Management
- Quality Management in Organizations.
- Undertaking through the implementation of the business plan.
- Innovation, Management and Conservation Sources for sustainable development.
- Innopolis-Knowledge is Freedom.

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