



Faculty of Law Sciences

School of International Studies

Proposal for the implementation of Good Manufacturing Practices and their documentation
in Piggis Sausage Factory, with the purpose of exporting its products to the Peruvian
market.

Thesis prior to obtaining the Bachelor's Degree in International Studies minor in Foreign
Trade

Evelin Isabel Muñoz Cárdenas

Dr. Mario Molina

Cuenca, Ecuador

2011

Dedication

The present thesis is dedicated to my daughter Arianna Valentina for being the person who inspired me and gave me the strength to develop my final thesis. It is also dedicated to my husband, my parents, my brothers, and my entire family members who have been supporting me through this project.

Acknowledgment

I am very thankful to Piggis Sausage Enterprise for giving me the access to its technological plant. A special thanks to the Manager, Carlos Pacheco for his constant support, as well as Dr. Byron Cajas, Engineer Vilma Jiménez, Dr. Veronica Peralta, and Dr. Maria Montaleza for all their given help.

Also a sincere thanks to my thesis director, Dr. Mario Molina and Engineer Ximena Moscoso, as well as to, Economist Luis Tonón, Director of International Studies School for motivating me and approving my project topic, which I am developing with the intent of applying it in the company mentioned above. I would,also like to thank Mr. Diego Almeida and Economist Clara Basantes for supporting and helping me with didactic material.

Contents

Dedication	II
Acknowledgment	III
Contents	IV
Chart Index.....	VII
Graphic Index.....	VIII
Annexes.....	VIII
Summary	X
Abstract	XI
Introduction.....	1
CHAPTER 1. HISTORY OF THE PIGGIS COMPANY	2
1.1 Mission and vision of Piggis	2
1.1.1 Mission.....	2
1.1.2 Vision	2
1.2 History of the Piggis Company	3
1.3. Structure of the Company.....	5
1.3.1 Map of Processes	6
1.4 Products	7
1.4.1 Variety of Hams	7
1.4.2 Variety of Mortadellas	8
1.4.3 Variety of Sausages.....	9
1.4.4 Variety of Chorizos	10
1.4.5 Variety of Smoked products.....	11
1.4.6 Variety of Meats.....	12
1.4.7 Variety of products for Christmas.....	13
1.5 Market	14
1.5.1 Product Definition.....	14
1.5.2 Uses.....	14

1.5.3	Properties	14
1.5.4	Marketing standards	14
1.5.5	Current Market	15
1.6	Peruvian Market	15
1.7	Conclusions	16
CHAPTER 2. GOOD MANUFACTURING PRACTICES		17
2.1	Concept of Good Manufacturing Practices	17
2.2	Concept of Quality	18
2.3	Quality Control	19
2.4	Technical obligations in good manufacturing practices.....	20
2.4.1	Infrastructure	20
2.4.1.1	Factory location, structure and hygiene	20
2.4.1.2	Facilities	20
2.4.2	Equipment	21
2.4.3	Raw materials.....	22
2.4.4	Hygiene and sanitation of Piggis staff	23
2.4.5	Clothing.....	24
2.4.6	Toilets and washers services	25
2.4.7	Access to the factory plant	25
2.4.8	Hygienic in the process	26
2.4.9	Storage of raw materials and finished transport of products	26
2.4.10	Control of production processes.....	27
2.4.11	Documentation	29
2.4.12	Safety Requirements and Manufacturing Standards	38
2.4.12.1	Sausages	39
2.4.12.2	Ham	40
2.4.12.3	Mortadellas	42
2.4.12.4	Chorizos.....	43
2.4.12.5	Smoked products and Other Meats.....	44
2.5	Manufacturing Standards	46
2.6	Packaging, Labelling, and Boxing	46

2.7 Storage, distribution, transport, and communication with customers.....	47
2.8 Distribution and transport	48
2.9 Customer’s Communication.....	48
2.10 Quality Assurance	49
2.11 The Good Manufacturing Practice as a quality assurance instrument	51
2.12 Application of the checklist for the official Piggis food system.....	52
2.13. Preliminary diagnosis of GMP in the Operators	68
2.14. Training of Good Manufacturing Practices for employees.....	71
2.15. Diagnosis of Good Manufacturing Practices in equipment and utensils, disinfection and production operations.	72
2.15.1 Points of possible solution	73
2.16 Conclusions	74
CHAPTER 3. ECUADORIAN LEGISLATION FOR GOOD MANUFACTURING PRACTICES	75
3.1 Ecuadorian standard for GMP.....	75
3.2. Checklist.....	76
3.2.1. Definition, payroll, and documents	76
3.2.1.1 General information about the food processing plant.....	77
3.2.1.2 Location and condition of facilities	78
3.2.1.3 Design and construction.....	78
3.2.1.4 Areas	78
3.2.1.5 Floors	79
3.2.1.6 Walls	79
3.2.1.7. Roofs.....	80
3.2.1.8. Windows, doors and other openings.....	80
3.2.1.9 Stairs, elevators, additional structures	81
3.2.1.10 Electrical and water systems.....	81
3.2.1.11 Lighting.....	81
3.2.1.12 Ventilation	82
3.2.1.13 Temperature and humidity.....	82
3.2.1.14 Toilets, showers, changing rooms	82

3.2.1.15. Water Supply	83
3.2.1.16. Steam Supply	84
3.2.1.17. Disposal of waste	84
3.2.2. Equipment and Utensils.....	85
3.2.3 Staff	89
3.2.4. Raw materials and supplies	92
3.2.5 Production Operations	95
3.2.6 Packaging, labeling, and packaging	98
3.2.7 Storage, distribution and transport.....	99
3.2.8 Quality assurance and control	100
3.3 Conclusions	104
CHAPTER 4.PERUVIAN MARKET ANALYSIS TO EXPORT GOODS	106
4.1 Legal requirements to export goods from Ecuador to the North of Peru.....	106
4.2 Standards ISO 22000	109
4.3. Analysis of the Peruvian market to export.....	112
4.3.1 Peruvian Market.....	112
4.3.2 Historical Demand	114
4.4 Analysis of the Peruvian meat market	127
4.5 Conclusions	131
Final Conclusions.....	132
Bibliography.....	134

Chart Index

Chart # 1 Ham	7
Chart # 2 Mortadellas.....	8
Chart # 3 Sausages	9
Chart # 4 Chorizo.....	10
Chart # 5 Smoked Products.....	11
Chart # 6 Meats	12
Chart # 7 Products for Christmas	13
Chart # 8 Specific regulatory requirements for sausage making	40

Chart # 9 Specific requirements for Ham production	41
Chart # 10 Specific requirements for Mortadella production	42
Chart # 11 Specific requirements for Chorizos production	43
Chart # 12 Smoked meat specifications	45
Chart # 13 Tariffs	109
Chart # 14 Main origin countries of the meat sector in Peru	113
Chart # 15 National projected demand of meat products in tons-Peru	115
Chart # 16 2005-2011 Projected National Offer of Meat products tons-Peru	117
Chart # 17 Unsatisfied demand of Meat products in Peru	119
Chart # 18 Prices of Meat products in Peru	121
Chart # 19 Prices per Kilo.....	121
Chart # 20 Competitors of Piggis in Peru	122
Chart # 21 Peruvian Population per city - potential sources to export Piggis.....	124

Graphic Index

Graphic # 1 General flowchart of Piggis Sausages PIGEM	5
Graphic # 2 Map of Latin America.....	114
Graphic # 3 National projected demand of meat products in tons – Peru.....	116
Graphic # 4 National projected offer of meat products.....	118
Graphic # 5 Unsatisfied projected demand of meat products in tons in Peru	120
Graphic # 6.....	123
Graphic # 7 Peruvian Exports and Imports.....	129
Graphic # 8 Economic growth per country (percentage variation 2007-2008).....	130

Annexes

Annex 1	1
Annex 2.....	2
Annex 3.....	3
Annex 4.....	4
Annex 5.....	5
Annex 6.....	6
Annex 7.....	7

Annex 8.....8
Annex 9.....10
Annex 10.....11
Annex 11.....12
Annex 12.....13
Annex 13.....15
Annex 14.....23
Annex 15.....26
Annex 16.....29
Annex 17.....32
Annex 18.....34
Annex 19.....36
Annex 20.....37
Annex 21.....42
Annex 22.....43
Annex 23.....56
Annex 24.....64
Annex 25.....67
Annex 26.....72
Annex 27.....75

Summary

This paper aims to propose the implementation of the Good Manufacturing Practices as a tool for the correct processing of its products in Piggis Company. The purpose of this Monograph is to project the export of the Piggis's products to the Peruvian market, with an ultimate goal of expanding to the international market. To achieve this goal, we worked directly with the company members, developing forms of quality improvement. During this process, we noted the improvements needed to be implemented, the changes to be performed, the standards of hygiene to be followed by the employees, the control processes, the receipt of raw materials, how to operate equipment and tools, and the use of a handbook on the workplace.

We visited the Ministry of Health and the Ecuadorian System of Metrology, Standardization, Accreditation and Certification (MNAC) in Quito in order to apply for information on the official process in Ecuador, and the forms that accredit the inspections and GMP certification in Ecuador.

The Peruvian market has been analyzed, using statistical tables of offer and demand in the Peruvian meat industry.

Abstract

El presente trabajo tiene como objetivo proponer a la empresa de Embutidos Piggis la implementación de las Buenas Prácticas de Manufactura como una herramienta principal para la correcta elaboración de los productos.

La finalidad del presente proyecto es que la empresa se proyecte a la exportación de sus productos al mercado Peruano, permitiendo así ampliarse a lo largo del mercado internacional. Para lograr este objetivo se trabajó directamente en la empresa elaborando los formularios de mejoramiento de calidad, durante este trabajo se pudo detectar las mejoras que se debe implementar, los cambios que se deben realizar, las normas de higiene que deben seguir los empleados, el control de procesos, la recepción de la materia prima, la manera de operar los equipos y utensilios y los manuales en la planta de trabajo.

Se visitó al Ministerio de Salud Pública y al Sistema Ecuatoriano de Metrología, Normalización, Acreditación y Certificación (MNAC), en Quito para obtener información del proceso oficial en Ecuador y a su vez los formularios que emplean los inspectores que acreditan y certifican las BPM en el Ecuador.

Se analizará el mercado Peruano, al cual se tiene previsto exportar, dando a conocer mediante cuadros estadísticos la oferta y demanda que han tenido en la industria cárnica y el análisis de la industria cárnica en el Perú.

Introduction

The Piggis Sausage Factory is located in Cuenca-Ecuador. It is dedicated to the production of a great variety of meat products. It seeks to fulfill the demands of the market in Cuenca getting into the domestic and international market with quality products, complying with the current regulations.

The proposal is to give the company a basic model for the implementation of Good Manufacturing Practices, with the goal of improving its quality, as well as strengthening its presence in the Cuencano market. This proposal seeks to implement a system of good practices, meeting the quality standards required by local, national, and international levels.

The company propels and the industrial growths together with the market grow. It is willing to reach all the necessary changes to achieve a good positioning in the local and international market, using quality marketing tools, as well as technology that facilitates the processes of industrialization, with no emissions and the highest quality.

CHAPTER 1. HISTORY OF THE PIGGIS COMPANY

1.1 Mission and vision of Piggis

1.1.1 Mission

The Piggis Sausages Enterprise has as a mission to:

"Produce and commercialize the best Ecuadorian meat products through rigorous quality policies, excellence service and customer satisfaction, backed up by top technology, a trained human resource and committed to the business objectives and quality processes that respect the environment." (Jaramillo)

The company's mission is to develop products of excellent quality with very good presentation, under strict sanitary norms, unfit for human consumption, with reasonable prices for the consumer. These features allow a positioning in the Cuenca market with an expansion to national and international levels, which differs from the competition.

1.1.2 Vision

The Company's vision is to

"delight the client's taste with the best meat products, becoming for the next decade a ranked and recognized organization in the food industry, as well as developing health food using high quality and safety standards with a clear service orientation, integral to our customers that also enable us to get into to international markets" (Jaramillo)

The vision emphasizes the importance of the consumer satisfaction with the products made under high-tech machinery, always taking as a priority the excellent presentation and quality of the product.

1.2 History of the Piggis Company

The Piggis Enterprise is a Sausage factory located in Cuenca whose main objective is to produce and market meat products of mass consumption, involving a continuous process of improving their presentation and service in order to meet customer needs and the requirements of local, regional and national levels.

It should be noted that the history of Piggis started from an idea of Mr. Carlos Pacheco Vidal in 1988, with the unconditional support of his wife, Mrs. Rebecca Pacheco and the very encouraging collaboration of his father Mr. Carlos Gilberto Pacheco. This great idea was consolidated on September 30, 1999, emerging as a new industry in Cuenca, initiating the process of production using craft machinery and implementing subsequently the latest technology; hoping to become a major brand renowned thanks to its high quality products.

The name of the company was a Mr. Carlos Pacheco children idea, Andrea and Fernando. They mentioned that it was a very difficult task because they thought they needed a very easy name to remember for potential customers setting it apart from the competition. Then they took the initiative to call the enterprise Piggis because of the protagonist of the Muppets, the famous pig Miss Piggy well known in those days

"Get the sausages with the best flavor, unique and unmatched, capturing its products with all the secrets of the old formulas of good taste" (Jaramillo)

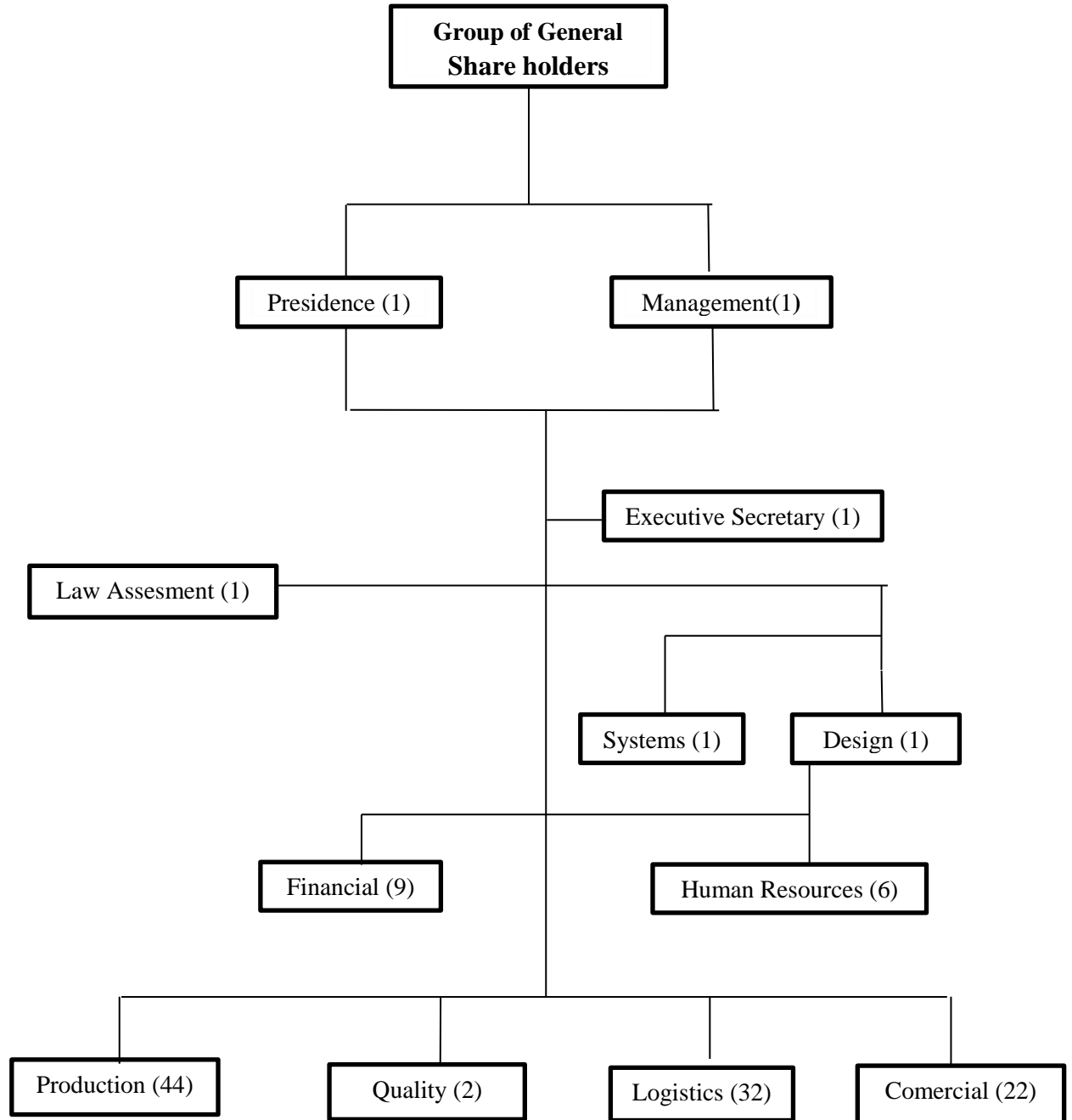
Because of the effort and dedication of this great family, this company has achieved distinction in the Cuencano market, becoming competitive compared to other established companies. The evolving process that the company has had in regards to its production has made it possible to continuous improvement, resulting in products distinguished thanks to its flavor and presentation. It is the result of a great team that has made it possible to become one of the leading sausage companies in our city.

It is important to mention that a sausage enterprise is not only focused on delivering excellent product presentation, but the products to have a good flavor, good color, nice smell, and a reasonable price. The products need to stand out from the competition and provide nutrients in these foods that benefit consumers.

The Piggis Enterprise hopes to improve the efficiency on its production. Therefore it is implementing the Good Manufacturing Practices as it is a "basic and essential tool for obtaining safe products." (Jaramillo) By doing that, the Company aims to avoid errors in production and to prevent deviations during manufacturing. All areas of the company should know about quality standards by approved the inspections of internal quality supervisors.

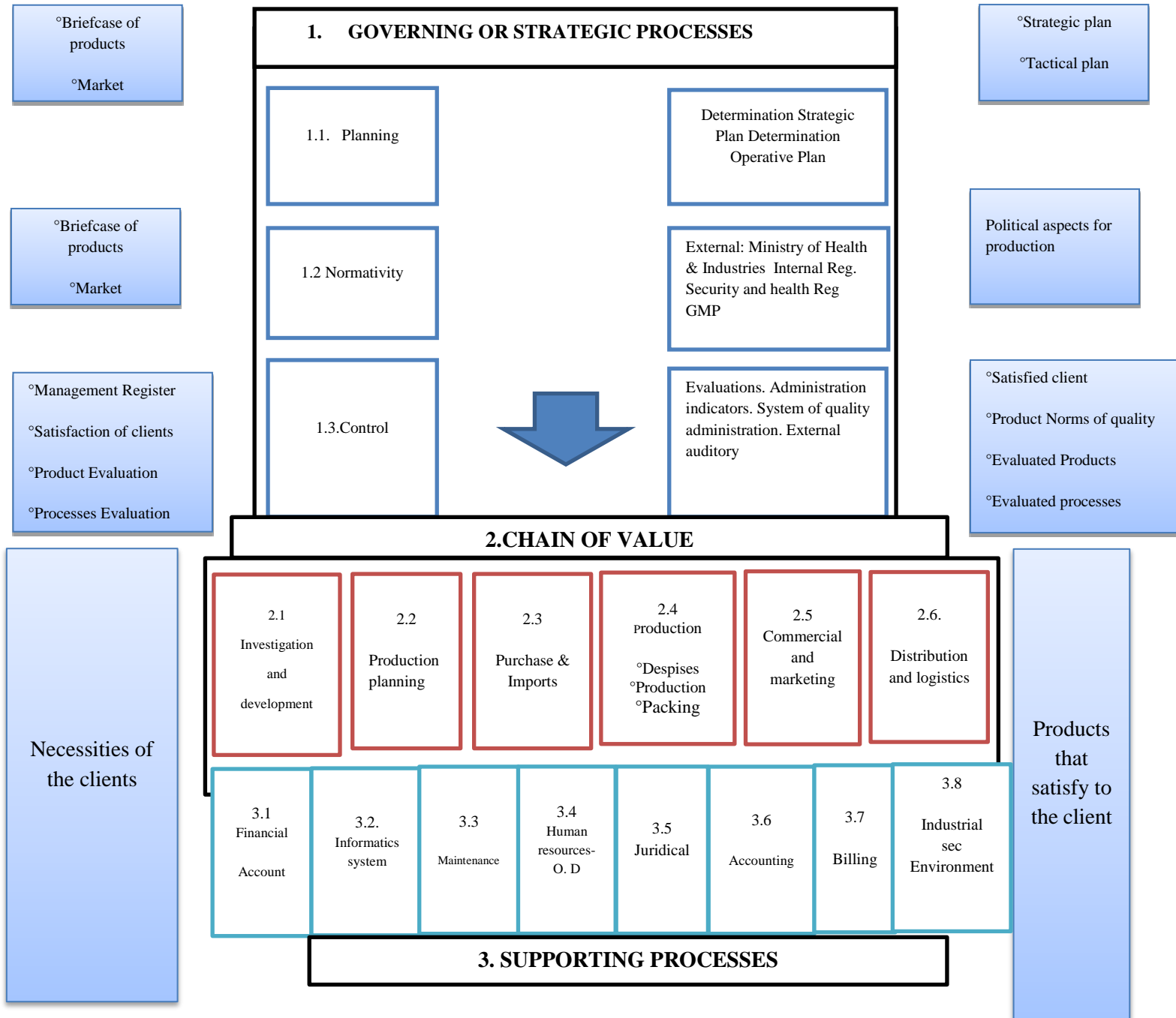
1.3. Structure of the Company

Graphic # 1 General flowchart of Piggis Sausages PIGEM COMPANY



Source: Piggis

1.3.1 Map of Processes



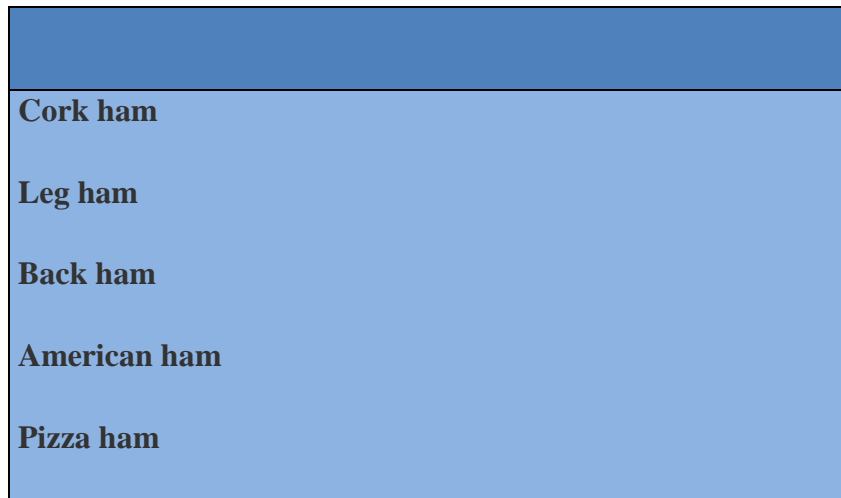
Source: Piggis

1.4 Products

The enterprise has a great variety of products being this the main important reason to mention them.

1.4.1 Variety of Hams

Chart # 1 Ham



Cork ham
Leg ham
Back ham
American ham
Pizza ham

Source: Piggis Products, Ham,

Preparation: Author

The above products come in packages of 2, 4 and 6 kg.

Vacuum packages from 150, 250, 500 and 1000 grams.

1.4.2 Variety of Mortadellas

Chart # 2 Mortadellas



Mortadela Bologna
Extra Mortadela
Chicken Mortadela
German bologna
Special Mortadella
German bologna mortadela
Extra Taco
Chicken Taco
German Taco
Special Taco

Source: Piggis products, sausages,

Preparation: Author

These products come in 1.3, 2, 4, 4.50 and 6.80 kilo packages

Presentations in grams come from 250, 500 and 1000 grams.

1.4.3 Variety of Sausages

Chart # 3 Sausages



German sausage
Sausage and cheese
Frankfurt Beef Sausage
Beef hot dog sausage
Frankfurt cocktail sausage
Chicken cocktail sausage
Vienna sausage
Hot- dog
Red special sausage
Economic red sausage
Fry sausage (pork belly)
Grill Sausage (lamb tripe)
Paisa Sausage (lamb tripe)
Longaniza sausage (lamb tripe)

Source: Piggis Products, Sausage.

Preparation: Author

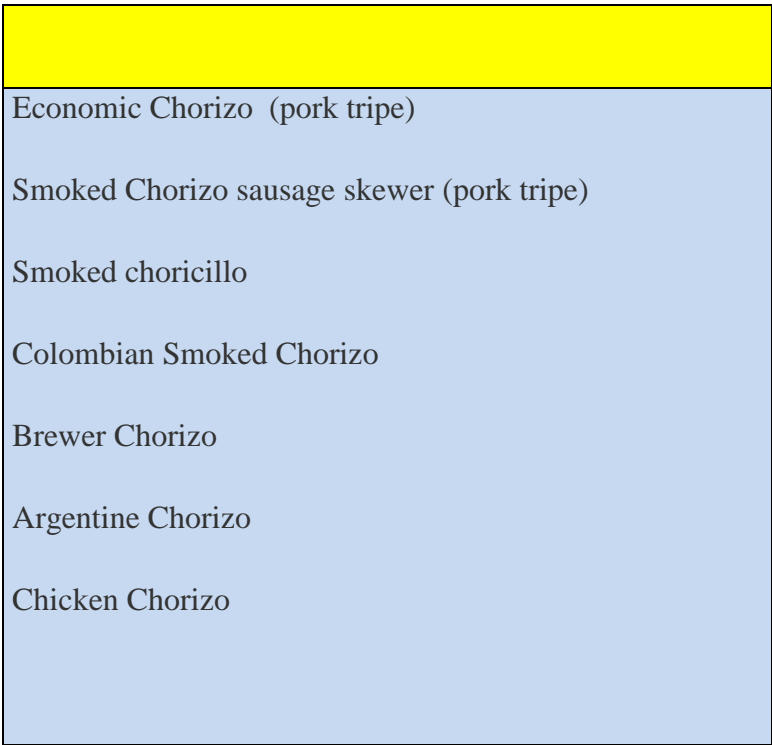
Its sales in the market is performed in vacuum packs from 1, 2, 2 ¼, 5 kilos and in packages of 250, 450 and 500 grams.

It should be noted that in the table above from the hot-dog sausages through the longaniza sausage are sold in bulk, according to the customer's needs.

The length of sausages are 12 cm, 15 cm, 16 cm, 18 cm and 21 cm and the diameter of these is approximately 17, 22 and 24 cm.

1.4.4 Variety of Chorizos

Chart # 4 Chorizo



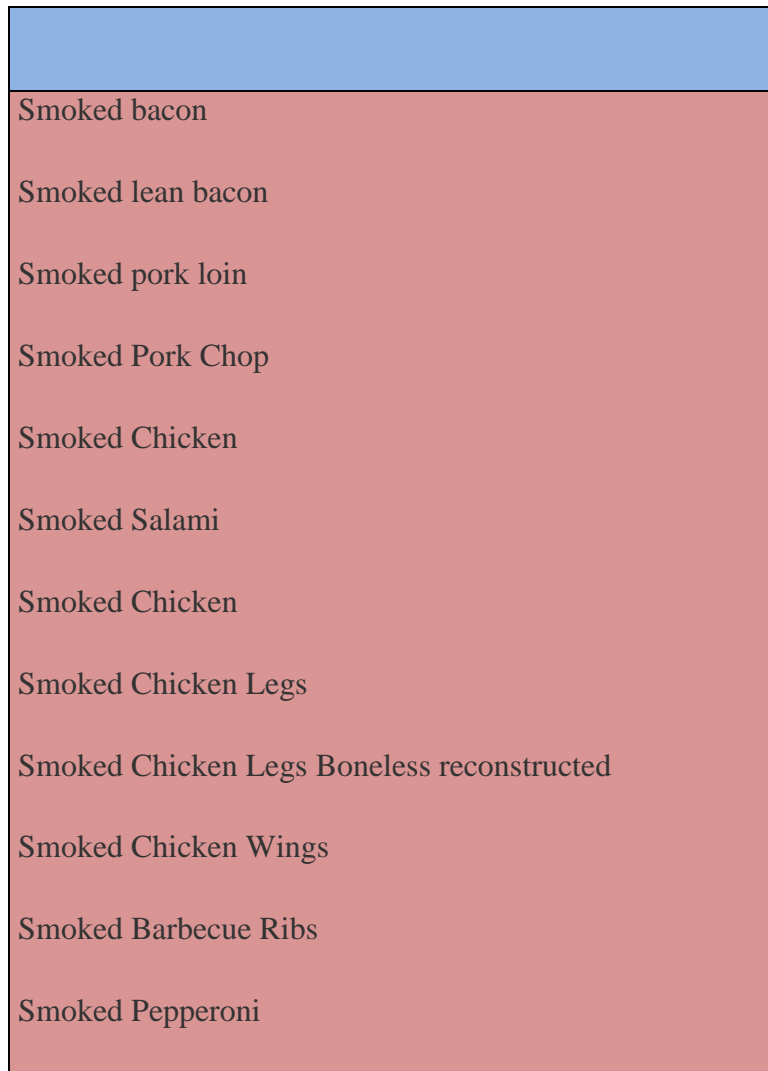
Source: Products Piggis, Chorizo,

Preparation: Author

In the market we can find them in presentations of 150, 250 and 500 grams in a length of 7 cm, their sale is according to what customers want in bulk.

1.4.5 Variety of Smoked products

Chart # 5 Smoked Products



Source: Piggis Smoked Products

Preparation: Author

Importantly, the products are sold in 1 kg, 150 and 200 gr., and the sale is given according to the weight that the customer desires.

1.4.6 Variety of Meats

Chart # 6 Meats

MEATS
Sirloin for grill / oven / fry
Pulp broil / oven / grill / fry
Roast loin grill skirt / oven / grill / fry
Black Pulp broil / oven / grill / fry
Rump Roast barbecue / oven / grill / fry
Salonillo broil / oven / grill / fry
Grilling Meat paddle / oven / smoke / grill / fry
Pulp roast / oven / grill / fry
Crossed simmer / mold / stew / soup
Simmer neck / mold / stew / soup
Rib simmer / mold / stew / soup
Chest to cook / soups
To cook over low heat Lagartillo
Caucara cooked and then baked
Salon simmer, then baked and fill

Source: Piggis Products, Meats,

Preparation: Author

These products are sold in kilos, pounds, pieces and cuts which are typically Argentine.

1.4.7 Variety of products for Christmas

Chart # 7 Products for Christmas



Smoked Pork
Smoked Suckling Pig
Smoked Loin
Smoked Chicken
Smoked galantine
Smoked Prague Ham
Smoked pineapple ham
Smoked Visking Ham
Smoked Christmas Ham
Unsmoked ham
Smoked beer sausage
Smoked rolled boneless
Smoked Salami
Smoked Boneless Pepperoni
Smoked glazed ham

Source: Piggis Products, Christmas,
Preparation: Author

Each of the products listed below are sold in pieces and kilos, according to the needs of each customer.

1.5 Market

1.5.1 Product Definition

The company elaborates the following products: Variety of Hams, Bologna, Hot Dogs sausages, Chorizos, Smoked meats and Special products for Christmas uses.

1.5.2 Uses

Piggis products are consumed by people of upper, middle and lower social class. It is usually served at breakfast, dinner and offices, and are consumed by students and workers because of its easy preparation.

1.5.3 Properties

Piggis has products intended for human consumption, the full range of products that make part of the sausage family are rich in protein and energy, and the pleasant taste of the products is desired by a large portion of consumers.

1.5.4 Marketing standards

- **Presentation:** The presentation must comply with the quality standards demanded by the market, it is important to use a striking presentation because it can affect the customer's decision when buying the product.
- **Packaging:** The sausages must be made with natural casings, fulfilling current quality standards.
- **Labeling:** Containers must comply with the current standards, labeled with product name, production date, expiration date which are the priority requirements.
- **Substitute or Complementary Goods:** sausages can be substitute for chicken, fish, guinea pig, rabbit, cheese, margarine, butter, jam; but people often prefer sausages due to its easy use and good price.
- **Complementary:** As complementary products to the sausages we have bread, rice, potatoes, and vegetables.

- **Geographic Location:** Its main market is the city of Cuenca; secondly we have the distribution in the provinces of Ecuador. The main customers are wholesalers, retailers, authorized shops, pizzerias and restaurants. The future plan is to meet the demand of the Peruvian market.

1.5.5 Current Market

The top products sold in the market are: American ham, sausage and white sausage with cheese.

The Piggis Competition is: La Italiana and La Europea brands which are competing directly with Piggis in the city of Cuenca. The sausage factories Juris, Pronaca and Don Diego are the national competitors, since Piggis distributes its products throughout the country.

Marketing Channels: Piggis products are sold in direct sales. The most important are: pizzerias, restaurants, shops, markets, suppliers.

The sales system could be: cash and credit.

1.6 Peruvian Market

The Peruvian market has been selected because in recent times it has shown a significant economical growth (9% approximately). It is important to notice that during these days, Peru has become one of the most attractive countries for the industrial development. Peru has strong demanding standards for the entrance of any new industry, demanding quality and excellent promotion. Such is the case that many of the companies in Colombia are interested in maintaining export based relationships with Peru, because of the economic growth and investment opportunities, resulting in good stability for trading. Investments in Peru have grown at a rate of 20%.

Peru is an excellent starting point for the Piggis Company to expand its products, particularly because there is a good bilateral relationship between Ecuador and Peru, which is favorable to the introduction of new products. We have as an advantage that the

Ecuadorian product can be introduced to the Peruvian market with a moderate and affordable price. Chapter four will present an extensive study of the Peruvian market.

1.7 Conclusions

- Piggis Sausages Company is one of the largest companies in the city of Cuenca in relation to the production and marketing of sausages.
- It is important to have a clear idea of the beginnings, history, products, company structure, and the global market that the company is focused on as a point of departure in order to concentrate on improving current products.
- The global world and the growth of industry take the company to expand its products to different markets and should improve the product and capture the consumer's acceptance.
- We must analyze very carefully the Peruvian market before the introduction of the sausages on this market.

CHAPTER 2. GOOD MANUFACTURING PRACTICES

2.1 Concept of Good Manufacturing Practices

The Good Manufacturing Practices "are procedures to ensure safe products. These practices are part of a quality assurance which ensures that products are made in a homogeneous and controlled way, in order to afford appropriate quality standards, which are appropriate to use in accordance with the requirements with the commercial market" (Mattia).

The GMP is a basic tool for all business related with the food processing, in order to guarantee that products are safe for consumption and optimum for exportation. All manufacturing processes should always be reviewed and systematized to ensure that the production of each sausage is recognized in the market. In order to get safe products the sausages must be processed correctly, using methods that help each operator to develop the product with the same layout, shape, flavor and color.

The Good Manufacturing Practices enable the establishment to ensure that the products are safe and suitable for human consumption, being suitable for export to new markets. In addition, the company is projected to start the implementation of HACCP (Hazard Analysis and Critical Control Point); as well as the application of ISO 9000.

GMP are applied to all industries engaged in food production, establishing hygienic standards strictly enforced to ensure safe food production for consumption. It is oriented to small and medium enterprises, fostering the implementation of manufacturing systems for food, now certified by GMP, to expand to international markets.

GMP are international practices applied to the manufacturing industry. All factories worldwide are seeking to get certified, in order to get well known that their production is all done under strict quality controls, making their products attractive to the potential client and opening doors to introduce this merchandise into new frontiers.

Safe products are a food industry's responsibility. That is why the GMP integrate the company's infrastructure with the people who elaborate the products.

The main idea of GMP is to avoid mistakes, cross-contamination in the manufactured product, and to ensure traceability of the processes. It is important to notice that every production process comply with established hygienic conditions, from receiving the needed raw material to distribute the finished product.

The infrastructure of the company, as well as how to handle food, the food packaging and the distribution of it, are important facts as they ensure the products to be suitable for consumption. In order to guarantee that there is no cross contamination and that the products do not cause any damage in human health, a constant maintenance of the factory must be developed, in order to avoid the proliferation of germs that could contaminate the product.

The food distribution methods are another condition that must be taken into account. We must be very careful with it because an incorrect use of the temperature and some lack of adequate cleaning in the transporting vehicles, the product may contaminate other products during the distribution process. The application of GMP in all parts of the world has the same purpose: Suitable Products for consumption.

The company intends to apply GMP to export the products to a new market, Peru. During this project we will study the current conditions of the company and the areas to be improved in order to obtain certification.

2.2 Concept of Quality

Throughout the project, quality production processes will be implemented. This is the policy that Piggis is implementing in its search for excellence. The most successful concept is "quality benefits the client who receives a good product" (Ramos)

In fact, quality is an effort, because there is a group of people working together within the company, seeking to achieve the customer satisfaction.

Excellent quality products should be considered, not only for their presentation, but for their customer acceptance and their strict production methods used during the manufacturing process; achieving a successful final quality product in the market on local, national, and international levels.

The pursuit of an excellent quality product has come from the craft stage of food production. Little by little, as the technology has advanced, more sophisticated machinery has been developed and the digital world makes it possible to offer better quality and large variety of products.

It is noteworthy that the technology allows a much faster and more efficient production methods, as well as wider distribution in large quantities of products, being a very different process when using traditional methods. Incorporating processing techniques has a great importance in all food manufacturing processes, because applying it in most of the cases tends to decrease the cost of labor. Manufacturing products using high technology can offer quality results, maintaining permanent customers and getting growing demands.

2.3 Quality Control

The quality control department is a very important part of every Company, due to it takes charge of the quality control of all the production in each process from the initial to the final consumer.

Quality control is defined as:

"Techniques and activities used to satisfy operational requirements for quality. It aims to keep under control the process, and eliminate causes of unsatisfactory behavior at important stages of the cycle of quality, in order to achieve better economic results “ (Cantu, Jura - Koontz - Weihrich -)

The Quality Control Department carries out about the inspections in every business. It is responsible for preventing deficiencies or abnormalities in production, verifying that the

production techniques that have been used in the manufacturing process is satisfactory. All employees are responsible for developing and controlling the production, always thinking about the continuous improvement of the manufacturing process and generating higher quality to get better incomes and benefits.

2.4 Technical obligations in good manufacturing practices

2.4.1 Infrastructure

2.4.1.1 Factory location, structure and hygiene

The plants, according to the rules and norms, are located in places free of the dangers of flooding, smoke, dust, etc., to avoid affecting the products, keeping them free from contamination.

After having visited the factory, it was noted that the company is in a place that allows the correct transit of trucks for the distribution of the products, but it is recommendable to assign a larger and more comfortable area.

On the internal structure, it should be noted that the construction of the factory has been correctly designed to prevent the entry of mice, flies, insects, etc., as well as giving the facility to clean and disinfect the area. The space is large and each section does a correct work independently of one another, in order to avoid cross contamination. Water is also used for the process of the products. The Piggis Company is in an exclusive area with a large properly water supplier with correct temperature.

The following list will describe the structure of the company:

2.4.1.2 Facilities

- The walls do not contain toxic materials, are smooth and the height is appropriate.
- The floor has a drain for daily cleaning.
- The roof is built to reduce condensation and proliferation of dirt.
- The windows and doors are easy to clean and disinfection is daily carried out by the cleaning staff.

- The drawers that come into contact with food are easy to clean and disinfect. There is an exclusive machine for continuous cleaning, using non-toxic materials. The detergent used is colorless and odorless.
- Although it should be noted that the factory needs a modern design for its floor to make it easier to clean. This idea is currently being analyzed by the assigned inspection authority for certification.

2.4.2 Equipment

All the equipment that exist in the Piggis Company is installed according to the manufacturing processes: Cutting area, production area, cooking area, packaging area and shipping area. The German machines are all stainless steel. They do not emanate any toxic substances that contaminate or leak into the product being developed. Ongoing maintenance and proper cleaning of all equipment is easy using good hygienic practices.

The hygiene of the equipment is supervised by the head of production and quality supervisors to ensure good hygiene, proper operation and maintenance. The liquid disinfectant used exclusively for the machinery is suitable for the proper maintenance of it.

The transportation equipment such as the wheel barrow is always kept clean and is easy to wash. There are also equipment manuals accessible to the maintenance staff indicating the proper use of the machinery. If there is any equipment malfunction it goes to the maintenance area to be repaired. Repairs are completed using nontoxic liquid and materials to avoid any effect on future production of food products. There is a report made by the maintenance department, recording the problem with the machinery and the materials used to complete the repairs, thus creating a record of the problem.

Disinfection of the equipment is done at approximately 16:00 pm at the end of the workday, with liquid machinery detergent cleaning it on its internal or external surface depending on necessary.

The location of the equipment is in accordance with the processes that are used for the manufacture of the products. All equipment are properly installed to avoid any electrical accident, being properly connected according to the manufacturer's technical specifications. The equipment comes with operation manuals. Training is required for the operator so that there is no mishandling of equipment.

2.4.3 Raw materials

The raw material in the food process has great importance. Therefore any raw material containing parasites, toxic substances, or items being in the process of decomposition will not be accepted. Such material must be inspected prior to the preparation of sausages. The quality control department is responsible for performing laboratory tests and inspections once raw material arrives.

There are specific areas to receive each product; for example there is one area responsible to receive all raw materials like additives, spices, proteins, starches that have been requested by the company. It is properly stored in places free from contaminants and in optimal conditions.

It is also necessary to have good lighting, temperature control and ventilation, to prevent any contamination of the products. The water is drinkable and installation is properly designed for the supply and distribution throughout the factory. There is a frozen area separated from the other areas. It is exclusively for the delicate treatment of the products. Ice is made with treated water in an exclusive chamber for ice production.

There is no clutter and disorganization among the products that arrive at the company and at the processing plant. Meat products arriving at the company are daily received, properly inspected and examined by the company's quality control inspector, who takes care of measuring the temperature, pH, color, odor, and any possible presence of a damage substance. If there are any anomaly, the product is rejected.

At Piggis, products are properly stored in refrigeration chambers for the next production process. It is important to note that these products should remain at safe temperatures and in order to ensure its good conditions, avoiding the presence of any micro-organism. If any is found, the product is rejected.

The raw material is properly used according to the formulas of the product preparation. Production is planned a day ahead of time, according to the demand. Hygiene and quality parameters are analyzed by the quality control department of the factory according to the requirements.

2.4.4 Hygiene and sanitation of Piggis staff

The staff, in the process of implementing the Good Manufacturing Practices, has received training about the good work habits and hygienic handling of production machinery. Workers have learned the correct handling of the products and good hygienic practices for the food production. The staff has received several weeks of training, emphasizing the importance of the GMP for the Piggis Company.

It was shown the following standards to the workers, being strict requirements:

- To communicate the boss if any symptoms of illness are found in one of the employees. In the case of any accident, employees are not allowed to handle food under any circumstances until the company doctor checks if everything is on good conditions and approves it.
- A proper use of the uniform.
- The daily washing of their boots.
- The continuous use of masks.
- The proper use of mesh cap.
- They are not allowed working with earrings, rings, watches or bracelets during the production process.
- It is forbidden to eat and smoke in the plant.
- To wash their hands at the beginning of the day and during work as often as it is required.

The Quality Supervisor is responsible for reviewing each of the employees and to ensure that they are familiar with these important standards of cleanliness. It is the responsibility of the Quality Supervisor to educate and supervise them, resulting in hygienic products and helping to preserve the health of customers.

According to the rules available by the company, the supervisor must meet the following responsibilities:

- To check the existence of liquid soap in the dispensers.
- To check all the corridors, offices, restrooms, showers, and business premises for cleanliness.
- To provide enough toilet paper in the bathrooms.
- To remind the workers about the rules for each area, so they can respect and remember the processes.
- To monitor the worker's hands to be clean, not to contain any kind of jewelry or nail polish, as well as being sure the employees wash their boots before entering the plant.
- To review the water processing and treatment before they enter the plant.
- To monitor the cleanliness and good maintenance of the lockers.
- To be aware of the proper use of the uniform, being sure it is clean and neat before production begins.
- To remind workers about the correct use of the mask.
- To check the operator's hair is in good condition.
- To safeguard the security of visitors to the company.

2.4.5 Clothing

Uniforms are numbered according to the days worked:

- 1 Monday and Tuesday;
- 2 Wednesday and Thursday;
- 3 Friday.

For the admission to the plant, personnel should bathe daily and change their street clothes to their assigned uniform. It must be hygienically clean and disinfected. Each employee has his own locker which should be well maintained. Regular supervision of the lockers is carried out by the quality control department. In addition, each operator is responsible for washing their uniforms at home. In the locker room, the ventilation should be adequate in order to maintain hygiene and cleanliness. In addition, the

supervisor is responsible for making sure the workers to maintain the cleanliness of the locker room to preserve their health and the consumers.

2.4.6 Toilets and washers services

The quantity of the existing toilets and showers in the workers dressing rooms is sufficient and in accordance with the number of employees working in the company. Showers are built with stainless steel for the correct cleanliness of the employees. The sink is located at the lower level, before entering the plant. There are signs which remind them that hand washing is mandatory before entering the plant, and that all employees must wash and disinfect their hands with soap before starting daily work activities. Each sink has a liquid soap dispenser, disinfectant, and paper towels. Disposable paper towel dispenser should preferably be hands-free because there may be bacteria.

There is a person who is responsible for consistently cleaning, disinfecting and maintaining these areas. Everyone should wash and disinfect their hands at the start of the workday, after coughing or sneezing, before re-entering the plant, and after touching any kind of container that could be contaminated.

It is important to remember that the control is strict, since we are in the process of implementation Good Manufacturing Practices (GMP).

People who handle food are required to receive proper training on techniques for handling clean and safe food, and they must also be fully aware about the danger of the lack of a personal hygiene.

2.4.7 Access to the factory plant

To enter the plant, all employees and visitors to the company must comply with all standards of cleanliness, starting with the disinfection of hands and going through the disinfection process which consists on water tank with chlorine about 15 cm high by one meter long and wide, draining on one end, and immediately new disinfectant and water pumped in on the other end so that the boots are properly disinfected. The worker's

boots have been previously washed with a brush and antibacterial soap. All employees and visitors must wear masks and a mandatory cap with mesh.

Plant personnel must wear a plastic apron that must be washed at the end of the day. The entrance to the plant consists on a door with nylon fringe, also known as an air curtain. It is important to mention that there are doors of this type in all areas of the company.

At the end of the day employees must pass through the same disinfection process, washing their hands and boots in order to access the locker room.

2.4.8 Hygienic in the process

It is important to remember that to obtain proper hygiene in the preparation of the sausage, raw materials must be free from foreign matter or toxic substances. This is why the Quality Control Department is in charge of monitoring and controlling the proper storage and handling of raw materials in order to avoid cross-contamination.

The development and manufacturing process must create uniform products, to comply with the formulas of production of each product. When planning to make the product, the first thing we need to do is to respect its production formula, taking into consideration the availability of the meat and the raw materials. The product packaging must be free from contaminants, ensuring that it is in good condition so they do not contaminate the product.

2.4.9 Storage of raw materials and finished transport of products

The storage of the products must be organized and classified in its own containers to prevent contamination of the primary product. The raw meat must be properly stored in refrigeration chambers, with a specific temperature control. The product classification is specific to each one, because each one has a file which makes its production record from the raw material to the finished product.

From the time raw material arrives, it is inspected to detect any problem. The head of each area is responsible for seeing the conditions in which raw materials and supplies arrive, with the unique propose of avoiding deviations or failures in production. If any anomaly is reported, the Quality Supervisor takes prompt corrective measures and thus

prevents failures in the production process. This allows them to achieve the desired ended product quality and to reduce company losses for defective products.

For the transfer of the products, vehicles must be properly outfitted with a refrigeration system, since the sausage should not be spoiled and kept fresh, as well as avoiding contamination. Trucks are washed daily. The company must be very careful in transporting products to comply with all rules and strict measures during the process of product delivery. To avoid contamination, vehicles must be always stored in a sanitary condition. The Piggis Company is responsible for the proper distribution and product delivery to the consumer, the cooling system in vehicles is controlled systematically to maintain an optimal distribution of production.

2.4.10 Control of production processes

Using GMP, it is important to follow certain processes that ensure the correct application of the quality products:

- Form and processing environment
- Personal Hygiene
- Control of formulas
- Classification and identification
- Reprocess and Repair

The controls of production processes allow us to determine if there is anything odd in the primary product. The quality control department is responsible for the careful analysis of the raw material, in order to ensure a quality product, certifying that it is apt for human consumption. It is also important to mention that all pest control materials should be stored in separate areas, being always clearly identified. There should also be signs reminding the operators about the rules to be followed.

All materials used in the plant for pressing and packaging the products must be properly marked, identified and classified by each type of product. It should also be noticed that the ice that is used for the manufacture of products is done with potable water. The product is not exposed to pollution, pipes, walls, etc.

The cooling of the products is of real importance, that is why the sausages after the cooking processes are refrigerated immediately in cold chambers at temperatures of 10 ° to 15 °, according to the appropriate product characteristics.

The raw material must be kept separate from the cooked product, in order to prevent cross contamination. We must be sure that cooked food is not contaminated.

Here there is an example of the process control in production:

1.- On receipt of the cattle, we can mention the presence of quality auditors. This process is done at 6:00 am.

- The analysis of the type of meat that is received, controlling it to be in optimal conditions in order to continue the process of developing products, discusses the real state of the beef, the control of temperature, weight, pH, color, odor and if there is foreign matter. After all this process, the quality auditor indicates if the product is accepted or rejected.
- The beef is hung on stainless steel hooks that have been previously disinfected the day before. Then, it is weighed in kilos for the production.
- Go through the cutting process, classifying the meat according to its texture, fat and use.
- According to the classification given to the machine, obtaining consistency in the mix of the meat suitable for combine of the product to be performed, always checking the weight in kilos.

2.- Go through the pre mixtures in which each product is made with its own ingredients. We use the example of the chicken sausage. Its preparation consists on: Proteins Supramax, chicken meat, chicken skin, beef, pig skin, antioxidants, proteins, preservatives, salt and nitrite, pure salt, water and ice in a Laska mixer, fulfilling their development in accordance with the rules established in INEN according to the technical standard Ecuador 1338, which states that "the sausage must provide consistent and uniform texture free of pores or voids" (Ecuadorian Institute of Standardization)

3 .-It proceeds to weigh the mix to see if the desired weight is obtained by processing it. The paste obtained from the mixer goes to the filler establishing the type of sausage that is desired, always in a uniform shape.

4- The sausages are hung on mobile carts to send them to the cooking area, it is done immediately to prevent contamination, cooking for 40 minutes at temperatures of 80 ° C, then switched to cooling machines and finally to refrigerated rooms.

5 .- Then, the sausages go directly to the shipping area for retail, but note that first the Quality Control Department performs the analysis of the real state of the product to ensure they don't have any physical or microbiological contaminant, and so on in order to approve its departure for sale.

If there is any problem in production, it is reported immediately, sending the product to modify, implying a total loss of production.

2.4.11 Documentation

The Piggis Quality Control Department has developed a documentation system called Quality Forms, which allows documentation from the entrance of the raw material to the finished product. It is a thorough control of all the production processes.

All manufacturing procedures and controls are backed up by documents. This allows us to get a quick and easy product tracking, especially to determine whether a defect existed throughout the process. The documentation allows us to follow the history of each product from receipt as raw material to finished product, including the product transportation and distribution.

The documentation sheets must always contain the lot number, in order to identify it since it is the main product identification. All documents bearing the company must be available for review at any time.

Here are the eighteen forms that the company is currently using. The rules of the GMP demand that the company present the documents that indicate the production controls during the implementation of the GMP.

Form 1

Health conditions for the receipt of Meat Raw Material

- Date / Time
- Provider
- Driver
- Plates
- Quality Certificate Yes / No
- Health Status
- Product Type
- Lot supplier
- Temperature
- PH
- Color
- Odor
- Presence of any Foreign Matter
- Approved Yes / No
- Corrective Actions

Form 2

Sanitary Conditions in receiving of non-meat commodities

- Date / Time
- Provider
- Driver
- Plates
- Quality Certificate Yes / No
- Health Status
- Product Type
- Supplier Lot
- Presence of Lumps

- Compact powders
- Color
- Odor
- Taste
- Presence of Foreign Matter
- Approved
- Corrective actions

Form 3

Sanitary Conditions when receiving materials (casings and packaging)

- Date / Time
- Provider
- Driver
- Plate
- Quality Certificate Yes / No
- Health Status
- Material Type
- Lot supplier
- Presence of pests
- Strange odor
- Pollution Free
- Approved

Form 4

Control of the preparation of premixes

- Type of premix
- Date processing
- Preparation Time
- Responsible

- Total number ready
- Ingredients used
- Quantities used
- Lots of additives and ingredients
- Internal Lot assigned
- Prepared by
- Observations

Form 5

Control of emulsification

- Type of emulsion
- Operator
- Machine
- Batch No.
- Date / Time
- Lot MPC
- Internal Lot premix
- Lot starch
- Lot soy
- Lot flour
- Time of emulsification
- Vacuum Yes / No
- T ° paste
- T ° emulsified
- Time of rest before pressing
- T ° paste or emulsion before pressing

Form 6

Control of premix delivery

- Date of preparation
- Person responsible for preparation
- Location in the cellar
- In which product to use
- Total number ready
- No. of order in processing micro ingredients
- Internal Lot premix
- Theoretical concentration of nitrite (ppm)
- Approved laboratory
- Date of delivery to production
- Who gets into production
- Quantity delivered in production

Form 7

Sausage Control

- Batch No.
- Time of rest before pressing
- T ° paste or emulsion before pressing
- Calibration used
- Weight of parts
- Operator
- Prepared by.

Form 8

Cooking Control

- Date
- Product
- Lot
- No. of pot / oven
- Check in time
- Check Out
- Drying time
- Cooking time
- T ° core
- T ° cooling
- Approved / Reject / Quarantine
- Prepared by

Form 9

Control of cooling methods for finished package

- Date
- Product
- Lot
- Check in time on camera
- Camera Check Out
- Rotation (color, day)
- Conducted by chief winery
- T ° core
- Piece size
- Color
- Approved Yes / No
- Quarantine

- Corrective actions
- Performed by packaging supervisor

Form 10

Control of vacuum packaging

- Date / Time
- Product
- Lot
- T ° product packaging
- Film (micron)
- Slice thickness (mm)
- Vacuum (PSI)
- Observations
- Made by
- Reviewed by
- Product Texture
- Uniformity of the slice
- Sealing Edges
- Presence of foreign bodies
- Appropriate location labels
- Observations
- Approved Yes / No
- Quarantine

Form 11

Bulk Product Control

- Date / Time
- Product
- Color

- Odor
- Taste
- Texture
- Approved Yes / No
- Quarantine
- Observation
- Made by.

Form 12

Final Product Room

- Date / Time
- Lot
- Rotation (Color)
- Observations
- Made by.

Form 13

Registry of cleaning, disinfection of premises

- Refrigerators
- Released (yes / no)
- Order as
- Corrective actions

Form 14

Registration wash tubs

- Date / Time
- Equipment and materials
- Released (yes / no)
- Corrective actions
-

Form 15

Register of transport cleaning

- Date / Time
- Plates
- Responsible
- Released (yes / no)
- Corrective actions
- Made by.

Form 16

Registry of pest infestations

- Date
- Responsible
- Type of pest
- Observations

Form 17

Record of customer complaints

- Date
- Seller
- Zone
- Client
- Product
- Lot
- Date processing
- Expiration date
- Texture
- Bite
- Color
- Odor

- Taste
- Vacuum Packaging / without vacuum
- Size
- Weight
- Golds
- Corrective actions
- Received by

Form 18

Registry of cleaning and sanitizing equipment and materials

- Date / Time
- Equipment and materials
- Released (yes / no)

The complete company documentation can be found in the annex of this project.

2.4.12 Safety Requirements and Manufacturing Standards

It is essential for the working group to fully and correctly perform their duties, keeping always in mind their individual responsibilities. Employees should actively participate in the training talks for better performance and better knowledge. It should be a work environment taking as the main goal the improvement of the productivity and workers to feel satisfied with their effort and with incentives received from the company.

The health of the employees has been mentioned as playing a role within the manufacturing requirements, which is why the leaders responsible for each area should ensure the good health of their workers. Measures should be taken in order to prevent any type of contagious disease or illness from spreading inside the company as it would be detrimental to the company and the workers.

It is important to emphasize that hygiene and the protection from contaminants are important issues in the manufacturing process, ensuring that food is well prepared. That is why it is necessary that all employees abide by the rules: To wash their hands properly before begin the working day, to clean and use the proper uniform, to cover their hair

properly, not to use rings or nail polish, to use protective gear such as gloves, masks, and finally to clean boots. It is considered of transcendental importance to know the specific requirements for the development of each product. The Ecuadorian Institute of Standardization (INEN) is responsible for publicizing the requirements and standards to be met by food producing companies, which is why compliance with hygiene standards in the manufacturing process makes the product apt for consumption and not injurious to health.

Below, it is shown the products and its requirements by its classification.

2.4.12.1 Sausages

According to the research made at INEN (as shown in table No.8 Permitted Additives for the Manufacture of Sausages), the same permitted additives are used by Piggis Company in its sausage. "In the manufacture of sausages there must not be excess beef fat in lard or pork fat replacement using industrial pork fat". (Ecuadorian Institute of Standardization)

There are very important and appropriate measures to be taken into account when achieving compliance with the ordinances of INEN. These measures must be followed even more closely because the company is in the process of obtaining the GMP certification.

Chart # 8 Specific regulatory requirements for sausage making

ADDITIVES	MAXIMUM* mg / kg	TEST METHOD
- Ascorbic and iso ascorbic acid And their sodium salts	500	NTE INEN 1 349
- Sodium nitrite and / or potassium	125	NTE INEN 784
Polyphosphates (P205)	3000	NTE INEN 782
Binders such as starch, dairy products, home meal Vegetable product, up to 5% content for cooked and blanched sausages and a maximum of 3% content for raw and cured sausages NTE INEN 787		NTE INEN 787
Auxiliary substances: white or refined sugar, in limited quantity for good manufacturing practices.		

Source: INEN 1338 Meat and meat products, sausages, 1996

Preparation: Author

2.4.12.2 Ham

Another product is the Piggis Ham, which the company manufactures under the same provisions of INEN that state: "The ham should be prepared with meat in perfect condition, from healthy animals slaughtered under sanitary conditions. Pieces of meat

must be registered and marked with safe inks, being examined by the inspector and according to the NTE INEN 1 218." (Ecuadorian Institute of Standardization) The importance of raw material in the preparation of products, results in the development of the consumer product that is safe and with high quality, maintaining in this way a good presentation, keeping the original flavor and achieving customer satisfaction.

Chart # 9 Specific requirements for Ham production

ADITIVE	MAXIMUM * mg / kg	TEST METHOD
Ascorbic acid and isoascorbic	500	NTE INEN 1 349
NTE INEN 1 349 500 and their sodium salts NTE INEN 125	125	NTE INEN 784
784. Sodium nitrite and / or potassium NTE INEN 3 000	3000	NTE INEN 782
782 Polyphosphates (P2 05). The addition of nitrate to Matured ham can be done in such a way that the residue does not exceed 600 mg / kg and residual nitrite does not exceed 200 mg / kg.		NTE INEN 785

* Maximum calculated on the total net content of the product.

Source: 1339 INEN Ham Meat and meat products 1992 Requirements
Preparation Author

2.4.12.3 Mortadellas

Mortadellas are another type of product the company manufactures, offering to the consumer a new product choice. According to the definitions of the INEN rules: Mortadella "sausage is made from ground or emulsified meat, mixed or not, of: beef, pork, chicken, turkey, and other edible tissues of these species, and permitted additives and condiments; smoked or not and scalded." (Ecuadorian Standardization Institute). These are food choices that aim to know each customer's likes. The company must make these products according to the requirements of the existing standard for it.

Chart # 10 Specific requirements for Mortadella production

ADDITIVE	MAXIMUM *	TEST METHOD
Ascorbic acid and its salts	mg / kg	
Sodium nitrite and / or potassium	500	NTE INEN 1359
Polyphosphates (P2O5)	125	NTE INEN 1359
	3000	NTE INEN 1359

* Maximum calculated on the total net content of the final product

Source: 1340 INEN Mortadella Meat and meat products 1988 Requirements

Preparation Author

2.4.12.4 Chorizos

The chorizos are another product made by Piggis, that is why it is necessary to present the requirements according to the standards that INEN emphasizes: Chorizo "Sausage is made from ground beef, mixed or not with: bovine, pork, chicken, turkey, and other edible tissues of these species." (Ecuadorian Standardization Institute)

Chart # 11 Specific requirements for Chorizos production

ADDITIVES	MAXIMUM* mg / kg	TEST METHOD
- Ascorbic and isoascorbic acid And their sodium salts	500	NTE INEN 1 349
- Sodium nitrite and / or potassium	125	NTE INEN 784
Polyphosphates (P205)	3000	NTE INEN 782

* Maximum calculated on the total net content of the final product.

Source: 1344 INEN Sausage Meat and meat products 1992 Requirements

Preparation by Author

2.4.12.5 Smoked products and Other Meats

The main and most frequently consumed food is meat. According to the requirements it must be produced under perfect conditions because it is for direct consumption. I will introduce you the requirements for the smoked meats established by INEN: "Smoking should be done by direct action of smoke from burning wood, sawdust, shavings, dry, hard and softwood, free of dust " (Ecuadorian Standardization Institute)

There are requirements for each of the smoked products, that is why it is important to mention an example of the smoked Piggis products such as the smoked meat, as detailed below in Chart No. 12:

Chart # 12 Smoked meat specifications

ADDITIVES	UNIT	MIN	MAX mg / kg	TEST METHOD
Heating loss	%	----	50	INEN 777
Total Fat	%	----	*	INEN 778
Protein	%	18	----	INEN 781
Ash (chloride free)	%	----	6	INEN 786
PH	----	----	6.2	INEN 783
Sorbic acid	mg / kg	----	100	INEN 791
Ascorbic acid or its salts	mg / kg	----	500	INEN 1349
Nitrite of sodium and / or potassium	mg / kg	----	125	INEN 784
Polyphosphates	mg / kg	----	3000	INEN 782
* For pig meat 20% max.				
* For meat of other species allowed 10% max				

Source: 1347 INEN Meat Smoked Meat and meat products 1985 Requirements
Preparation Author

2.5 Manufacturing Standards

Proper manufacturing should not produce any health risk to consumers, therefore:

- The handling of food should be such that no microbial growth is generated.
- The work environment must be suitable.
- The product must be properly inspected to meet sanitary requirements.
- The water that processes the foods should be clean and free of debris.

2.6 Packaging, Labelling, and Boxing

The finished product is stored in cooling chambers of 10 ° to 15 ° C, and then it is sent to the distribution area. Many products, such as: sausage, bologna, hams, etc, that are daily made, are packaged for retail in the called vacuum packaging. Proper handling procedures can extend finished product's life.

This area is divided into sub - sections:

- The first section is responsible for the packing and the sealing of all matters relating to sausages and controlling stock in existing chillers, which will dispatch on demand.
- In the second section we can find the slices of mortadella. This section is responsible for expediting the orders that are required daily and at last minute.
- The third section is uncharged of the wholesale slices, a continuous line thermo-forming. The cutting of the slices are scheduled according to what the client requests, ranging from 1 mm to 3 ½ mm.

Product packaging must be selected to be optimal for each product as detailed below:

- Batch number of the product, which allows withdrawing the products helping to maintain an effective rotation of it in stock.
- Health records, expiration date and especially a correct weight and price.
- The polyethylene films used for packaging are scheduled to be printed with the date of manufacture, expiration date, batch number and price on the film. The sealer machines, Multivac packaging, do not have direct contact with the

staff hands as it is automatically programmed to perform the job of packaging and labeling.

Products such as mince sausage are packaged and sealed in a sausage transparent film. There is no scheduled chopper but it is a direct contact product with the operator, which prints the same seals with the corresponding specifications of the product, name, weight, batch number, expiry date, production and price.

Product packaging refers to the quantity or weight, and it is specified according to what the company makes. This is highly variable because products don't have the same weight: it varies from 20 mg, 30 mg, 50 mg, and so on.

It has been verified that all workers know the risks and what should be taken in the handling of the machines.

2.7 Storage, distribution, transport, and communication with customers

All products that have passed through the cooking process are immediately placed in cold storage chambers at temperatures of 10 ° to 15 °C. Here, it is controlled how long the product will remain. Besides, the air speed is important to identify the product so that this product reaches a perfect condition and proper temperature to prevent spoilage.

An important point within the GMP to be considered is to always store products in cold rooms, where the product does not receive direct sunlight and with some ventilation, high shelves and classified by product. Another important point is to correctly classify each product so there is no confusion. Therefore, allowing less handling of the storage bins and making cleaning easier keep the area in order.

Next, all the storage rooms that the company have:

- Chamber of animals for cutting
- House for classified meat (70 -30) (80-20) (90-10)
- House for processed and frozen meat
- Cooling chamber for hams
- Refrigerated packing area
- House for finished product

- Intestinal parts room

2.8 Distribution and transport

The product distribution is according to the demand registered by order in different parts of the country. The products are sold in all the provinces, at markets, shops, and restaurants. The idea is to perpetuate and maintain the Piggis brand in the consumer's mind.

The area offices are responsible for coordinating the proper distribution of the sausages in packages, using vehicles that keep the product fresh and free of any contamination and spoilage. This area is one of the most important since it is responsible for respecting the dispatch order and weighing correctly the orders of all customers to different areas where it will be sold. They must prevent ground contact for the product and ensure a proper transport to the vehicles or delivery trucks.

The area office perfectly coordinates the day and time for orders that will be sent to their destination. It means that every day is designated with the exact time for the departure of the trucks within the product areas: Local, provincial, coastal area, mountain area and eastern area. In this way the trucks do not disrupt traffic, respecting the arrival time of the product, and it is notified to the distributor and consumer when the product will arrive.

The area office oversees and supervises the cleaning of the trucks and especially the cleaning of the refrigerators belonging to the distributors in the provinces outside the city. The products are transported in cardboard boxes, trying to avoid the stacking of the boxes, taking care so that the product remains in a good presentable condition.

2.9 Customer's Communication

It is important to know the opinion of the consumer, in order to try to get the best product quality.

According to information obtained from the company sales force, I can mention that most customers are satisfied with the product. The company is responsible for supporting and receiving products that for some reason did not receive proper

distribution, with the option to return or exchange the product, maintaining good customer relations if the product needs to be returned to the company.

Once the product is delivered, the customer should be asked to fill out a survey regarding service and product quality. This would be very beneficial and enriching for the Piggis Company, working to know real customers' needs and to achieve strategies of product improvement.

The company receives a report of the returned product – if there is any - from the customers, stating the reason why the product has been returned. Any suggestions from customers are welcomed by the company. The idea and intent of Piggis is to grow and improve the quality of the sausages. A factor of great consideration is to strengthen consumer confidence in sausages that are made in the company.

2.10 Quality Assurance

As it has been mentioned throughout this project, the company's main objective is based on developing Piggis optimal products, with a presentation that is pleasing to the consumer, creating standardized products that meet appropriate health standards especially pleasing the palate of consumers, with affordable prices in the domestic market and soon in the Peruvian market, increasing sales volume of products, thus becoming competitive in the market.

To achieve all these objectives, it should be implemented a good quality control system, with a plan and methodology that try to ensure a maximum product quality and a safe human consumption, ensuring that the processes are carefully controlled from the receipt of raw material until the dispatch of the finished product.

The Piggis Company has several registration documents:

- The receiving report register conveys the sanitary conditions of meat, raw materials and the non-meat raw materials.
- The Raw Material documents, filled with all the basic data of the raw material, provide the supervisor with the information to fulfill their responsibility for indicating acceptance, rejection or quarantine of the raw material, ensuring

quality for the production of sausages, so Piggis ensures that consumers are getting quality and healthy products for their palates.

- The company has started to implement the rules of good manufacturing practices to achieve GMP certification.
- Piggis is keeping records of all the plant's operations, the process of each machine that the company uses, ensuring that the plant has a cleaning and sanitation program for the removal of the product that might be remaining from mixtures that have been developed during the day.
- Facilities, sausage equipment, premix machines, processors, packaging, etc. must be disinfected to start the day. The quality control department that monitors every implementation with hygienic process ensures proper cleaning of the equipment.
- The company has production manuals that the plant managers and head of research and development for Piggis are constantly improving, with the aim of developing better products. Production workers must follow exactly those processing steps and use the proper ingredients for each product, ensuring excellent quality.
- The quality control department records the details of machinery and equipment, working daily to improve the product from the beginning of product manufacture, with regard to machinery, cooking, packaging, storage and distribution of it.
- The quality control laboratory is periodically conducting quality control tests that monitor compliance with hygiene standards, ensuring a correct manufacturing procedure. The process of sampling and analysis by the laboratory immediately provides results, offering information regarding to non-conforming events in the factory and a record of production for the company files.
- The quality control laboratory is responsible for developing a program of periodic sampling at random to the control quality product. It also defines procedures for sampling and analytical procedures. The results are known immediately to all relevant heads of each area or process area to take into

account the improvements to be performed and also to inform production workers.

- The control of the quality assurance performed by the laboratory: The laboratory is allowed to conduct sampling of the product, where the sample was taken, the number of samples taken, the type of product that was analyzed, whether or not it was vacuum packed and the date of the sampling. The results are provided to senior management, the chief of research and development, and the plant manager.
- The forms for results of the analysis are recorded in the file systems of the Piggis documents. When there are anomalies, corrective actions are taken immediately. In most of the analysis, the results obtained by the laboratory bacterial presence are non-existent.
- Results of microbiological tests are recorded so as to facilitate the identification of potential trends or problems.
- According to what quality control indicates, microbiological documents define the requirements to validate the effectiveness of cleaning and sanitation activities in the plants.
- The quality control department must select and supervise the person in charge of food production, always trying to promote excellence in the development of products.

2.11 The Good Manufacturing Practice as a quality assurance instrument

Good manufacturing practices play a major role in the development of products. Ensuring the quality is "to keep under control the production process since the arrival of inputs and raw materials until the processing control" (Quality Assurance) This means maintaining a strict control of: Suppliers of inputs and the raw materials entering to the factory. If there is any change in the product, immediately the quality control supervisor sends a letter to the supplier of the product, indicating the novelty of the input or raw material, requesting the change of it, otherwise the factory will change to another provider.

All these developments are recorded in the forms of receiving raw meat or receipt of non-meat commodities.

During the process, we took into account the type of documentation and process controls that each manager from all areas is responsible for, as well as the monitoring and fulfillment of the proper recording of data in the control documents of the company, the establishing quality control practices to ensure compliance with well-known processes and to make sure the production schedule is properly known.

The post production control refers to the control of storage, transport and distribution of the products, maintaining proper control over the storage of products in an orderly manner, as well as to be properly checked before being distributed to customers, that the proper control in transport is performed to avoid contamination and prevent potential unwanted developments in the distribution by delivering a truly optimal product for consumption with no abnormalities in them.

It is noteworthy that in the Piggis Company the main purpose is that the products achieve wide acceptance and be considered safe products with excellent quality in the global market we live in.

2.12 Application of the checklist for the official Piggis food system

Before requesting inspection by the delegate of the Ecuadorian System of Metrology, Standardization, Accreditation and Certification it is necessary to perform an intense and thorough review of the following items by the inspector assigned by Piggis.

- General features
- Facilities
- Equipment
- Personel
- Raw material
- Operating System
- Packaging System

- Storage System
- Safety System

The parameters set in each of the topics discussed must be met before the inspection so there will not be abnormalities and therefore the required certification will be given.

In the present project, the verification forms of GMP compliance permit Piggis to be bound by the parameters provided by the official inspector delegated by the Ministry of Health and the System of Metrology, Standardization, Accreditation and Certification. They give the information the company must know, according to the official system regarding food. Piggis should check they know the requirements in the information sheets. The following description will indicate us the records that should be applied.

Form N ° 1

General Plant Features

- Name and address.
- Location: Sector, parish, county, state, address, phone, fax, email.
- Category: Industry, small industry, micro and small workshop.
- Legal representative: Full name and profession.
- Technical Representative: Full name and profession.
- Production Manager: Full name and profession.
- Quality Manager: Full name and profession.

- Operating Permit: code, number, date of issue.
- Plant activities: production, packaging and distribution.
- Types of Foods: Prepared, packed, packaged, distributed.
- Purpose of inspection: To obtain certification, recertification, sampling, and others.
- Type of Inspection: Total, partial or specific.
- Those who make the inspection, names, identity card, an institution to which they belong.
- Observations.

Form N ° 2

Facilities: Minimum conditions

- Risk of contamination or alteration.
- Location in populated areas.
- Unhealthy sources.
- Area free from insects, rodents and birds.
- Pest control measures.

- Good condition of the walls and gates.
- Unprotected holes.
- Materials of walls smooth and easily cleanable.

Building Design

- Protection of internal areas from pollutants.
- Enough space for the development of each activity.
- Personal hygiene facilities.

Workspaces

- Distributed according to the flow of processes.
- Signalling system according to the processes.
- Easy movement of material.
- Ease movement of personnel.
- Hygiene Plan for each of the areas with an implemented control system.
- The control system is performed by plant personnel or outside personnel.
- Management System for flammable products.
- Security and contingency plan.

- Storage areas to fulfill the technical specifications

Floors:

- Constructed with materials appropriate for the work of the company, smooth, waterproof, durable and easy to clean.
- Condition of floors: in good condition and clean.
- Drains with enough slope to facilitate cleaning

Walls

- Built with the technical specifications: smooth, easily washable material, waterproof, without loose particles, fully sealed joints with no gaps.
- Current state of the walls: clean and in a good condition.

Ceilings:

- Construction materials: waterproof material to facilitate cleaning.
- Roof State: clean, smooth, no loose particles, easy to clean.

Windows, doors and other access:

- Construction materials to be clean, easy to clean, no loose particles, protection against pests.
- Current status of windows, doors and other access: in good condition, no dust, sealed, double door systems, no holes.

Stairs, elevators, additional structures

- Durable construction materials, easy to clean, safe from contamination, facilitating the flow of raw material and personnel.
- Current status of stairways, elevators, complementary structures: in good condition, no dust, easy to clean, easy access.

Electrical and water networks

- Construction of electrical networks: open, closed, fixed to ceilings or walls.
- Visible signage system up and running.
- Cleaning procedures and records established to date.
- Labeling systems streamlines: potable water, non-potable water, steam, fuel, air, and wastewater.

Lighting

- Types of lighting: natural, artificial, mixed.
- Intensity of lighting: good, average or low.
- Lighting location: factory floor, packaging, boxing.
- Ensure that the lighting does not change the color of the products.
- Current lightning state: clean, protected and in a good condition.

Ventilation

- Ventilation: natural with appropriate filters, mechanical, direct, indirect, climatic comfort.
- Location: in places where the airflow to other areas is avoid.
- Status: clean, no steam, or dust.
- A functioning cleaning program working, with updated records.

- Maintenance program with established dates of replacement and exchange of parts and pieces.
- Management plan for compressed and cooling air.
- Control of air pressure.

Temperature and environment humidity

- Up and running temperature control system.
- Record daily temperature and humidity.

Toilets, showers, and lockers

- Construction: sufficient according to the number of staff, separate it for men and women, with sink, shower and toilet.
- Construction materials according to the technical standard for an ease use and cleaning.
- Location: away from the production areas and areas for the management of raw materials and finished products.
- Status: clean and in good condition.
- Sufficient supplies of liquid soap, paper towels, containers with lids to waste materials.
- Maintenance system: a schedule of cleaning, disinfection, labeling registers for its permanent use.

Water Supply

- Supply municipal system, deep well, cistern of supply.
- System of control: protection, physical control, microbiological.
- System of registration: volume registered for processing.

- Current state: conditions of hygiene, protection, maintenance, labeling, materials used for their supply and use.

Supplies of steam

- Supply: for the productive process.
- Current state: it has filters, supply control, registrations.

Waste disposal

- Generation of residuals: liquids, solids, gassy.
- Final disposition: industrial effluents, drainages, evacuation, sewer system with appropriate traps.
- Specific areas for handling, gathering and storage.
- Facilities designed to avoid contamination.
- Current State: handling of containers, use of disinfectant, odor and pest control.

Form N° 3

Equipments and Utensils

- Elaborated with materials such as: nontoxic, resistant, inert, non-loose particles, easy cleaning, easy disinfection, resistant agents of cleaning and disinfection.
- Elaborated to fulfill the functions of each process under secure conditions, without risks to the raw material or to the employees.
- Current State: Good and clean.

Cleaning, disinfection, and maintenance of equipments

- Plan for the use and maintenance of equipment with clear instructions for the employees.
- Plan for the replacement of parts and pieces according to their durability.
- Maintenance instructions. Those are readily available to the workers as they operate in their teams.

- Plan for calibration of teams: within and outside the factory.
- Plan for team trainings for the programming of machinery and for participants' registration.
- System of lubrication, registration and control of lubricant changes.

Other accessories

- Production surfaces
- Pipes, conduits.
- Substances used during the different processes for cleaning, disinfection and maintenance.
- Maintenance plan and handling of the accessories based on the instruction characteristics of use.

Form N° 4

Personnel

General data

- Total of employees: number of men, number of women.
- Personnel of plant: number of men, number of women.
- Executive staff: number of men, number of women.

Education

- Professional profile for each workspace.
- Training programs and training of the personnel.
- Manual of functions, tasks, responsibilities of the personnel.

State of health

- Identification card indicating health status.
- Programs of preventive medicine: frequency, registrations, emergency situations, causes of repeating conditions.

- Emergency plan: training for emergencies, first aid, emergency alert, fires, contaminations.

Hygiene and protection measures

- Norms of hygiene and strictly established cleaning regimens.
- Strict use of the uniforms, equipment and working materials.
- Forbidden use of personal accessories.

Personnel's behavior

- Signaling indicating not to smoke, no jewelry, make-up, beards or mustaches.
- Use of caps, gloves, boots.
- Handling of fire extinguishers, hydrants, exit doors and alarms.
- Knowledge of the safe-deposit system and protection.
- Knowledge of all the norms of hygiene and cleaning.

Form N° 5

Raw materials

- Certification from the suppliers of raw materials and inputs.
- Registration of these certifications.
- Written requirements for providers of raw materials and inputs.

- Written specifications for each raw material.

- Specifications are based in the official regulatory rules.

- Inspection and classification of the raw materials during their arrival

- Innocuousness analysis and quality of the raw materials.

- With what frequency is the registration of the analysis completed?

- It has been established a record of execution of the specifications when there is a change in the supplier, or when the verification of the laboratory reveals contradiction to the analysis certificate for ingredients from well-known supplier.
- Each received raw material lot is analyzed with a sampling plan.
- Register the results of the analysis.
- The storage is based on the nature of the raw materials.
- Document the special conditions that each raw material requires.
- Classify the raw materials according to their use.
- To identify the raw materials: in external containers (secondary) or in internal containers (primary).
- Expiration dates (when it corresponds).
- Absence of altered or not acceptable raw materials for human consumption.
- The packages/containers are made from materials not susceptible to deterioration. Substances do not come off upon contact with the product, and are easily disposed or cleaned.
- Applied System for the effective rotation of the stored lots.
- To register the environmental conditions of the storage areas: Cleaning, temperature, humidity, ventilation, illumination.
- Other areas are separated from the production areas.

- Defined policies in case of refunds of raw materials that do not know established specifications. It takes a registration of the refunds and a written procedure to enter raw materials to areas of high risk of contamination.
- Defrosting of the raw materials under appropriate conditions of time and temperature.
- Defrosted raw materials are not to be re-frozen.
- The stored food additives are the ones authorized for the use in the products being manufactured. It is properly labeled, including their period of useful life.

Water

- Water that is used as a raw material supply falls under specifications that correspond to the respective INEN Standard, establishing the parameters evaluated: physical, chemistry and microbiological processes.
- How often to register assessments of the treatment system for drinking water: water treatment monitoring, how often this monitoring is recorded.
- Ice made from potable water is produced, handled and stored under aseptic conditions, checking the safety controls as they apply to ice and documenting these controls.
- Steam for contact with food is generated from potable water.
- The chemicals used to treat boiler water are approved by INEN and other recognized international institutes.
- Cleaning and washing of raw materials, equipment and materials are done with treated drinking water.
- Reuse of reclaimed water production processes.
- To have a specific storage system for this water.
- Performing chemical and microbiological control of this water, documentation of the frequency of these checks resulting in controls that ensure the suitability of the distribution system of this water as it is separated and identified.

Form N ° 6

Production Operations

- Planning of the activities of manufacturing / production.
- Written specifications for the manufacturing or production processes
- The manufacturing processes / production are validated, verified as to meet compliance.
- The areas are suitable for the established production volumes.
- To check the cleanliness and operation of the equipment before the production begins.
- The documents clearly define production processes and are commonly used by operators.
- To follow written procedures at each stage of production process.
- The staff in this is area aware about their roles and the risks and the errors that may occur.
- To adapt the design of the areas for the type of production.
- The production areas are sufficiently spacious.
- To distribute properly the machinery equipment and the raw materials used in the auxiliary material.
- To define the areas according to the nature of the products processed.
- To take precautions to avoid cross contamination.
- To determine the critical points.
- To monitor critical points.
- To locate cables and hoses properly as part of the equipment.
- The liquid supply systems must have a filtration system that is commonly used.
- To keep windows closed in all production areas.
- To adequately protect the windows to the aisles with insect mesh, cleaned according to established procedures, maintain order.
- To record the following environmental conditions: moisture ventilation temperature, pressure, control devices in good working order.

- In areas of production, during the development of activities to establish procedures for production, use record checks effectively, taking precautions to avoid the risk of confusion and contamination.
- To use appropriate protective equipment for handling raw materials.
- Written instructions for the manufacture of each product.
- Each operation is guaranteed with the signature of the person performing the task.
- To record a document at each important step during production.
- To warn personnel to report any abnormalities in the process.
- To communicate to the technical manager any abnormalities detected by production in order to record in the history of the lot and take corrective actions in each case.
- Procedures and precautions to avoid cross contamination.

Form N ° 7

Packaging, labeling and boxing.

- Areas for packaging, labeling and boxing are separate and clearly identified.
- Staff in these areas know the risks of possible contamination.
- To complete the filling / packaging of the finished product in the shortest time possible to avoid contamination.
- The filling / packaging fulfills the requirements of the regulations.
- Written procedure for the packaging line.
- Containers and packaging are approved by quality control, approve in writing and place stickers of approval.
- To keep track of the packages, labels and packaging leftovers.
- Written procedures for the cleaning and sterilization of containers that will be reused.
- To conduct monitoring during the filling and packaging process, and record the results which are part of the history of the batch number.
- Qualified Providers containers and packaging.

- Ensure the suitability of packaging material.
- The primary packaging to know the required specifications for food containers.
- Finished products are packaged and labeled according to their condition: Quarantined, Approved, or Rejected.
- The information contained on the labels meet the requirements of the standard.
- What is the destiny for the labels that are not used: without marking a number or expiration date. Marked with a number and expiration date
- To consolidate orders and labeling, record this operation, part of the history of the product lot.

Form N°8

Storage, distribution and transport

- The warehouse / storage of finished products have appropriate sanitary conditions, making programs written for cleanliness and hygiene of the store / storage, pest control, implement these programs, how often.
- To create appropriate environmental conditions to ensure food stability.
- To maintain special temperature and humidity for foods required because of its nature.
- Written procedures for handling the products stored in warehouse / storage.
- Specific areas: quarantine, approved products, rejected products, returns.
- Each area has shelves or pallets to store food properly separated from sections (minimum 10 cm.)
- Procedures to ensure that the first thing in is the first thing out (FIFO)
- Foods are properly identified and stored indicating their status.
- A warehouse / storage area exclusively for the market return and written procedures for returns.
- Transportation of raw materials, semi-finished and finished products should have appropriate sanitary conditions, as well as materials that pose no threat to its safety and quality and to allow easy cleaning of the vehicle.

- To ensure the temperature and humidity conditions of the products.
- Vehicles used exclusively for transporting raw materials or food for human consumption.
- Programs written for cleaning vehicles.

Form No. 9

Assurance and Quality control

- Quality Control Department.
- Laboratory for quality control in all production processes.
- Equipment Calibration System: dates of calibration, maintenance, change of parts, performed by the plant personnel or the outside personnel.
- Manual of procedures for handling and testing of samples, analysis of raw materials and of containers and packaging, goods in process and finished products.
- Batch records analyzed of water, raw materials, goods in process and finished products returned by customers.
- Plan for a monitoring quality assurance.
- Supplier management: ongoing communications about new and improved product's delivery.
- Procedures for the use of machinery, equipment, utensils and others.
- Protocol for control of raw materials, materials, equipment, machinery, work in process and finished product.
- Security measures: development control chip suppliers, raw material and finished product in process.
- Procedure for customer service and claims.
- Procedure in case of quarantine, handling labels.
- Procedures for waste management analysis.
- The used equipment is adapted to the requirements of the product.
- Teams are equipped with technical manuals, reference cards with specifications, instructions for the maintenance, calibration record / maintenance.

- The sampling activity in writing.
- The activities are properly monitored.
- The reagents are: properly located, properly labeled, prepared according to standardized methods, written down, appropriately controlled quality and efficiency, properly stored.
- Control techniques are: clearly established, understandably written, standardized procedures, properly filed, written without corrections.
- Under routine control: raw materials, packaging materials and boxing products in the process.
- Finished products: physical-chemical parameters, microbiological parameters of these controls are part of the history of each batch of finished product.
- Periodic checks regarding the effectiveness of the quality assurance and control, through self-inspections and by external audits.
- Periodic reassessments are made: raw materials and boxing, packaging materials, reagents.
- The reference substances and patterns are managed according to specific rules, properly stored, prepared according to written procedures and the registration of their uses.

The official forms relevant to the food system will be shown in annexes.

2.13. Preliminary diagnosis of GMP in the Operators

For a period of approximately four weeks, before starting the process of implementing the GMP, I observed the development of all Piggis operators within the premises. It was concluded that they did their job but not followed the strict rules according to the Ecuadorian GMP regulations in force.

It is essential to mention that they should promote personal hygiene, hand washing, a correct use of the uniform, and the correct use of their hats, boots, using mask and gloves; ensuring that the employee is in perfect health, and plan for sanitary standards training.

In the area of vacuum packaging, a pilot plan was made in which a quality inspector took a sample of an operator's unwashed hands who works in direct contact with the products. It was determined that there should be more constant hand washing and the correct use of a disinfectant. In the area of condiments they should train other people to collaborate and help the person who was in charge of this area.

At the end of the pilot plans and observations made, the company began to make a plan to improve all the problems and try to get a better situation in a remarkable way, making it easier for operators to implement the GMP in the company.

To try to improve and recognize the anomalies that was found in each employee. The quality control supervisors conducts an assessment of each areas who would inform to the heads of each factory area the mistakes their workers were making, as well as presenting a document indicating what would emphasize the operators in order to prevent the same mistakes, as well as reminding them that the most important thing is to avoid physical, chemical and biological pollution.

The following will present the checklist that the Piggis GMP management coordinator made for the diagnosis of operators.

GMP DIAGNOSTIC CHECKLIST OF FOOD HANDLER PERSONEL

Art. 24 How do you ensure staff to maintain personal hygiene?

How do we know staff is fully trained for their job?

Art.25. Are there health certificates to certify food handlers?

How often are their medical checkups?

What proof of health preventive measures are there?

How would it be ensured that no employee with a potential health conditions is in direct contact with the exposed food?

Art. 26 Personal hygiene and protective measures.

1. Are there written personnel rules regarding extensive contamination and product safety?
2. What is the provision of uniforms? How many are there? What is the design?
3. Regarding washable clothing: where is this washing being done?
4. How do you ensure the proper washing of the hands of operators who are in contact with food. How often do they wash them?
5. Do they have a mask for critical operations?
6. What is the condition for the gloves?
7. What is the condition for the shoes?

Art. 27. Personal behavior.

1. Are they covered their hair, beards and side burns in critical areas?
2. Are the nails short, clean and without nail polish?
3. Do you notice the lack of jewelry, watches, ornaments, excessive makeup and perfumes?
4. Are the lenses used made of plastic? Are they insured?
5. Are there visible behaviors of not eating, drinking, smoking or chewing any object or product?

Art. 28. Do the visitors and office staff know about the health protection standards outlined?

Art. 29 Education and training.

- 1.- Is there a training program on sanitation, hygiene and food handling?
- 2.- Are there staff training exercises for new hires? ¿ For long term workers?
- 3.- The training for plant personnel and maintenance involves a minimum:

- a. - Designation of areas.
 - b. - Types of uniforms and accessories allowed and not allowed.
 - c. - Conduct standards in all areas including toilets.
 - d. - Caution to be taken to avoid cross contamination and any risk.
 - e. - Control and management of critical points.
 - f. - Surveillance and monitoring of operations.
 - g. - Critical limits.
 - h. - Connective actions.
- 4.- Are there announcements alluding the need for mandatory compliance and observance?
- 5.- What steps are taken to prevent workers in contact with raw materials at an early stage from coming into contact with the product in the final stage.

Source: BPM Instructor Piggis

2.14. Training of Good Manufacturing Practices for employees

After obtaining the results of the operators, Piggis proceed to make the first GMP training to employees, letting them know why and for what its purpose is applied in the enterprise. Employees were interested on it, and pledged to work responsibly with the company to implement GMP. There were many questions that were clarified by the supervisors and quality control inspectors. For eight weeks, trainings were conducted relevant, with slide shows and educational materials. At the end of this training, assessments were made for each of them, obtaining favorable results for the company.

After obtaining the results of the checklist that was held in the company in trainings held in Piggis, the emphasis is on personal hygiene, hand washing, the importance of giving notice if there is any suspicion of disease and a proper food peanut ling. They stressed that they must be fully trained for their work, they were trained about sanitary standards,

hygiene practices and the importance of developing optimal consumer products to consumers free of contaminants. They were also given information about the importance in quality cleaning equipment and the correct use of uniforms.

2.15. Diagnosis of Good Manufacturing Practices in equipment and utensils, disinfection and production operations.

Equipment and utensils in the company are used with cleaning materials suitable for disinfection. There should be an emphasis at the end of the day by washing all production machinery, it must be cleaned and disinfected at the end of the workday.

The following, discloses checklists for equipment and tools that allow the company to know the status of the machines by the management coordinator.

GMP DIAGNOSTIC CHECKLIST OF PIGGIS EQUIPMENT AND UTENSILS

1 .- The equipment and utensils:

- a. - Is it made from materials that do not react with food?
- b. –Is it easy to clean, disinfect and inspect?
- c. – Does it have devices to prevent contamination by lubricants, coolant, etc?
- d. - Are food contact surfaces removable?
- e. - Are the surfaces covered with food contact paint with any other type of paint material?
- f. – Are pipes leading hooks food inert, non-porous, waterproof and removable?
- g. –Does it allow the installation of equipment, continuous flow of material and personnel wise?

Section 11. Do the manifold vacuum equipment prevent the spread of dust in the environment?

Is there any program for cleaning, filter change and pre-filters?

Does it prevent dust return to the injectors an exhaust fan?

Section 12. Monitoring of equipment

12.1 .- What policy is taken for the installation of equipment?

12.2 .- Does the equipment or instrumentation equipment have a suitable operation control and maintenance?

12.3 .- What is the system for calibration control for the instruments of control in critical processes?

12.4 .- There are:

a.- List of equipment and instruments that require calibration, control and maintenance.

b- Plans and programs verifying calibration of equipment and instruments.

c- Listing of responsible for calibrations.

d- A list of qualified contractors.

e. - Methods of calibration and reference standards.

f. - Calibration records, identifying the team, working range, resulting from the calibration of instruments and responsible firm.

12.5 .- How plans, implements, monitors and recording prevent maintenance and connective? Are activities documented?

Source: BPM Piggis.

2.15.1 Points of possible solution

After tabulating the results of the checklist, it is important to know that:

Instructions should be developed for all cleaning machines directly to the pipe or hot water up to 40 ° depending on the equipment.

It emphasizes that you must hold the proper cleaning of equipment working to prevent the spread of bacteria.

It must acquire contact surfaces of stainless steel food.

To ensure that the hoses that supply water approved materials are the norm.

Provided hooks or renew reception of meat.

To ensure that the light fixture is right for workers.

To adopt a ventilation system to eliminate odors, steam and dust.

To provide drinking water to all areas of the plant.

It is convenient to keep better control indicating equipment maintenance, all materials have been used for repair.

They should look for a plan that minimizes water condensation on the ceiling, thus it prevents the formation on fungus that exists in one of the Piggis channels.

2.16 Conclusions

- The analysis of each of the points highlighted with GMP regulations will help the company to take into account the recommendations to be followed in order to achieve the certification of the GMP.
- The company needs to define changes that will benefit all employees. In each of the reference points that were described, it is targeted implementations or changes that the company must apply.
- It should be emphasized that it is appropriate to take precautionary Piggis release of vapor from the main mixing machine and mold being formed in one of the channels and becomes detrimental to production.
- Piggis should encourage to employees and workers about cooperation to maintain order and comply with the rules that have been imposed on the company to implementation of GMP.

CHAPTER 3. ECUADORIAN LEGISLATION FOR GOOD MANUFACTURING PRACTICES

3.1 Ecuadorian standard for GMP

On November 4, 2002, the government of Gustavo Noboa Bejarano by Executive Order 3253, approved the publication in the Official Gazette No. 696 about the Rules of Good Manufacturing Practices for processed foods. It can be mentioned that companies increased taking interest in improving the quality of production, promoting and to improve to its customers optimal products for consumption; as well as to ensure that regulations are made under health code stating that "It is important for the country to have updated standards for the food industry to develop foods clatching to standards of Good Manufacturing Practices" (Ministry of Public health of Ecuador) with this mention in his government it was restructured some points that now should be improved with much precision, remembering that Good Practices result on better quality for consumers, products free of contaminants and safe for consumption. Since this concept, it is emphasized more significant mentions health code and food regulations, informing each of the points with its most basic definitions.

As mentioned before, the following requirements of good manufacturing practices refers to the way in which the plant must be designed manufacturing production standards to follow, well location, all its internal and external infrastructure, the distribution of areas, the temperature that must be designed, the easiness they must have when assembling, with regard to supplies of water, ice, steam, water disposal channels liquids, equipment and utensils, personal hygiene, raw materials, etc.

Important requirements that should be supervised at all businesses, especially those that wish to apply the GMP, as they ensure the safety of workers and motivate their infrastructure is adequate in order to be well prepared for any food. These requirements have been mentioned in the course of the project.

It is also mentioned the way it should be processed foods with health standards that must be developed, from receiving raw materials to completion, and delivery.

All processes should be supported properly in documents.

Products must be packaged and labeled correctly in order to distinguish them in the environment.

It is also mentioned that the cleaning, the correct production process and the pollution-free products manufactured by capturing raw material will be adequately and properly recorded. It is the fundamental basis for the entire manufacturing process of the food distribution in order to ensure that sausages are products properly kept and healthy for human consumption.

The quality assurance is another important point mentioned by the rules of GMP, stresses that quality is the basic tool to ensure products to be reliable and safe for the customer. They mentioned that the receipt of raw material must be registered and patented as to the delivery of excellent products. The company must always be aware of the supervision and control of pests within its premises.

Finally, it is also mentioned the procedures for certification of GMP. It is important to know each of the points the company will have to comply by the time the inspector comes to the company and know about each specification during the process of preparation and implementation of GMP. The supervisor is responsible for granting certification to the factory.

The Rules of the GMP are very clear and concise and the company must take them into account in order to implement each of the titles. This regulation has articles that mention all the points along the development of this project. However it is important to mention this point because it has been taken as a reference along the projection of this work.

3.2. Checklist

3.2.1. Definition, payroll, and documents

To obtain the Certificate of Good Manufacturing Practices according to Decree 3253, it states that "the Ministry of Health is responsible for delegating the Ecuadorian System of Metrology, Standardization, Accreditation and Certification (MNAC)". (Ministry of Health of Ecuador). This agency is responsible for delegating inspectors who will conduct the visit and monitor everything related to technical and sanitary requirements.

The Ecuadorian System of Metrology, Standardization, Accreditation and Certification Inspector will coordinate the visit of Certification of Good Manufacturing Practices, coordinating directly with the overall quality of the company. The inspector carries a very comprehensive documentation which verifies that the company complies with the rules of GMP (ranked from 0 to 3 points MNAC), finding and verifying that the company is rated as excellent.

It is important to publicize the checklist that the supervisor brings to the company and its main concepts detailed below:

General Information .- This refers to the main features of the company, leading to start the detailed and comprehensive report to be presented for inspection.

3.2.1.1 General information about the food processing plant

1. Name / Social reason
2. Location
3. Category
4. Legally responsible
5. Technical Manager
6. Production Manager
7. Quality Control Manager
8. Operating Permission
9. The activities include food processing plant.
10. Type (s) of food processing / packaging or packaged / distributed
11. Reason for Inspection
12. Inspection
13. Date of inspection
14. Comments

3.2.1.2 Location and condition of facilities

This refers to the place and the infrastructure conditions that will be rated according to the distribution for the different processes that need to comply with the Decree of the GMP.

Facilities

- Minimal risk of contamination and alteration.
- The plant is located outside populated areas.
- In pockets of unhealthy.
- Clean outside areas free of insects, rodents, birds.
- Design and construction of the plant making it difficult for pests to enter.
- There are no cracks or holes in the outer walls of the plant.
- There are no unprotected openings.
- Surfaces and materials are inert and facilitate cleaning and disinfection.

3.2.1.3 Design and construction

- It provides protection to the internal areas of dust, insects, rodents, birds, other elements.
- It has facility for staff hygiene.

3.2.1.4 Areas

- The different areas are distributed along the process flow.
- Properly labeled.
- Allows the transference of materials.
- Allows staff movement.
- Allows an appropriate
 - Maintenance.
 - Cleaning.
 - Disinfection.
- The necessary hygiene is maintained in each area.
- Internal areas define and maintain their hygiene level.

- In critical areas, disinfection is applied.
- The operations are recorded in their:
 - Cleaning
 - Disinfection
- For critical areas, they are validated programs in their:
 - Cleaning
 - Disinfection
- On the ground and in the environment is there a good handle flammable?
- The storage area have flammable products:
 - Away from the plant.
 - Along with the plant.
- The construction of the storage area is adequate.
- It keeps sufficiently ventilation, clean and in good condition.
- The pattern of movement of employees and equipment does not allow cross-contamination of products.
- The plant has a physical or operational separation of incompatible operations where there is cross-contamination.

3.2.1.5 Floors

- It is constructed with materials that are
 - Resistant
 - Smooth
 - Waterproof
 - Easy to clean
- In good conditions.
- The inclination allows adequate drainage to facilitate cleaning.

3.2.1.6 Walls

- With washable materials.
- Smooth.
- Waterproof.
- Not shed particles.

- Light-colored.
- Clean.
- In good conditions.

3.2.1.7. Roofs

- In perfect cleaning conditions.
- Flat.
- Washable.
- Waterproof.
- You have suspended ceilings.
- The false ceilings material do not allow the accumulation of dirt.
- Not shed particles.
- Facilitate the maintenance and cleaning.

3.2.1.8. Windows, doors and other openings

- Materials that are built do not allow contamination
- Easy to clean.
- Not emit particulate material.
- Good conditions.
- Structures allow cleaning and dust removal.
- In the glass windows, saved precautions of breaking it.
- The doors are smooth and non-absorbent.
- The identified critical areas are communicated directly to the outside.
- In the critical areas there are two systems or two-door service.
- There are proofing systems of insects, rodents and other.

3.2.1.9 Stairs, elevators, additional structures

- The material is resistant.
- These items are washable and easy to clean.
- There are materials that pose no risk of contamination in the food.
- They are located so as not to impede the regular flow of the production process.
- There are additional structures on the production lines.
- Precautions are taken so that these items do not contaminate food.

3.2.1.10 Electrical and water systems

- The electrical network is:

Open

Closed

- Terminals are attached to walls and ceilings.
- There are written procedures for cleaning the grid and its terminals.
- These procedures are completed.
- There are corresponding records.
- They are identified with a different color flow lines:

Drinkable water

No drinkable water

Steam

Fuel

Compressed air

Wasted water

- There are visible signs to identify the different flow lines.

3.2.1.11 Lighting

- The lighting in different areas is:

Natural

Artificial

Natural-artificial

- The intensity of the lighting is adequate to ensure that processes and inspection activities are carried out effectively.

- The lighting does not change the color of the products.
- There are artificial light sources on the processing and packaging lines.
- To store the necessary safeguards in case of breakage of these devices.
- The accessories provide artificial light:
 - Are clean
 - Are protected
 - In good condition

3.2.1.12 Ventilation

- The ventilation system available to the plant is:
 - Natural with appropriate filters
 - Mechanical
 - Direct
 - Indirect
- The (old) system (s) used provides a suitable climate comfort.
- The (old) system (s) used allows to prevent condensation of vapor, dust ingress, etc.
- They are isolated so as to avoid the passage of air from a contaminated area to a clean area.
- There is a written schedule for cleaning system (s) of ventilation.
- Records of compliance with the cleanup program.
- There are written procedures for maintenance, cleaning and changing filters on fans or air conditioners.
- Records of application of these procedures.
- In the microbiologically sensitive areas, positive air pressure remains.
- Use compressed air or air cooling air directly in contact with food.

3.2.1.13 Temperature and humidity

- That mechanisms used to control temperature and humidity.

3.2.1.14 Toilets, showers, changing rooms

- There are sufficient.

- They are separated by gender.
- They are communicated directly to the production areas.
- Floors, walls, doors, windows are clean and in good condition.
- They have adequate ventilation.
- These services are in perfect conditions of cleanliness and organization.
- They are equipped with:
 - Liquid soap
 - Towels
 - Automatic equipment for drying
 - Covered containers for the used material
- Water for washing hands is common.
- The basins are located at strategic sites in relation to the production area.
- There are records of the assessment of effectiveness of disinfectants used.
- There are visible notices alluding to the requirement to wash hands after using the toilet and before resumption of work.

3.2.1.15. Water Supply

- The water supply to the plant is:
 - Municipal network
 - Deep Well
- The deep well or cistern is located near the production area.
- Water controls are performed:
 - Physical chemical
 - Microbiological
- There are records of these checks.
- Water used in the production process meets the requirements of the NTE INEN.
- The water storage facilities are properly designed, constructed and maintained to prevent contamination.
- Chemical treatment of water is permanently monitored.
- The distribution system for different processes is suitable.
- The volume and water pressure are required for production processes.

- Drinkable water systems and drinking are clearly identified.
- There are no interconnections between potable water supplies and unsafe ones.
- The water system is in perfect hygienic conditions.
- They perform cleaning and regular maintenance of the systems.
- There are records of these procedures.

3.2.1.16. Steam Supply

- Steam is used in the production process.
- Food grade chemicals.
- If this second case is applied, it should be described the products used.
- If the production process requires the head of steam, it should contact with food available filter systems for the passage of steam.
- It provides automatic filter control.
- There are records of these checks.

3.2.1.17. Disposal of waste

- The plant has a waste disposal system and waste:
 - Liquid
 - Solid
 - Gaseous
- The disposal of sewage and industrial effluent complies with current regulations.
- The drainage and sewage disposal systems are equipped with appropriate traps and vents.
- There are specific areas for handling and storage of waste prior to collection of the establishment.
- Drains and waste disposal systems comply with existing national rules.

- Solid waste is properly collected.
- The plant has adequate facilities and equipment and well maintained for the storage of waste and inedible material.
- These facilities are designed to prevent contamination of products and the environment.
- Containers used for waste and inedible material are clearly identified and plugged.
- There is a particular system for the collection and disposal of toxic substances.
- Waste containers are removed and cleaned and disinfected with an appropriate frequency to minimize the potential for contamination.
- Waste areas are remote from the production area.
- There is an adequate system of collection, storage, protection and disposal to avoid contamination.
- The handling, storage and collection of waste prevents the generation of odors and pests shelter.

3.2.2. Equipment and Utensils

The main basic working tools for the development of products within a workplace also correspond to the type of production process that takes place in the plant.

- Equipment is the kind of production process that takes place at the processing plant.
- Designed, constructed and installed so as to know process requirements.
- They are located along the forward process flow.
- Teams are unique to each area.
- The materials that are built equipment and utensils are:

Non-toxic

Resistant

Inert

Not shed particles

- Easy to clean
- Easy to disinfect
- They resist the cleaning and disinfecting agents
- They are designed, constructed and installed to prevent contamination during operations.
- Where necessary, the team must escape or vent to the outside to prevent excessive condensation.
- Operators have written instructions for handling each team.
- Next to each machine.
- Specific instructions are given on precautions in the handling of equipment.
- Equipment and utensils used for handling inedible material not used for handling inedible products are clearly identified .
- The plant has a preventive maintenance program to ensure the effective operation of the equipment.
- Inspection of equipment, adjustment and replacement parts are based on the manufacturer's manual or provider thereof.
- Teams are kept in conditions that prevent the possibility of contamination:

Physics

Chemistry

Biological

- For used equipment calibration reference standards.
- The service for the calibration is: Own
- In this second case, a written contract is required.
- It records the frequency of calibration.

Cleaning, disinfection and maintenance.

- There are programs written for cleaning.
- Disinfection.
- Maintenance of equipment and utensils.
- Evaluate the effectiveness of programs.
- Describe the substances used for disinfection of:

Equipment

Utensils

- It is validated the effectiveness of these substances.
- There are records of these validations.
- Determine the incompatibility of these substances in processed products.
- The concentration used and the contact time is adequate.
- Frequency done
- Disinfection
- It has programs written about the equipment maintenance.
- Frequency in performing.
- There are records of equipment maintenance.

- Substances used for lubrication of equipment and utensils:
- There are lubrication procedures.

Other Accessories

- Surfaces in direct contact with food are located so as not to cause any diversion in the flow of the production process.
- Materials made are:

Resistant to cleaning and disinfecting agents

- No corrosive
- Non-absorbent
- Not shed particles
- Non-toxic
- Easy to clean
- Easy to disinfect
- System (s) used (s) for cleaning
- Disinfection
- Maintenance
- Frequency with it is done: Cleaning
- Disinfection
- Maintenance
- Substances used for cleaning
- Disinfection
- Maintenance

- It is validated the effectiveness of these substances
- These validations are registered.
- The pipes for the conveyance of raw materials, semi-finished and finished products are:

Resistant materials

Inert

Nonporous

Waterproof

- Easily removable when cleaning.
- System used for cleaning and disinfection of the pipes fixed.
- It is validated the effectiveness of this system.
- Substances used this cleaning and disinfecting
- It is validated the effectiveness of these substances.
- It has been determined the incompatibility of these materials with products moving through the pipes.

3.2.3 Staff

The group of people working in the product development within the company, should be properly trained to use work teams. They have rights and duties that must comply with and abide within the workplace.

Education

- It has defined the requirements to be known by the staff for each work area.
- It has programs of enabling and training on GMP

Proper

External

- It has staff evaluation programs
- There is a program or procedure for new staff related with work, tasks and responsibilities to be assumed.
- Initial training is reinforced and updated periodically.

Health Status

- Staff working at the plant have valid health card.
- Apply preventive medicine programs for staff.
- How often.
- Records of the implementation.
- There is a record of accidents.
- There are specific groups for emergency situations.

Firefighting groups

First aid groups

- Staff who has infectious diseases or skin lesions, is temporarily isolated.
- There is a record of these situations.
- If another breakout occurs, the causes are investigated.
- In case of any reincidence presented, it will be investigated the main causes of the contagious disease.
- Identified causes are registered.

Hygiene and protective measures

- It has been written standards of cleanliness and hygiene for staff.

- Staff knows the rules.
- The company provides adequate uniforms for staff.
- From colors that allow to display their cleaning.
- Perfect cleanliness of uniforms.
- The uniform washing is:
 - In the plant itself
 - External Service
- The type of process requires the use of gloves.
- The made material does not generate any pollution.
- It restricts the movement of staff uniforms outside work areas.
- The type of shoes that uses the plant personnel is adequate.
- There are instructions posted in conspicuous places for staff.
- The need to properly wash their hands before starting work.
- Each time they use health services.
- After handling any material or object that can contaminate food.
- There is the need to wash hands before putting on the gloves.
- The type of process requires the disinfection of hands.
- What substances are used for:
 - Hand washing
 - Hand sanitizer
- They validate the effectiveness of the substances used for disinfection.
- Staff wears:
 - Caps
 - Masks
 - Washables
 - Disposables
 - Clean
 - In good state

Personal behavior

- There are signs and warnings about the clear instructions on the prohibition of: smoking or eating in work areas.

- Visitors use clothes in the production area.
- Use jewelry.
- Use makeup.
- Signaling systems are used.

For the evacuation of the staff.

- To differentiate the operations.
- There are written safety rules.
- Staff knows the rules.
- It has full safety equipment and appropriate:

Fire Extinguishers.

Hydrate.

Doors or escape routes.

Others (Alarm, sprinkle valves)

- Under optimum conditions for usage.
- Appropriately distributed.
- Staff is trained to handle these equipment.

3.2.4. Raw materials and supplies

These are the most important elements for the manufacture and processing of the sausages. They must also be governed by a strict control of income within the company.

- The suppliers of raw materials and inputs are certified.
- Are these certificates registered?
- You have written requirements for suppliers of raw materials and inputs.
- Written specifications for each raw material.

- These specifications are part of the official regulations.
- Inspects and classifies the raw materials during their reception.
- Conducts safety and quality of raw materials.
- How often.
- There are records of these tests.
- It has established a record of compliance with specifications when:
 - There is a change in the provider.
 - There is a change in the origin of the ingredients in a known supplier.
- The laboratory testing reveals contradiction to the certificate of analysis. }
- Each batch of raw material received is analyzed with a sampling plan.
- The recorded test results.
- In order to storage the raw material, it is considered the nature of each.
- There are special conditions that require raw materials.
- They classify commodities according to its use.
- They are properly identified:
 - In its external packaging (secondary)
 - In its internal packaging (primary)
- They consist expiration dates (if applicable).
- Lack of raw material altered or unfit for human consumption.
- Containers / packaging / containers / packaging materials:
 - Aren't susceptible to deterioration.
 - Do not emit substances to raw materials in contact.
 - Are easy for destruction or cleaning.
- A system for effective rotation of the lots stored.
- There are environmental conditions in storage areas:
 - Cleaning
 - Temperature
 - Humidity
 - Ventilation
 - Lighting
- These areas are separated from the production ones.

- It has a definite policy for the refunds for raw materials that are outside the specifications.
- Record of returns is kept.
- It has a written procedure for raw materials to enter areas of high risk in contamination.
- The melting of raw materials makes it suitable conditions:
 - Time
 - Temperature
 - Other
- Raw materials may not be refrozen.
- Food additives are stored being authorized for the use in food manufacturing.
- They are properly labeled.
- Its life span is registered.

Water

- Water used as raw material, is it safe?
- Its specifications correspond to the standard established by INEN.
- Evaluate the parameters:
 - Physical chemical
 - Microbiological
- How often are these assessments recorded?
- Treatment System used for drinking water:
 - It monitors the water treatment
 - How often
 - Ice is made from potable water
 - Ice is produced, handled and stored under aseptic conditions
 - Check ice safety

- Controls to apply
- Record these controls
- Steam for contact with food is generated from water
- The chemicals used to treat boiled water are approved by INEN and other recognized international organizations.
- Cleaning and washing of raw materials. Equipment and materials are cleaned with water:

Drinkable

Treated

- Reuse of reclaimed water production processes.
- It has a specific storage system for this water.
- It performs chemical and microbiological control of this water.
- How often.
- There is record of these controls.
- The results of the controls ensure the fitness for use.
- The distribution of this water is separated and identified.

3.2.5 Production Operations

It consists in all the activities that take place within the company. Step by step, each of the production processes must comply with the development of the products and what to include within it.

- There is a business planning manufacturing / production.
- There are written specifications for the manufacture or production process.

- The manufacturing processes / production are validated.
- The areas are suitable for volume production set.
- The cleanliness and proper functioning of equipment before beginning production are checked.
- The documents detail the production clearly.
- They are commonly used by operators.
- They know about the written procedures at each stage of the production process.
- The staff in this area knows about their roles, and the risks and errors that may occur.
- Are production areas spacious enough?
- Are the areas properly distributed?

The equipment and machinery.

The raw materials used.

The auxiliary material.

- Areas are defined according to the nature of the products processed.
- Have precautions been taken to avoid cross contamination?
- Are critical points well determined in the process?
- The critical control points.
- The cables and hoses that are part of the teams have an appropriate location.
- The liquid supply systems have filtration.
- They are commonly used.
- The windows of the production areas are closed.

- The windows to the hallways are adequately protected.
- With insect mesh.
- The following environmental conditions are registered:

The cleaning process according to the established procedures.

Order

Ventilation

Humidity

Temperature

Overpressure

- Control devices are in good working order.
- In production areas, during the development of activities, they are available from the production process.

They are used effectively.

Checks are recorded.

Precautions are taken to avoid confusion and contamination risks.

- Use of proper protection for the handling of raw materials is susceptible.
- There are written instructions for the manufacture of each product.
- Each operation is guaranteed with the signature of the person performing the task.
- Each major step of the production is recorded in a document.
- The detected abnormalities are reported:

To the production technical manager.

There are records in the history of the lot.

Corrective actions are taken in each case.

These corrective actions are recorded.

- It has procedures and precautions to avoid cross contamination.

3.2.6 Packaging, labeling, and packaging

It is the shape and the presentation of the products which will be introduced to the market.

- Areas for packaging and labeling are separated.
- They are clearly identified.
- Staff in these areas knows the risks of the potential cross-contamination.
- It makes the filling / packaging of the finished product as quickly as possible to avoid contamination.
- The filling / packaging know about the requirements of the existing standards.
- It has a written procedure for the packaging line.
- Containers and packaging are approved by quality control.
- This approval is in writing.
- Approval labels are placed.
- Track in the packages, labels and packaging leftovers are kept.
- It has written procedures for cleaning and sterilization of packages that will be reused.
- These procedures are validated.
- Controls are carried out during the process of filling and packaging.
- It records the results of these controls.

- These results are part of the history of the lot.
- It has qualified suppliers of packaging.
- It ensures the suitability of packaging material.
- How to verify compliance.
- Finished products are packaged and identified according to its status:

Quarantine

Approved

Rejected

- The information contained in the labels knows the regulatory requirements.
- What destination labels are given to excess: No mark lot number and expiration date
- Marking a lot number and an expiration date.
- The consolidated orders end labeling.
- This operation is recorded.
- Part of the history of the product lot.

3.2.7 Storage, distribution and transport

- There are programs written for:
Cleanliness and hygiene of the store or warehouse.
- Pest Control.
- How often.
- The environmental conditions are well appropriated in order to ensure the stability of the product.
- It keeps special temperature and humidity required by its nature.
- These conditions are verified.
- How often.

- There are checks.

Products

- There are specific areas:

Quarantine

Approved Products

Rejected products

Market Returns

- Each area has shelves or pallets to store the food.
- They are separated conveniently from:
 - Floor (minimum 10 cm.)
 - Walls
- A procedure to ensure the first thing gets in also gets out (FIFO).
- Foods are properly identified and stored indicating its status.
- There is a store exclusively for market returns.
- It has written procedures for returns.
- Transport of raw materials, semi finished and finished products meet appropriate sanitation and hygiene conditions.
- They are constructed of materials that pose no threat to the safety and food quality.
- These materials allow easy cleaning of the vehicle.
- The conditions of temperature and humidity ensure quality and safety of each product carrying.
- There are vehicles used exclusively for transporting raw materials or food for human consumption.
- There are programs written for the cleaning of vehicles.
- How often is the cleaning applied?

3.2.8 Quality assurance and control

It is the main tool for the entire manufacturing process as it ensures that the product is for optimal consumption for the customer. (Ecuadorian System of Metrology, Standardization, Accreditation and Certification (MNAC)).

- The plant has an assurance department and quality control.

- The quality control laboratory has its proper equipment to perform all relevant tests.
- All equipment is calibrated
- How often is the calibration made?
- Calibrations are registered.
- This service is:
 - Own
 - By a third person.
- There is a written contract for the service by a third person.
- Methods / analytical tests are validated.
- It has written procedures for sampling:
 - Raw materials.
 - Pack and packaging materials.
 - Work in process.
 - Finished products.
- The batch records are analyzed:
 - Physical-chemical testing.
 - Microbiological testing.
- There are records of the changes in the system of quality control.
- Tests are performed to determine water quality.
- Are the changes recorded in the water system?
- It has a procedure for monitoring.
- Assurance and quality control
 - It ensures that the quality system work permanently.
 - Regular communication with suppliers.
 - They monitor each batch produced
 - It maintains product samples.
 - Secure storage conditions.
 - It performs stability testing of finished products.
 - It oversees against samples.
 - It checks returned products.
 - They inform the production of abnormal operations.

- Approved / rejects products, materials, procedures, etc. according to specifications.
- These functions are written and recorded.
- The Department of assurance and quality control features:
 - Specifications of raw materials.
 - Specifications of packaging materials.
 - Procedures for sampling.
 - Manuals and procedures for use of equipment.
 - Control Protocols for:
 - Raw materials.
 - Packs and packaging material.
 - Work in process.
 - Finished products.
 - Control water.
 - Control of areas for controlled atmosphere.
 - Safety.
 - Program and registration of equipment calibration.
 - Policy and stability trials register.
 - Supplier Registration.
 - Index of storage and handling of raw materials.
 - Chip handling and storage of finished products.
 - Validation procedures.
 - Procedures care claims and returns.
 - Policy / procedure for product recalls.
 - It has quarantine labels, approval and rejection.
 - The working papers are filed.
 - The primary records are paginated and numbered.
 - There are records of test results will each successive:
 - Raw material
 - Finished product
 - Protocols are issued in different areas of the department compiling results of analysis / partial tests.

- The protocols and documents have a properly filed control.
- How long?
- They are suitable for areas to make the controls:
 - Physical chemistry.
 - Microbiological.
 - In process.
 - Others
- Procedures for the treatment of waste analysis.
- The equipment used is adapted to the requirements of the product.
- The teams have:
 - Technical Manuals.
 - Cards with technical references.
 - Instructions for maintenance.
 - Registration for the calibration or the maintenance.
- They are properly monitored.
- The reagents are:
 - Properly located.
 - Conveniently labeled.
 - Prepared according to standardized methods / written.
 - Properly controlled in quality and effectiveness.
 - Properly stored.
- Control techniques include:
 - Properly set.
 - Written in an understandable.
 - Commonly used.
 - Properly filed.
 - Written without erasures.
- It is routinely monitored.
- Raw materials.
- The container and packaging materials.
- Items in process.

- Finished products:
 - Records of batches analyzed.
 - Physicochemical parameters.
 - Microbiological parameters.
- These controls are part of the history in each batch of finished products.
- It periodically checks if there is an effectiveness of the quality assurance and control.
- By order inspections.
- Using external audits
- Periodic reassessments are conducted of:
 - Raw materials
- Packs and packaging material
- Reagents
- Managed under separate rules
- Properly maintained
- Prepared according to written procedures
- Registered uses

Complete verification forms GMP enforcement according to the official system of food to be found in the Annex of this project.

3.3 Conclusions

- The GMP regulations are very clear and precise. They do not have any requirements that go beyond what a company can know, and that offers reliable, quality and safe products.
- Compliance requirements are necessary today, as the product manufactured under strict quality standards allow the customer to consume great products.
- The quality assurance allows us to know that it is very important to manage the best product distribution.

- Inspections to be conducted in the company must comply with all requirements for certification.
- The collaboration of all Piggi's staff is a responsibility and necessary task that must be met, getting as a result the needed certification.

CHAPTER 4.PERUVIAN MARKET ANALYSIS TO EXPORT GOODS

4.1 Legal requirements to export goods from Ecuador to the North of Peru

I will begin by publicizing the concept of export, being: "Any goods or services sent to another part of the world for commercial purposes. The export is the legitimate traffic of goods and / or national services of a country. " (Wikipedia)

According to foreign trade rules, in order to make the exports of a product, every business must know the following important requirements:

There is a trade agreement between the parties, the distributor and the exporter company PIGGIS, they both must have as a reference point a wholesale distributor of white sausages that will be in charge of introducing the product to the market. By agreeing to the marketing, it will be determined the number of containers to be sent every week or every month. The introduction to the market price should remain relatively for a period of six months to be able to acquire acceptance and the market demand.

As an exporting company, Piggis must strictly comply with quality standards of product required by the GMP, as the negotiation and agreement will be the point of reference in order to maintain the excellent quality of the white sausages. Piggis exporting company must register in a website on the National Customs Service of Ecuador.

The Ecuadorian Customs Corporation requires to all exporters to submit the following documents: (Customs in Ecuador)

The Unique Export Customs Declaration

The exporter's RUC

Original Commercial Invoice

Prior Authorizations (when needed)

Certificate of Origin

Register as an exporter in the National Customs Service

Transport document.

4.1.1 Pre-shipment procedure

In all exports, it is necessary to take the advice of an entrenched customs agent because he is the person who takes care directly of every important diligence with Customs in Ecuador. The adviser is responsible for processing and submitting all documentation in Customs in order to fill and obtain the approval document for export. The visit strengthened the customs agent; Rosa Cumbe actualized us about the procedure for exporting.

As a first requirement, it is the presentation of the Order of loading and revealing e-mail to the National Customs of Ecuador, who intends to export and complete the form requesting the name of the exporter, exporting product details, the quantity, weight and a provisional bill until accepted. Once the National Customs Service of Ecuador accepts, the shipping order will proceed to move all goods to the Customs area.

4.1.2 Attached documents and post-shipment stage

Piggis, as a company that wishes to export, must submit to the Customs Bill of lading (BL), which is a document or a contract of carriage when the goods will be sent by ship. The BL has all the necessary information about the container, its name, capacity, quantity shipped, number of pallets or boxes, net weight, gross weight, all properly identified and recorded in documents. The company can transport all goods by road, as far as there are refrigerated containers, such as Evergreen and Maersk Sea Land.

The payment is 30% deposit and the balance is on submission of the Bill of Lading that the product can be sent to Peru. In the case of exports, FOB price to be paid until the merchandise is shipped in the container and placed aboard the ship. The CIF value contains the merchandise when it is already prepaid, and the insurance cover.

To prepare the goods for shipment, it usually requests a deposit of 30%. Once the export has been accepted, the Piggis Company has fifteen days to regularize all exports.

National Customs Service requires to proceed in order to submit the following documents:

- Export Customs Declaration
- Shipping Order
- Original final commercial invoice
- Tickets
- Original Prior Authorizations

The moment the container is in the export process, it must be submitted a copy of the Bill of Lading to collect the balance accordingly. When the products arrive to Peru, the client is directly responsible to carry out all Customs clearance procedures in accordance with the laws of this country.

Foreign trade has exceeded the boundaries of different countries. One of the great advantages of our country is the acting possibility in the national production to other places. With the certification of GMP and the export procedure, Piggis is opening new markets, is expanding its production and allowing the country to be recognized for its excellent quality products. The export of white sausage by Piggis Company will certainly have wide acceptance in Peru.

Tax Tariff

The Tariff heading is according to the National Integrated Tariff Customs Service. The number of Regional Sub party with which should be exported is:

Sub-heading Details

16010000 Sausages and similar products of meat, offal or blood.

Chart # 13 Tariffs

Product Code (TNAN)	0
Antidumping	0%
Advalorem	30%
FDI	0.5%
ICE	0%
IVA	12%
Safeguarding Percentage.....	0%
Value safeguard	
Safeguarding for Value Application	
Consolidated ceiling	30%
ICE Increase	0%
Assigned to Specific Right	CER
Measurement Unit Gross Kilogram (KG)	
Order 1458. R.O.	
Executive Remarks	489s 16/12/2008
it's Perishable product	NO

Font: CAE

4.2 Standards ISO 22000

All food companies have any contamination problem in the products. That is the result of poor hygiene in the formulation. ISO 22000 provides a solution to these problems as it becomes an opportunity to achieve a quality product. The following will highlight the importance of ISO 22000 standards for production. ISO 22000 is "an international

standard based on the principles of Hazard Analysis and Critical Control Point (HACCP). (Hispanyan, Services)

This International Standard covers the principles of the Hazard Analysis Critical Control Point (HACCP) and the proper procedures to implement this plan in the future as the company is projected to reach the certification of ISO 9001. ISO 22000 is projected as an image and ensures compliance with safety regulations for food. This rule permits to export in a safe and guaranteed way to consumers. The application of this internationally recognized standard is applicable to the food system worldwide.

It is important to know the necessary rules to achieve ISO 22000. Piggis management system achieves food security, according to information gathered from the “general operating ISO 22000, Dr. Byron Cajas Piggis management coordinator” (Cajas)

- It must be planned, designed, implemented, operated and maintained a system of food safety management that provides insurance products to consumers.
- Demonstrate compliance with applicable standards and legal requirements on food safety.
- Analyze customer requirements and maintain adequate communication with them.
- They ensure that the hazards that may affect food are identified and brought to a process of evaluation and control.
- It is important for the production manager to immediately notify the auditors of quality everything related to food safety.
- You must disclose all information that relates to the development of the information.
- It must make regular assessments and update the food safety system.

- To close the gap between business management and safety management.
- It allows easy HACCP certification.
- It is imperative to present the requirements that include, among others sub-programs:
 - Facilities
 - Conditions of Production Equipment
 - Raw Material Specifications
 - Procedures and Plans of cleaning and sanitizing
 - Control for the Storage and Use of Chemicals for Cleaning
 - Personal Hygiene
 - Pest Control
 - Quality Control Systems for Packaging
 - Conditions of Reception, Storage and Food Distribution
 - Traceability of Raw Materials and Finished Products
 - Research and System Feedback and consumer complaints
 - Labeling Specifications
 - Training System Employees' .

Dr. Cajas, said: "The implementation of ISO 22000 can be done in combination with other standards of food safety management, completing the gap between GMP, HACCP and ISO 9000". (Cajas)

Piggis projects the implementation of the GMP and HACCP system. It is therefore essential to make public in this project as it goes along with the importance of that certification that can enhance business opportunities and access to new markets, as far as

the company wants to project. It is important to build on that rule because of its requirements for food, it is wicked fit for human consumption.

4.3. Analysis of the Peruvian market to export

The Peruvian market has shown it is open to imports, and its growth rate actually allows Piggis to export their products. There are countries like Colombia and the U.S. interested in investing in Peru because of the economic growth that it has proven. Industrialization has been growing. Nonetheless, it has begun to give priority to improving the growth industry in the main cities of Peru. This country wants to promote foreign trade in every way, opening doors to large-scale companies interested in investing directly in the country.

The Peruvian market points to the export of Piggis white sausage because it is located very closed to our province. In addition, the company must be very careful in knowing all requirements for the export of products. GMPs are the major international practice for export. The Peruvian economy has shown a significant growth in the private investment. It also has a good level of economic growth, as well as permitting investment from other countries interested in increasing incomes. It has resulted in the generation of jobs, but with low salaries.

The Peruvian economy grows at 8.78%, according to the statistical report of the IMF, becoming a very strong percentage, rebounding from a crisis that in previous years has shown low rates. Peru is open to all types of investments that benefit the economy of the country. All foreign investors in Peru have the same rights as national people. "To sign a contract with the state legal stability, which grants tax benefits customs tax for a 10 year period". (Galindo)

4.3.1 Peruvian Market

The demand study was been performed using a historical analysis of consumption of sausages in Peru, based on the fact that this country has a deficit of meat production from cattle. There are also direct distributor nations of beef in kilos and raw material for

sausage factories from Argentina, Brazil and Bolivia, supplying cattle of this country at different prices, becoming a product for direct consumption that is not accessible to all Peruvian people because of its costs. Peru is an excellent producer of poultry meat.

In the following table, it will be shown the major suppliers of beef countries in the Peruvian market.

Chart # 14 Main origin countries of the meat sector in Peru

COUNTRIES	PERCENTAGE
Argentina	34%
Brazil	23%
Bolivia	6%
Chile	4%
Rest of countries	12%
Uruguay	9%
U S A	12%

Source: Office of Peru

Prepared by: Author

Graphic # 2 Map of Latin America



Source: Map of Latin America

4.3.2 Historical Demand

Imports

The majority of the imports from Peru are directed to products such as: "crude oil, heavy oil, durum wheat, yellow flint corn, cakes, drugs, soybean oil" (PROEXPORT). Therefore, it reflects an important market niche for the export of sausages to the northern border with Ecuador. It is important to note that imports in Peru are much lower than exports.

Peruvian National Production

The Peruvian production of beef is in deficit, although it has a major poultry production. According to a study by the IDB, the industrialization of meat has not increased in the last 5 years. The low consumption of meat in this country has meant that beef imports will not grow.

Then it will release a study of the national projected demand in Peru, tons of sausages and its derivatives, which determines the extent of meeting the needs of food resources according to population and distribution of these foods. Next, it will be revealed a table that shows that the 30% of the population grows to 0.20 grams of daily sausage..

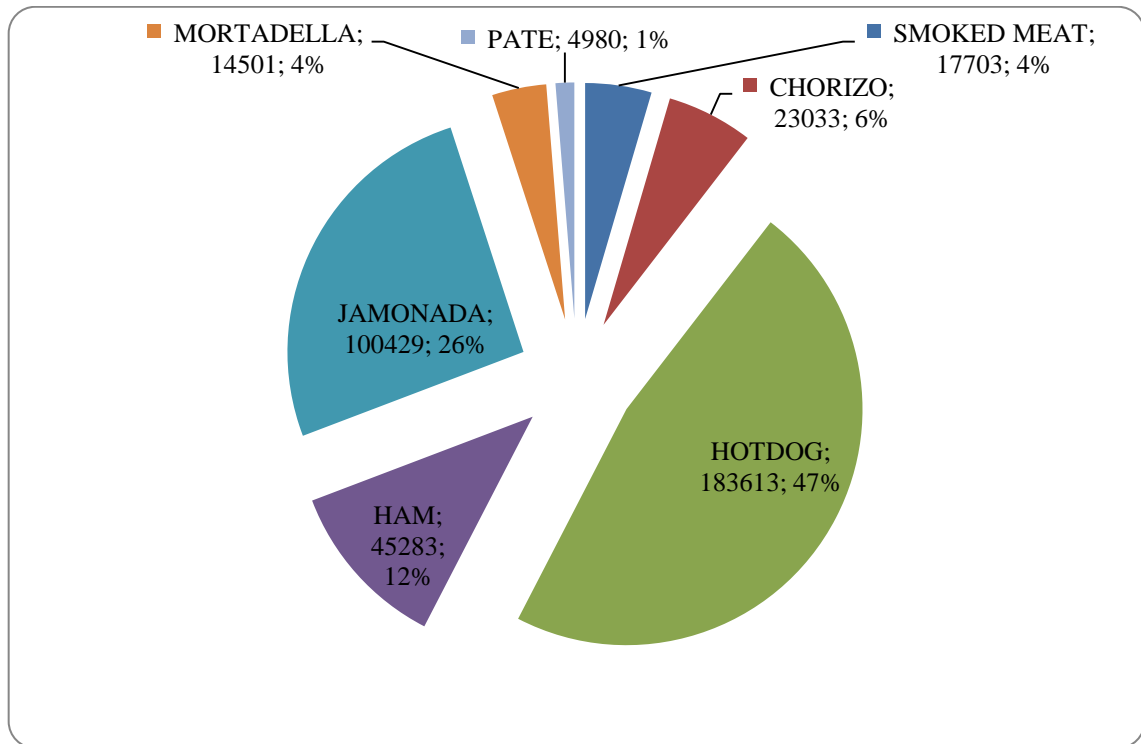
Chart # 15 National projected demand of meat products in tons-Peru

YEARS	MEAT	CHORIZO	HOTDOG	HAM	JAMONADA	MORTADELLA	PATE
2005	2080	2497	20087	5478	11990	1844	516
2006	2223	2742	22021	5809	12776	1920	575
2007	2370	2998	24023	6139	13561	1996	637
2008	2521	3267	26094	6469	14347	2072	704
2009	2676	3547	28233	6799	15133	2147	774
2010	2835	3839	30440	7129	15918	2223	848
2011	2998	4143	32715	7460	16704	2299	926
TOTAL	17703	23033	183613	45283	100429	14501	4980

Source: Sáenz Alaba Sausages

Prepared Saenz Alaba Sausages

Graphic # 3 National projected demand of meat products in tons – Peru



Source: Sáenz Sausages

Prepared by: Author

As the chart indicates, the growth is minimum, the demand of meat has been 4% for 5 years. Peru is deficient in cattle due to the bid price is higher for the income levels of the population. In turn, the most demanded product in the Peruvian market is the sausage, better known as hot-dog, with a rate of 47% of demand. The market demand for this product is very important for the Peruvian market analysis, even more if there are plans to export to that country.

Analysis of Supply

Piggis Ecuadorian supply is minimal for the large unmet demand that exists in Peru.

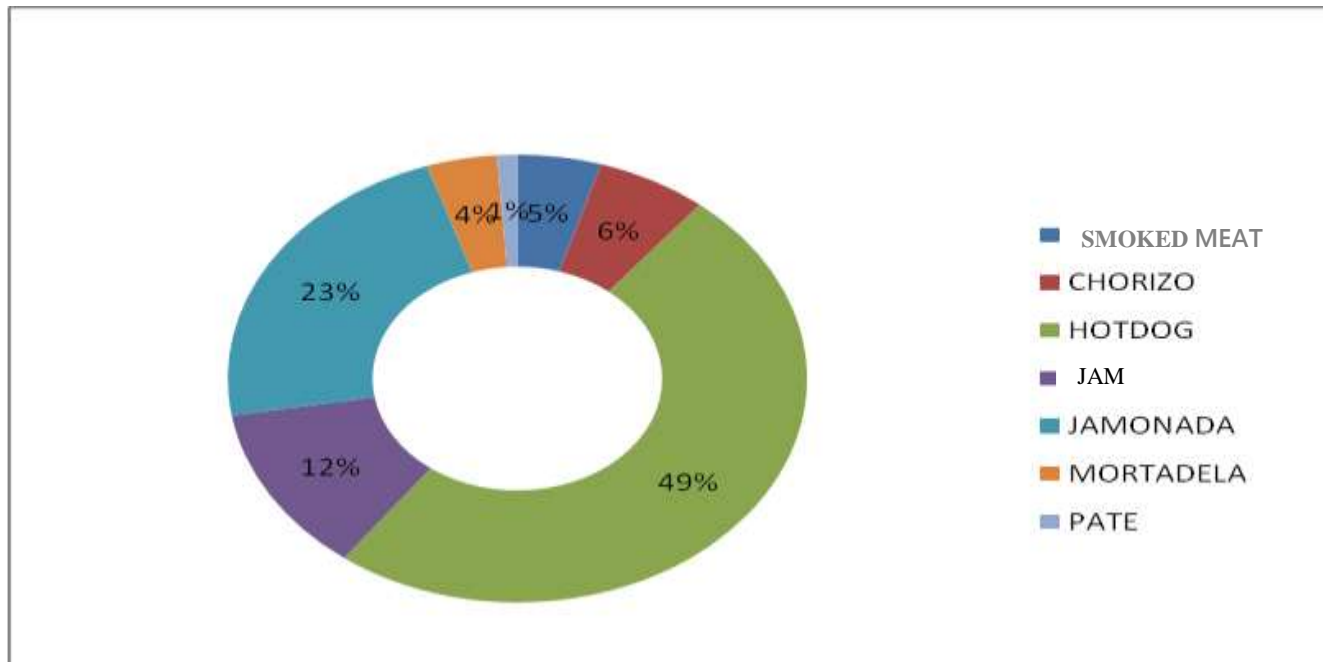
Chart # 16 2005-2011 Projected National Offer of Meat products tons-Peru

YEARS	MEAT	CHORIZO	HOTDOG	HAM	JAMONADA	MORTADELLA	PATE
2005	1495	1804	14515	3968	7824	1342	315
2006	1594	1982	15932	4206	8164	1397	351
2007	1695	2168	17402	4444	8479	1452	390
2008	1798	2362	18923	4682	8768	1507	431
2009	1904	2566	20497	4920	9032	1563	475
2010	2012	2778	22122	5158	9271	1618	521
2011	2122	2999	23800	5396	9484	1673	570
TOTAL	12620	16659	133191	32774	61022	10552	3053

Source: Saenz Alaba Sausages

Prepared:Saenz Alaba Sausages

Graphic # 4 National projected offer of meat products



Source: Sáenz Alaba Sausages

Preparation: Author

The supply of the Piggis sausages gets about 130 TM, being negligible compared to the 100,000 tons existing in the demand in Peru.

Projected national unmet demand in tons Peru

The following table shows the Peruvian unmet demand in sausages, proving that there is an interesting niche market for exports from Ecuador because of its location and quality of the offered product.

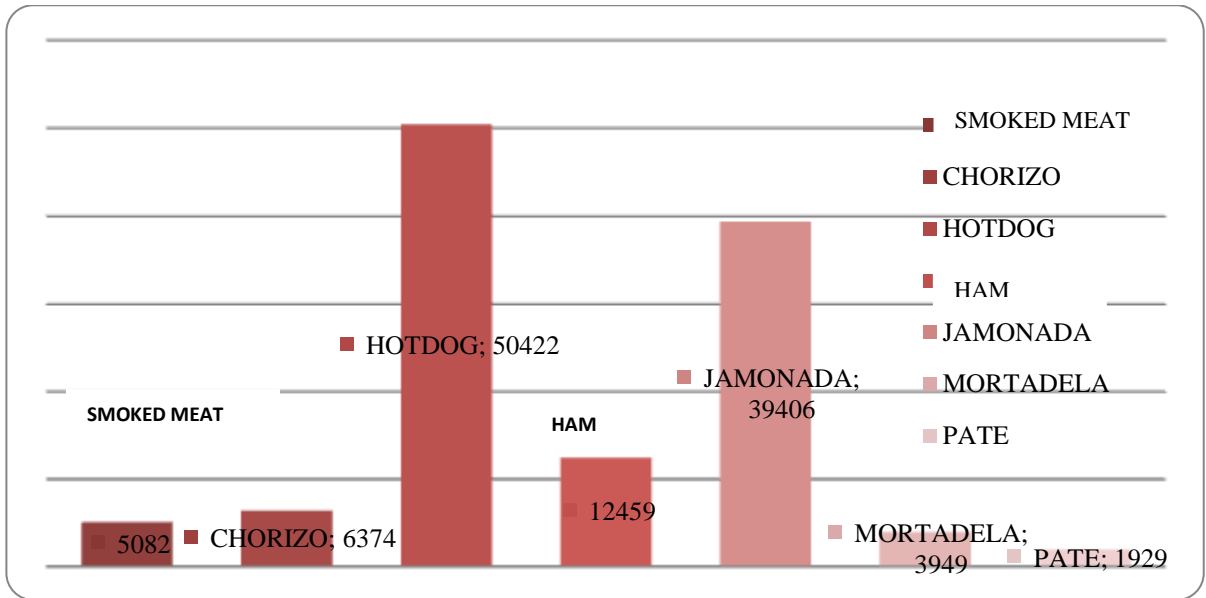
Chart # 17 Unsatisfied demand of Meat products in Peru

YEARS	MEAT	CHORIZO	HOTDOG	HAM	JAMONADA	MORTADELLA	PATE
2005	585	693	5572	1510	4166	502	201
2006	629	760	6089	1603	4612	523	224
2007	675	830	6621	1695	5083	544	248
2008	722	904	7171	1787	5579	564	273
2009	772	981	7736	1879	6100	585	299
2010	823	1061	8318	1921	6647	605	327
2011	876	1145	8915	2064	7219	626	357
TOTAL	5082	6374	50422	12459	39406	3949	1929

SOURCE: Saenz Alaba Sausages

Prepared: Saenz Alaba Sausages

Graphic # 5 Unsatisfied projected demand of meat products in tons in Peru



Source: Sáenz Alaba Sausages

Preparation: Author

In sausages, unmet demand is 119,621 tons. Piggis plans to enter the Peruvian market with 130 MT per year.

The following table will release price of sausages in Peru that are superior to those in force in Ecuador. For example, Hot-dog in Ecuador costs approximately \$ 2.50 a kilo and in Peru it is sold in \$ 3.90.

Chart # 18 Prices of Meat products in Peru

YEARS	HOT DOG	HAM	JAMONADA	MORTADELLA
2005	2.91	6.17	3.97	3.57
2006	3.06	6.48	4.17	3.75
2007	3.21	6.80	4.38	3.94
2008	3.37	7.14	4.60	4.14
2009	3.54	7.50	4.83	4.35
2010	3.72	7.87	5.07	4.56
2011	3.90	8.26	5.32	4.79
\$	1.41	3.00	1.94	1.74

Source: Saenz Alaba Sausages

Prepared: Saenz Alaba Sausages

Competition: The principal national and local competitors are: Italiana, Europea companies that are certified by the GMP. Piggis has been planning to export the products to an international market. These companies aim to obtain HACCP certification.

Next, costs of the competitors in Cuenca will be shown, with respect to the main products for export (Price in Kilos).

Chart # 19 Prices per Kilo

Company	Hot dog	Ham	Jamonada	Mortadella
La Italiana	3,39	5,85	5,08	3,35
La Europea	4,00	6,80	5,05	3,80
Piggis	3,20	5,81	4,50	3,63

Source: Italian, European, Delicatto

Preparation: Author

As a result, Piggis prices remain about the same price range as opposed to the competition, being even cheaper. Some of the national producers of sausages are Don Diego, Juris, Pronaca.

In the Peruvian market, there are located the following producers of the cured meat.

Chart # 20 Competitors of Piggis in Peru

PRINCIPAL COMPETITORS OF PIGGIS IN PERU		
RAZZETO	PREMIS	HUARAL
BRAET	EL NARANJAL	FRANCE DEL SUR
SUIZA	EMBUTIDOS SANTA CRUZ	AVICOR PRODUCTS
LAIVE	REDONDAS SP	CALLER
EL GORDITO	SALCHICHERIA ALEMANA	ALEMANA
		B Y V TRADING

Source: Directory of Peru

Preparation: Author

Piggis current installed capacity: The supply of current production in Cuenca and the installed capacity is about 60% occupied, so it can be used 10% of the capacity to export products exclusively to Peru, leaving a capacity of 30% for other markets.

Marketing

Export marketing policy

It plans to sell white sausage. According to the research of hot-dog in Peru, it ranks first in product demand in the market of around 130 MT.

Distribution channels

In every wholesale distributor, it is located a strong and qualified representative to the channel production in local supermarkets and mass market retail restaurants, shops, pizzerias and commissaries. Most sales are conducted at the northern part of Peru as: Loreto, Piura, Amazonas, Cajamarca, Lambayeque and Zarumilla because there are important areas for consumption of sausages. It is projected to serve an estimated population of 2'290 .903 people.

The following political map shows the Northern Peru where is projected to export.

Graphic # 6



Source: Political map of Peru

Preparation: Picasa

In the following table, it will be shown the northern cities of Peru, where plans to export the product of Piggis, have been made.

Chart # 21 Peruvian Population per city - potential sources to export Piggis

CITY	POPULATION
LORETO	881,342
PIURA	450,000
AMAZON	375,993
CAJAMARCA	283,767
LAMBAYEQUE	258,747
ZARUMILLA	41,054
TOTAL POPULATION	2,290,903

Source: Wikipedia

Preparation: Author

Transport and storage: It will be effectuated by road to the border areas in Ecuador. For the storage, coolers will be organized to maintain production until the total distribution.

Promotion and advertising: The distributor will be responsible for the promotion and advertising in order to introduce the product in the Peruvian market, asking for permission Piggis promotion.

Labelling: The products are exported with its original submissions of labels and should always be identified by the brand name, the medical record from Peru and the number of RUC.

Product Presentation: Piggis products are protected by a plastic called polyethylene films, which keeps the product's quality. It is clearly identified by the logo of the company, its seal of red information contains all the product data, usually weight (250 grams), relevant nutritional information, the lot identification, veterinary, ingredients, nutritional information, company information, security code and the cooling temperature as it should be maintained.

Advertising: Advertising will be focused as a natural product rich in protein and energy, high quality that can be consumed in a number of complementary products. It will be done through TV, radio, billboards and flyers.

Analysis of prices: After an analysis of the company to define the current cost product in Peru, and to allow projects to be competitive in this new place, the idea of this is to increase a sales volume. It is important to publicize the export costs, resulting in \$ 1.32 250 gram each packet of sausage.

Processing costs would be:

Certification of the Ministry of Industry and Productivity	\$ 120.00
Certificate of Origin	\$ 40.00
Concal certification (certification is free)	\$ 0.00
Copy of Health Record	\$ 1,500

Export Costs

If it is exported 130 MT at a cost of production of \$ 1.00 per pack of 250 grams of white sausage, that come packaged from the factory in a box containing 15 packs of sausages, a container land, the cost to obtain is the following.

EXWORK	\$ 520,000	
Export Packing	\$ 34,666	
Inland Freight	\$ 130,000	
Documentation Forwarding	\$ 1000	
FOB PRICE	\$ 685,666	
T. Value Shipping	\$ 520,000	100%
Increasing Value	\$ 165,666	31.86%

The package price of 250 grams is \$ 1.00 cost, and to obtain the export product in Peru it must be added the cost price (\$ 1.00) + the percentage of the increase.

Getting results:

White Sausage	ProductionCost	Unit Price + %
Value x package of 250 grams	1.00	\$1.32

Therefore, the export price of the product would be \$ 1.32. Currently the retail price in Ecuador is \$ 2.20 each pack of 250 grams. A wholesale dealer's discretion, with prior authorization and analysis of market prices in Peru, may consider the costs of sale in Ecuador, we must stress that the dealer has to bear the costs for a Customs clearance processes according to the laws of Peru.

Trademark. "The National Institute for Defense of Competition and Intellectual Property Protection (INDECOPI), and particularly the Trademark Office, is the entity responsible for registering trademarks or service in Peru" (Articuloz).

Piggis, for being a new company in the market, should register the trade mark to be able to begin a national distribution in Peru, and to know all the requirements that this

country requires. It is also mandatory that all brands need to register and verify if there is another product or another industry that has the same name.

4.4 Analysis of the Peruvian meat market

Sausages are an important staple food for Peruvians. The sausage factories in Peru are mostly characterized by financial stability with projections to invest abroad. The manufacturing plants are largely stand directly processed beef. Every manufacturing plant processes mostly beef meet, and the beef meet is imported from Argentina, Bolivia and Brazil.

The vast majority of sausage factories have ISO 9000 and ISO 9001, showing that these are companies with good international practice, of great strength and developing new challenges in the industrial growth. These companies are also very well established, offering the consumers a wide range product and with the idea of entering the Peruvian market.

Meat Companies: Razzeto, La Preferida, La Segovia, Laive and San Fernando are among the strongest companies in sales within the Peruvian market. These are widely accepted with sells of about 36,000 tons per year, reaching a turnover projected up to 12 million. These companies aim to continue to grow and encourage Peruvians to eat sausages replacing beef.

Although, there are excellent production factories in Peru, market for crafts produced sausages, evading all taxes and offer no guarantee of quality products. Then apply the benchmarking tool in a Peruvian company called Razzeto because sausage is a company, unlike other companies in Peru sausages, committed in dairy production as projected, and Piggis is focused on the distribution of its products to the northern part of Peru.

Manufacturing Plant: Razzeto is one of the most important industries in the sausage production; it applies all the quality standards according to the HACCP certification, complying with strict quality controls in the development of products.

Piggis has a large manufacturing plant and according to its products, it is projected to obtain the certification of Good Manufacturing Practices.

Competition: Direct competition such as Laive and Razzeto are the preferred embodiment. These are German factories eventually becoming really big and important for the Peruvian market. Some of the competition to Piggis are La Italiana, La Europea, Juris, Don Diego and Pronaca.

Plant Research: Razzeto plant is considered a pioneer in the research process. One indicator is the production processes that the company has implemented. Obviously not all controls can be shown in order to stay preventive of the competition due to it is in constant increase to expand the existing markets in Peru. For comparison with the plant Piggis, it is necessary to know some technical elements to be considered within Razzeto. However, the equipment and machinery are new and Piggis has updated its technology.

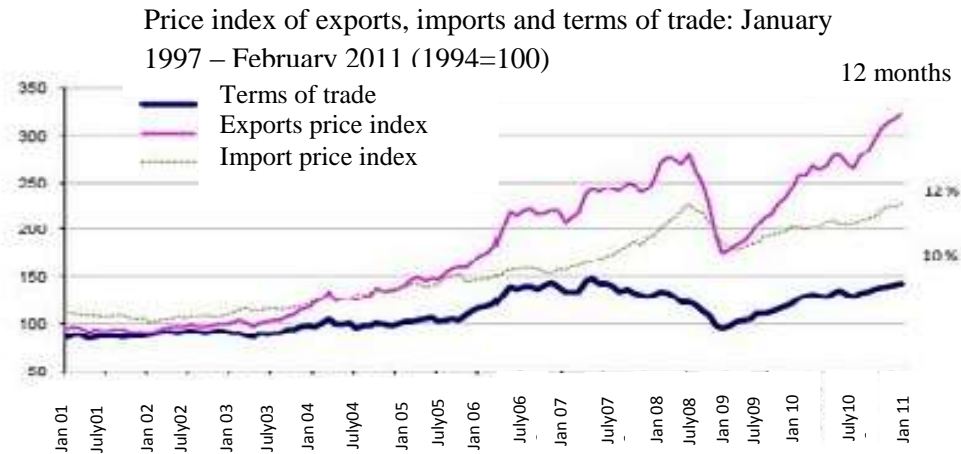
After several visits to the plant, Piggis ensures that there is necessary a decision to make changes in a short period, in order to achieve the implementation of GMP in all processes in the factory.

Projections of new certifications: Razzeto plans to obtain ISO 9000 certification in order to improve the quality of production and production processes, ensuring quality products for human consumption. Piggis is projected to the GMP and HACCP certification in order to capture the attention of customers in the country and spread throughout the international market. There are companies with quality certifications much broader in Peru trying to enter the Peruvian market. They began to project Piggis industrial growth. It is also important to mention that the company has had the opportunity to introduce the products to other countries, Piggis prefers to wait to get a certification that truly accredits the company and allows it to reach the international market demand.

Small craft sausages enterprises in Peru are renowned because of its flavor and a single display on packaging without mark records and health records without specifications. According to the study, conditions are developing products using traditional methods without the minimum health checks and without management of basic quality standards.

Photographs of a Peruvian artisan factory located in the Oxapampa plant, reflects that it has an inadequate infrastructure. Peru is aimed at a more remarkable productive and realistic growth, showing that it is overcoming a crisis. The following chart shows statistics of the growth of imports and exports that Peru has been maintained during the past year

Graphic # 7 Peruvian Exports and Imports



Source: Office of Peru
 Author: Peru Statistics Center

This chart shows that exports in the country have grown from a very important and remarkable point, although fewer imports are shown. There is still a growing trend and opening to obtain products necessary for the maintenance of its population. According to a research conducted, Peru points to an economic growth for the exports of raw materials, gold, etc.

Peru's economic growth

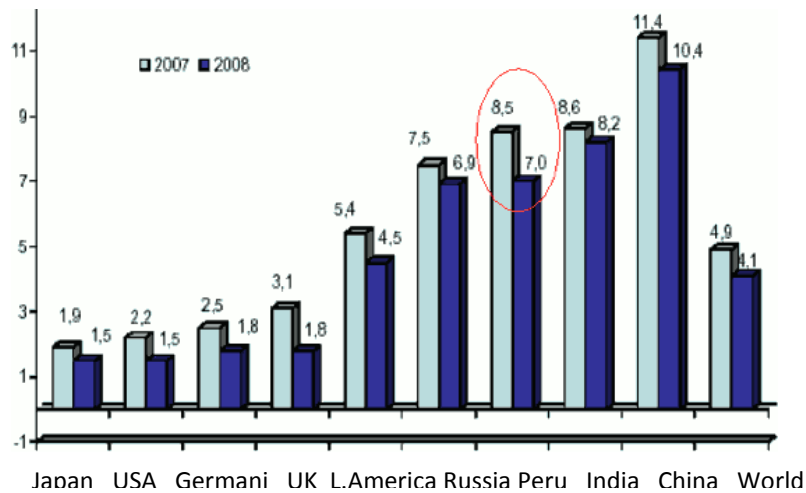
The International Monetary Fund announced that Peru has "registered enormous capital flows equivalent to 7% of GDP, to which the Government implemented strong and effective measures to ensure financial stability", (American Economy)demonstrating that the country has grown significantly and its GDP is increasingly improving.

Peru has become an example of economic progress and tries to stabilize its economy without jeopardizing its domestic production, attracting the interest of many developed countries and financial investors in order to have economic stability

The following chart shows that Peru is the only Latin American country with high economic growth, demonstrating a major sustainable development.

Graphic # 8 Economic growth per country (percentage variation 2007-2008)

Country economic growth 2007 - 2008 (percentage change)



Source: Forecast and IMF Concensus ²⁷

Prepared by: D. Mark Pair

Peru has been the only South American country having a global growth, being perhaps in the list of the most financially stable country over the next six years, becoming an attractive country to invest. Piggis Company must develop policies that allow expanding and marketing its products throughout the Peruvian market. Peru is certainly a country of a major investment, meaning very important revenue for the company.

Foreign trade opens doors and borders to the world of business, allows opportunities for new services and improves the industry. Opportunities open GMP great importance to

the international market, export of products is a clear example of quality of this production, capturing a greater demand and providing opportunities for new business.

4.5 Conclusions

- Exports are an important starting point for any company that wishes to obtain benefits from another completely different market in Ecuador.
- Trade agreements between countries facilitate the marketing of products.
- Piggis should set a goal of marketing, which allows improving the production achieving a position in the Latin American market.
- ISO 22000 standards open the door to the world market and allow faster entry of the products.
- Exports are an opportunity for accelerated growth in all industries.
- The company must follow very strict rules and laws that are required in Peru to the introduction of any foreign product.

Final Conclusions

- It is important for the company to train its personnel in order to have clear knowledge and skills to apply to the production, as well as to know that the GMP and strict compliance will result in a total quality product.
- It has been made a complete product description, including the safety relevant information such as its composition, physical / chemical structure, packaging, durability, storage conditions and distribution systems.
- All operators must be trained much deeper at an appropriate level, in order to make the operations of the company very well designed.
- The identification of the lots is essential to locate the products and maintain effective rotation of stocks that the market demands.
- The vehicles and containers for food should be kept in a proper state of cleanliness, repair and operation, not to become a contaminant of processed products.
- Insufficient information about the products and the inadequate knowledge of general hygiene can lead to inappropriate handling of the products in the food chain.
- When raw materials will be received, it should be inspected and sorted before processing and conducting to laboratory tests to establish whether its use will be appropriate and applicable for the purposes of the company.
- Products manufactured under conditions in which critical limits have been exceeded, potentially unsafe products.
- All corrections must be approved by the person directly responsible for quality and should be recorded giving the causes and consequences, increasingly looking to improve the functioning of Piggis.
- Each hazard to register with the company should be evaluated and should seek immediate solutions to the idea and the intention that it will keep a tighter control and the improvement will be immediate

- The controls should ensure that all proposed changes are reviewed before being implanted in determining food security.
- It must be regular assessments of the effectiveness of training and education programs, as well as the supervision and checks to ensure that procedures are effectively carried out.
- It would be important for all industries to concern about implementing the GMP system to assure consumers that products are made without prejudice to good health.
- The rules decreed by the government of Gustavo Noboa should be implemented and be a prerequisite for national implementation of all industries in Ecuador, not only those seeking to improve their business, but a requirement in all business.
- Piggis Company must improve and make a quickly process of implementing the GMP operation, to get possession as a major industry in Latin America.
- Good product is determined by the acceptance of the final consumer tastes, gaining a position in the global market.
- The food safety is the primary basis for the marketing of products becoming competitive in the market and offering products that meet manufacturing standards.
- Exporting to Peru will facilitate the company to improve its incomes and participate in the marketing practices of international trade beginning with a Latin American country, then look for alternatives to North America and all countries in the rest of the world.
- The Peruvian market is a big draw for other countries and even more for countries with existing trade agreements, which is why we must seize the opportunity to improve trade relations so with the neighboring country of Peru.

Bibliography

American Economy. IMF: Peruvian exchange market among the most stable. 26 de April de 2011. 26 de April de 2011 <<http://www.americaeconomia.com/economia-mercados/finanzas/fmi-mercado-cambiario-peruano-entre-los-mas-estables-de-america-latina>>.

Articuloz. Intellectual property regime. 14 de May de 2009. 18 de September de 2010 <<http://www.americaeconomia.com/economia-mercados/finanzas/fmi-mercado-cambiario-peruano-entre-los-mas-estables-de-america-latina>>.

Cajas, Byron. Good Manufacturing Practices Munoz Evelin. 26 de 01 de 2011.

Cantu, Jura - Koontz - Wehrich - . «Quality for Globalization.» Cantu, Jura. Quality for Globalization. Mexico: Mc Graw-Hill, 2004. 380.

Census Peru, Republic. Estadísticas del Peru. 2007. 2010 de Julio de 13 <www.cendoc.esan.edu.pe/>.

Customs in Ecuador. Export: Procedure to export Peru. 2010. 4 de May de 2010 <<http://www.aduana.gov.ec/contenido/procExportar.html>>.

Ecuadorian Institute of Standarization . Decree No. 1338 Official Register 984 Meat, Meat products sausages. Quito: Ministry of Public Health of Ecuador, 1992.

Ecuadorian Institute of Standarization. Decree No. 1339 Meat and meat products hams Official Register 973. Quito: Ministry of Public health of Ecuador, 1988.

Ecuadorian Standarization Institute. Decree 1340 Meat and meat products mortadellas official register 973. Quito: Ministry of Public health of Ecuador, 1988.

— . Decree 1344 meat and meat products chorizos, Official registered 17 2000-02-15. Quito: Ministry of health of Ecuador, 2000.

— . Decree 1347 meat and meat smoked products . Quito: Ministry of Public Health of Ecuador, 1985.

Ecuadorian, Institute. «Hams, Mortadellas, and meat products in Ecuador.» Ecuador: Oficial Gazette, 1988.

Enciclopedy Hispanya, consulting. Food safety consultancy. s.f. 15 de Abril de 2010 <www.corporacion3d.com>.

Galindo, H. Guide to Export to Peru. 2005. 15 de Abril de 2011 <www.proexport.gov.co>.

Hispanyan, Services. s.f. 15 de Abril de 2010
<http://www.corporacion3d.com/corporac/index.php?option=com_content&view=article&id=9&Itemid=21>.

Jaramillo, Vanessa. Piggis Manual. Cuenca: Graphics Hernandez, 2010.

Mattia, G. Food Practices. 08 de 04 de 2010. 08 de 04 de 2010 <www.aguilafumigaciones.com>.

Ministry of Health of Ecuador. Ejecutive Decree 696 Good Manufacturing Practices. Quito, 2002.

Ministry of Public health of Ecuador. Order Sausage Meat and meat products Ecuador Decree 696. Quito: Official Register No. 984, 1988.

Noboa, Gustavo. «Regulation GMP.» Official Record Published. Quito, 2002. Executive order 3253.

Oficial Register, 984. «Order sausage meat and meat products Ecuador.» Oficial Register 984 Patten 1338. Quito: Ministry of Ecuador, 1988.

PROEXPORT. Estadistics of Data from Peru. September de 2005. 5 de July de 2011
<<http://cendoc.esan.edu.pe/paginas/infoalerta/Agroexportacion/textocompleto/peru.pdf>>.

Quality Assurance, Quality. Quality Assurance. s.f. 15 de Octubre de 2010
<www.mundohelado.com/calidad>.

Quality, World. Quality. s.f. 2010 de 10 de 2010 <www.mundohelado.com>.

Ramos, E. «Manual for Good Manufacturing Practices.» E, Ramos. Manual for Good Manufacturing Practices. Lima: Satec, 2002. 220.

Standarization, Ecuadorian Institute of. Chorizos meat and meat products. Quito: Gazette, 1992.

Statistics, SA Peru Center Graphic. Exports and imports statistics in Peru. 2009. 10 de Junio de 2010 <www.blogspot.com/crecimiento-importaciones-exportaciones.htm>.

Wikipedia. Exports. s.f. 15 de Abril de 2010 <wwwl.wikipedia.org>.

Wikypedia. Main Exports to Peru. 2010. 3 de 07 de 2011
<[://es.m.wikipedia.org/wiki/Econ.%C3%Ada_DEL_Per%C3%BA](http://es.m.wikipedia.org/wiki/Econ.%C3%Ada_DEL_Per%C3%BA)>.

Annex 1



PIGGIS - HOME HEALTH CONDITIONS OF MEAT PRODUCTS

TRANSPORT GENERAL CONDITIONS OF PRODUCT						PRODUCT CONDITIONS												
DATE / TIME	PROVIDER	DRIVER	LICENSE PLATE	QUALITY CERTIFICATE	SANITARY STATE			TYPE OF PRODUCT	PORTION PROVIDER	T°	PH	COL OR	ODO R	PRESENCE OF EXTRANGE SUBSTANCES	APPROVED (YES/NO)	CORRECTIVE ACTION	DONE BY	REVIEW ED BY
					C	NC	AC											
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		
9																		
10																		
11																		
12																		
13																		
14																		
15																		
16																		
17																		
18																		
19																		
20																		
21																		
22																		
23																		
24																		
25																		
26																		
27																		
28																		
29																		
30																		
31																		
32																		
33																		
34																		
35																		
36																		
37																		

OBSERVATIONS

<p>State transport hygiene</p> <p>1. Floor/walls/ dirty ceilings</p> <p>2. Rusty rails</p> <p>3. Tubs/drawers</p> <p>4. Contaminating with chemical products</p> <p>5. Without table base with dirty floor</p> <p>6. Altered product</p> <p>7. Colors/strange odors</p>	<p>Corrective actions</p> <p>A. Revised product</p> <p>B. Cleaning of product</p> <p>C. The inspection of the status of product is approved</p> <p>D. Rejection of the product</p>
<p>Surface temperature</p> <p>Channels: ≤ 15°C</p> <p>Cuts: fresh ≤ 4°C; half frozen ≤ -3°C</p> <p>Imported: frozen ≤ -12°C</p> <p>pH</p> <p>5.6 a 7.0</p> <p>Sensorial sensorial</p> <p>N: normal; A: acceptable; D: deteriorated</p>	<p>Extrange substances</p> <p>State which one is present</p> <p>Corrective actions</p> <p>A. Sent to cameras frozen</p> <p>B. Microbiology analysis</p> <p>C. Pre-salt</p>

<p>INTERNAL AUDITOR: Chief I&D (2010-2011)</p> <p>Signature _____</p> <p>Date _____</p>
--

Annex 2



FIGGIS - SANITARY CONDITIONS FOR THE RECEPTION OF RAW MATERIAL NO MEAT

TRANSPORT GENERAL CONDITIONS						PRODUCT CONDITIONS											
DATE/TIME	PROVIDER	DRIVER	LICENSE PLATE	QUALITY CERTIFICATE	SANITARY STATE	TYPE OF PRODUCT	PORTION PROVIDER	PRESENCE OF GRUMES	COMPACTED DUST (YES/NO)	COLOR	ODOR	TASTE	PRESENCE OF EXCHANGE SUBSTANCES	APPROVED (YES/NO)	CORRECTIVE ACTION	DONE BY	REVIEWED BY
					C NC AC												
1																	
2																	
3																	
4																	
5																	
6																	
7																	
8																	
9																	
10																	
11																	
12																	
13																	
14																	
15																	
16																	
17																	
18																	
19																	
20																	
21																	
22																	
23																	
24																	
25																	
26																	
27																	
28																	
29																	
30																	
31																	
32																	
33																	
34																	
35																	
36																	
37																	
38																	
39																	
40																	

OBSERVATIONS		
State transport hygiene 1. Floor/walls/ dirty ceilings 2. Rusty rails 3. tubs/drawers 4. Contaminating with chemical product 5. Without jaba base with dirty floor 6. Altered product 7. Colors/strange odors	Corrective actions A. Revised product B. Cleaning of product C. The inspection of the status of product D. Rejection of the product	Sensory (color, odor, flavor) N: normal; A: acceptable; D: deteriorated Extrinsic Material: Indicate which one is present Corrective Actions A. Mix with other allotment B. Selection of wasted product C. Rejection of the entire allotment
		INTERNAL AUDITOR ChfI&D (2010 -2011) Signature Date

Annex 3



PIGGIS - SANITARY CONDITIONS IN THE RECEIPT OF MATERIALS (GUT AND PACKAGING)

TRANSPORT GENERAL CONDITIONS						PRODUCT CONDITIONS								
DATE/TIME	PROVIDER	DRIVER	LICENSE PLATE	QUALITY CERTIFICATION YES/NO	SANITARY STATE	TYPE OF PRODUCT	LOTE SUPPLIER	PRESENCE OF PLAGUES (YES / NO) which one?	STRANGE ODORS (YES/NO)	FREE CONTAMINATION	APPROVED YES / NO	CORRECTIVE ACTION	DONE BY	REVIEW BY
					C	NC	AC							
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														
11														
12														
13														
14														
15														
16														
17														
18														
19														
20														
21														
22														
23														
24														
25														
26														
27														
28														
29														
30														
31														
32														

OBSERVATIONS

State transport hygiene	Corrective Action:	Extraneous Materials:	Plagues:
1. Floor/walls/ dirty ceilings	A. Revised product	Indicate which one is present	Flying insects
2. Rusty rails	B. Selection of units in good condition		Land insects
3. tubs/drawers	C. Rejection of the product		Spiders
4. Contaminating with chemical products		Corrective Action:	Contamination by rodents
5. Without jaba base with dirty floor		A. Selection of downloaded product	contamination by birds
6. Wet cartons		B. Rejected the whole batch	

Internal Audit
Chief I&D (2010 -2011)
Signature
Date

Annex 4

FIGGIS - CONTROL OF THE PREPARATION OF PREMIXTURES						FIGGIS - CONTROL OF THE PREPARATION OF PREMIXTURES						FIGGIS - CONTROL OF THE PREPARATION OF PREMIXTURES					
TYPE OF PREMIX _____						TYPE OF PREMIX _____						TYPE OF PREMIX _____					
DATE OF ELABORATION _____						DATE OF ELABORATION _____						DATE OF ELABORATION _____					
TIME OF PREPARATION _____						TIME OF PREPARATION _____						TIME OF PREPARATION _____					
RESPONSIBLE _____						RESPONSIBLE _____						RESPONSIBLE _____					
TOTAL OF PREPARED MIX _____						TOTAL OF PREPARED MIX _____						TOTAL OF PREPARED MIX _____					
USED INGREDIENTS	AMOUNTS USED	ALLOTMENTS OF INGREDIENTS AND ADDITIVES	ASSIGNMENT ALLOTMENTS	DONE BY	OBSERVATIONS	USED INGREDIENTS	AMMOUNTS USED	ALLOTMENTS OF INGREDIENTS AND ADDITIVES	ASSIGNMENT ALLOTMENT S	DONE BY	OBSERVATIONS	USED INGREDIENTS	AMOUNTS USED	ALLOTMENTS OF INGREDIENTS AND ADDITIVES	ASSIGNMENT ALLOTMENTS	DONE BY	OBSERVATIONS

FIGGIS - CONTROL OF THE PREPARATION OF PREMIXTURES						FIGGIS - CONTROL OF THE PREPARATION OF PREMIXTURES						FIGGIS - CONTROL OF PREPARATION OF PREMIXTURES					
TYPE OF PREMIX _____						TYPE OF PREMIX _____						TYPE OF PREMIX _____					
DATE OF ELABORATION _____						DATE OF ELABORATION _____						DATE OF ELABORATION _____					
TIME OF PREPARATION _____						TIME OF PREPARATION _____						TIME OF PREPARATION _____					
RESPONSIBLE _____						RESPONSIBLE _____						RESPONSIBLE _____					
TOTAL OF PREPARED MIX _____						TOTAL OF PREPARED MIX _____						TOTAL OF PREPARED MIX _____					
USED INGREDIENTS	AMOUNTS USED	ALLOTMENTS OF INGREDIENTS AND ADDITIVES	ASSIGNMENT ALLOTMENTS	DONE BY	OBSERVATIONS	USED INGREDIENTS	AMMOUNT USED	ALLOTMENTS OF INGREDIENTS AND ADDITIVE	ASSIGNMENT ALLOTMENT S	DONE BY	OBSERVATIONS	INGREDIENTS USED	AMOUNTS USED	ALLOTMENTS OF INGREDIENTS AND ADDITIVES	ASSIGNMENT ALLOTMENTS	DONE BY	OBSERVATIONS

INTERNAL AUDITOR Quality Inspector / Laboratory (2010 - 2011)	Signature	Date
---	-----------	------

Annex 5

PIGGIS - CONTROL OF DELIVERIES OF PREMIXTURES													
DATE DEVELOPMENT	RESPONSIBLE PREPARATION	STORAGE UNIT LOCATION	IN WHAT PRODUCT WILL IT BE USED	TOTAL AMOUNT PREPARED	# ORDER OF MICROINGREDIENTS ELABORATION	ALLOTMENT PREMIX	THEORIC CONCENTRATION OF NITRITES	PREPARED BY THE LABORATORY (YES/NO)	DATE OF DELIVERY	WHO RECEIVES IN PRODUCTION	QUANTITY DELIVERED IN PRODUCTION	DONE BY	OBSERVATIONS
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													
16													
17													
18													
19													
20													
21													
22													
23													
24													
25													
26													
27													
28													
29													
30													
31													
32													
33													
34													
35													
36													
37													

INTERNAL AUDITOR Quality supervisor (2010 - 2011)	Signature	Date
---	-----------	------

Annex 6



PIGGIS - EMULSIFICATION CONTROL

TYPE OF EMULSION	OPERATOR	MACHINE	# BATCH	DATE/TIME	ALLOTMENT MPC	INTERNAL LOTE PREMIXTURES	STARCH ALLOTMENT	SOY ALLOTMENT	FLOUR ALLOTMENT	TIME OF EMULSION EXPOSITION	EMPTY YES/NO	T° PASTA	T° EMULSION EXPOSITION	TIME OF REST BEFORE INLAY	T° PASTA O EMULSION BEFORE CRAM	DONE BY
1																
2																
3																
4																
5																
6																
7																
8																
9																
10																
11																
12																
13																
14																
15																
16																
17																
18																
19																
20																
21																
22																
23																
24																
25																
26																
27																
28																
29																
30																
31																
32																

INTERNAL AUDITOR Quality Supervisor (2010 - 2011)		Signature	Date
--	--	-----------	------

BATCH MUST BE IDENTIFIED WITH THE INITIAL OF THE DAY TO BE DRAWN UP AND THE NUMBER YOU SEQUENTIALLY APPROPRIATE
 Example: L015

Annex 7

FIGGIS - EMBEDDED CONTROL

BATCH #	REST TIME BEFORE CRAM	T° PASTA OR EMULSION BEFORE CRAM	CALIBER USED	WEIGHT OF PIECES	OPERATOR	DONE BY
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						

INTERNAL AUDITOR Quality Supervisor (2010 - 2011)	SIGNATURE	DATE
---	-----------	------

FIGGIS - EMBEDDED CONTROL

BATCH #	REST TIME BEFORE CRAM	T° PASTA OR EMULSION BEFORE CRAM	CALIBER USED	WEIGHT OF PIECES	OPERATOR	DONE BY
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						

INTERNAL AUDITOR Quality Supervisor (2010 - 2011)	SIGNATURE	DATE
---	-----------	------

Annex 8



PIGGIS - CONTROL OF COOKING

DATE	PRODUCT	ALLOTMENT	No. PRESSURE POT/OVEN	ARRIVAL TIME	EXIT TIME	DRYING TIME	NUCLEUS T	COOLING TEMPERATURE	COOLING TIME	APPROVED	REJECTED	QUARANTINE	DONE BY	REVIEWED BY
1	CHICKEN SAUSAGE													
2	Sausage chicken													
3	Chicken Sausage													
4	Palm chicken sausage													
5	Palm chicken sausage													
6	Salchicha palm pollo cock													
7	Chicken sauge x 12 package													
8	chicken sauge cock emp													
9	Chicken sauge cuenca													
10	Chicken sauge cuenca													
11	Cooked chicken sauge Cuenca													
12	HOT DOG SAUGE 0 UNIT													
13	Hot dog sauge 0 unit cock													
14	Sauge hot dog 0 unit x 15													
15	Sausage hot dog 0 unit x 18													
16	Sausage palm 0 mermas cock													
17	FRANK NEW SAUSAGE													
18	Frank Sausage cock tied													
19	Frank new sausage x 15													
20	Frank new sausage x 18													
21	Frank new thick sausage													
22	Sausage palm frank x 15													
23	Sausage palm frank x 16													
24	FRANKFURT SAUSAGE													
25	Frank sausage x 15													
26	Frank sausage x 18													
27	Sausage kennel x 12													
28	Sausage kennel x 18													
29	Sausage frank cock env													
30	Sausage ahn x 21 delg													
31	Sausage ahn x 21 gruesa													
32	ESPECIAL SAUSAGE													
33	Economic sausage													
34	Especial Sausage													

35	Economic palm sausage																			
36	Especial pal sausage																			
37	Sausage cock elam emp																			
38	German sausage collagen																			
39	SMOKED SAUSAGE BREWER																			
40	Colombian sausage																			
41	brewer sausage																			
42	Broiler sausage																			
43	CHORICILLO SAUSAGE																			
44	Sausage Choricillo																			
45	Sausage salchipincho																			
46	SMOKED PORK																			
47	Smoked pork loin																			
48	Ahnn whole pork chop																			
49	Rib smoked pork																			
50	Bacon without grease																			
51	Bacon with grease																			
52	SMOKED CHICKEN																			
53	Smoked Chicken																			
54	Half smoked chicken																			
55	Smoked chicken wing																			
56	Smoked chicken legs																			
57	SALAMI AND PEPERONI																			
58	Matured Salami																			
59	WHITE SAUSAGE WITH CHEESE																			
60	White Sausage																			
61	Sausage with cheese																			
62	ARGENTINA SAUSAGE																			
63	Argentina Sausage																			

INTERNAL AUDITOR Quality Supervisor (2010 - 2011)	Signature	Date
--	------------------	-------------

Annex 9



PIGGIS - CONTROL OF COOLING CHAMBERS OF THE FINISHED PRODUCT FOR BALING

DATE	PRODUCT	ALLOTMENT	ARRIVAL TIME	TIME OF EXIT	ROTATIONS (COLOR, DAY)	NUCLEUS T	SURFACE OF THE PIECE	COLOR	APPROVED YES/NO	QUARANTINE	CORRECTIVE ACTIONS	DONE BY
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												
16												
17												
18												
19												
20												
21												
22												
23												
24												
25												
26												
27												
28												
29												
30												
31												
32												
33												
34												
35												

SUPPERFIAL STATE OF THE PIECES

A. SUPERFICE OF THE PIECE WITH RESIDIOUS
 B. DAMAGE PIECE
 SENSORIAL
 1. DIFERENT COLOR

CORRECTIVE ACTIONS

1. PRODUCT CHECK
 2. CLEANING OF THE PRODUCT
 3. THE QUALITY OF THE PRODUCT IS APPROVED

INTERNAL AUDIT

QUALITY SUPERVISOR (2010 -2011)
 SIGNATURE

DATE

Annex 10



FIGGIS - VACUUM PACKAGING CONTROL



FIGGIS - VACCUM PACKAGING CONTROL

DATE	PRODUCT	ALLOTMENT	T ^o PRODUCT PACK	FILM (MICRON)	BAG (MICRON)	THICKNESS OF THE SLICE	EMPTY	COMMENTS	DONE BY	REVIEW ED BY	TEXTURE OF THE PRODUCT	UNIFORMITY OF THE SLICE	SURFACE OF THE PACKAGE	SEALED BORDERS	PRESENCE OF FOREIGN BODIES	CORRECT LOCATIONS OF THE TAGS	OBSERVATIONS	APPROVED YES / NO	QUARANTINE
1																			
2																			
3																			
4																			
5																			
6																			
7																			
8																			
9																			
10																			
11																			
12																			
13																			
14																			
15																			
16																			
17																			
18																			
19																			
20																			
21																			
22																			
23																			
24																			
25																			
26																			
27																			
28																			
29																			
30																			
31																			
32																			
33																			
34																			
35																			

OBSERVATIONS
PACKAGE STATE
 A. EDGES SEALING NOT UNIFORM
 B. EDGES SEALING WITH RESIDOUS
 C. LOCATION OF LABELS IS NOT ADEQUATED
 D. WITHOUT EMPTYNESS

INTERNAL AUDIT QUALITY SUPERVISOR (2010-2011)
SIGNATURE
DATE

AUDITOR INTERNO: CHIEF I&D (2010-2011)
SIGNATURE
DATE

Annex 11



PIGGIS- CHAMBER OF FINISHED PRODUCT

	DATE	ALLOTMENT	ROTATION COLOR	DONE BY	OBSERVATIONS
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
INTERNAL AUDIT QUALITY SUPERVISOR (2010 - 2011)			SIGNATURE	DATE	

Annex 12

OFFICIAL FOOD SYSTEM

VERIFICATION FORM OF GMP COMPLIANCE

Carefully fill the information needed and the parameters that will verify the accomplishment of the Rule guide about good practices of manufacture of processed food

A.- General Information food processing plant

1.- Name/Social Reason

2.- Location: () () ()
 Urban location Rural location Industrial Zone

Province	Cantón	Parish
Streets and N	Number/fax	Electronic account

3.- CATEGORY () () () () ()
 Industry Medium Small industry Handicrafts Micro-enterprise

4.- LEGAL REPRESENTATIVE

Name	Signature
------	-----------

5.- TECHNICAL REPRESENTATIVE

Name	Signature	Profession
------	-----------	------------

6.- PRODUCTION MANAGER

Name	Signature	Profession
------	-----------	------------

7.- QUALITY CONTROL MANAGER

Name	Signature	Profession
------	-----------	------------

8.- OPERATION PERMIT

Code	Number	Expiration date
------	--------	-----------------

9.- Activities of the food processing machine encompass

() () ()
Production Container and packaging Distribution

10.- Types of food that are processed/packaged/distributed

11.-	REASON FOR THE INSPECTION	production in agreement with INEN		
	To obtain the certificate of OPERATION	()	
	To renew the certificate of OPERATION	()	
	For sample taking	()	
	For other motives	()	
12.-	TYPE OF INSPECTION	() Total	() Specific	() Partial
13.-	INSPECTOR COMISSION			
	Name	Institution		Identification papers
	_____	_____		_____
	_____	_____		_____
	_____	_____		_____
	_____	_____		_____
14.-	DATE OF INSPECTION	_____	_____	
		Starting hour	Final hour	
15.-	OBSERVATIONS	_____		

Annex 13
OFFICIAL SYSTEM OF FOOD

B.- SITUATION AND CONDITIONS OF THE FACILITIES		(Título III-Chapter I)		QUALIFICATION
FACILITIES			POND (1-3)	(N/A, 0-3)
1	MINIMUM CONDITIONS (Art.3)			
1.1.	Minimum risks of alteration and change			
1.2.	The plantation is located far away from populated areas			
1.3	Unsanitary bulbs			
1.4	Outside areas free of insects, rodents and birds			
1.5	The design and construction of the plantation makes it harder for plague to enter			
1.6	There are no holes in the outside walls of the plantation			
1.7	There are no unprotected openings			
1.8	The materials are inert and make the cleaning easier			
				QUALIFICATION
2	DESIGN AND CONSTRUCTION (Art. 5)		POND (1-3)	(N/A, 0-3)
2.1	Offers protection to the inside areas:	Dust		
		Insects		
		Rodents		
		Birds		
		Other contaminants		
2.2	The inside areas have enough space for a variety of activities			
2.3	There are facilities for the hygiene of the workers			
				QUALIFICATION
3	AREAS (Art. 6-I)		POND (1-3)	(N/A, 0-3)
3.1	The different areas are distributed following the designed process			
3.2	They are labeled correctly			
3.3	They allow the translation of materials			
3.4	They allow the movement of workers			

3.5	They allow a good:	maintenance		
		cleaning		
		desinfection		
3.6	The necessary hygiene is kept in all areas			
3.7	The inside areas are defined and keep hygiene standards			
3.8	In the critical areas disinfection is applied			
3.9	The following operations are registered:	maintenance		
		cleaning		
		desinfetion		
3.10	For the critical areas:	maintenance		
		cleaning		
		desinfetion		
3.11	These validations are registered?			
3.12	The operations on 3.9 are realized:	For the platation itself		
		Outsourced Service		
3.13	Is there good control of flammable products?			
3.14	The storage area for flammable products:	Far away from the plantation		
		Next to the plantation		
3.15	The construction of the storage area is in good conditions			
3.16	The storage unit is kept clean and stable			
3.17	The movement of materials and workers does not allow for any sort of contamination			
3.18	The plantation contains barriers that don't allow for any sort of contamination			
				QUALIFICATION
4 FLOORS (Art. 6-II)			POND (1-3)	(N/A, 0-3)
4.1	They are built of the following materials:	Resistant		
		Smooth		
		Waterproof		
		Easy to clean		
4.2	They are kept in a good state			
4.3	They are in perfect conditions of hygiene			

4.4	The inclination allows for a proper drainage for cleaning		
-----	---	--	--

5 WALLS (Art. 6-II)		POND (1-3)	QUALIFICATION (N/A, 0-3)
5.1	They are of washable material		
5.2	They are smooth		
5.3	Waterproof		
5.4	Do not have falling particles		
5.5	Clear and bright colors		
5.6	They are clean		
5.7	Good state		
5.8	The unions bewteen floors and walls are well kept		
6 ROOFING (Art. 6-II)		POND (1-3)	QUALIFICATION (N/A, 0-3)
6.1	They are kept in perfect hygiene standards		
6.2	They are smooth		
6.3	Easy to clean		
6.4	Waterproof		
6.5	They have fake ceilings		
6.6	The fake ceilings allow for them to be kept clean		
6.7	Do not have falling particles		
6.8	Allow for maintence and cleaning		
7 WINDOWS, DOORS AND OTHER OPENINGS (Art. 6-III)		POND (1-3)	QUALIFICATION (N/A, 0-3)
7.1	The material that they are made of does not allow for contamination		
7.2	The material allows for easy cleaning		
7.3	They are from a material that does not allow falling particles		
7.4	They are kept in a good state		
7.5	They're structures allow for easy cleaning of dust		

7.6	The windows have the necessary precautions if it was to break		
7.7	The doors are smooth and not absorbent		
7.8	They close easily		
7.9	The critical areas are located outside		
7.10	The critical areas have double doors for double service		
7.11	There are systems installed against insects, rodents and birds		

8 STAIRS, ELEVATORS, ADDITIONAL STRUCTURES		POND (1-3)	QUALIFICATION (N/A, 0-3)
---	--	------------	-----------------------------

8.1	The materials they are made of is resistant		
8.2	The elements are easy to clean		
8.3	They are materials that do not present a risk for the contamination of the food		
8.4	They are located in a way that do not block the movement of the materials and workers		
8.5	They are complementary structures on production lines		
8.6	Necessary precautions are taken so these do not cause contamination		

9 WIRING AND WATER NETWORKS		(Art. 6-V)	POND (1-3)	QUALIFICATION (N/A, 0-3)
------------------------------------	--	------------	------------	-----------------------------

9.1	The internet	open		
		closed		
9.2	The terminals are attached to doors and ceilings			
9.3	There are written procedures for the control of the internet			
9.4	The following procedures are met			
9.5	Is there all the relevant records			
9.6	These are all identified with a different color	clean water		
		not clean water		
		vapor		
		combustible		
		compressed air		
		waste water		
9.7	There are clear signs to identify the different categories			

		QUALIFICATION
10 LIGHTING (Art. 6-VI)		POND (1-3) (N/A, 0-3)
10.1	natural	
	artificial	
	natural-artificial	
10.2	The intensity of light is enough that it helps with inspection	
10.3	The intensity of the light does not affect the color of the products	
10.4	There are artificial lights that help with the product management	
10.5	There are enough safety measures	
10.6	they are clean	
	they are protected	
	they are kept in a good state	
11 VENTILATION (Art. 6-VII)		POND (1-3) (N/A, 0-3)
11.1	natural with appropriate filters	
	mechanic	
	direct	
	not direct	
11.2	The system or systems used bring climatic comfort	
11.3	The system or systems allow for the prevention and condensation of vapor, entrance of dust, etc	
11.4	Is (are) set (s) so as to avoid (n) the passage of air from a contaminated area to a clean area	
11.5	There is a written program for the cleaning of the ventilation systems	
11.6	Records of completed hygiene requirements	
11.7	There are written procedures for the maintenance, cleaning and change of filters in the ventilations	
11.8	There are records of the application of these procedures	
11.9	In the microbiologically sensitive areas the pressure is kept low	
11.10	Compressed air, cooling air, and direct air is used	

	contact with the food, and control of the air is used		
			QUALIFICATION
12	TEMPERATURE AND HUMIDITY	(Art. 6-VIII)	POND (1-3) (N/A, 0-3)
12.1	What companies are used for the temperature and humidity		
			QUALIFICATION
13	TOILETS, SHOWERS AND CHANGING ROOMS	(Art. 6-IX)	POND (1-3) (N/A, 0-3)
13.1	They exist in enough quantity		
13.2	They are separated by sex		
13.3	The areas of communication are informed		
13.4	The floors, windows and doors are kept clean		
13.5	They have proper ventilation		
13.6	These services are in perfect conditions		
13.7	They are packed with	liquid soap	
		disposable towels	
		automatic equipment for drying	
		containers with a cover	
13.8	The water for the washing of the hands is available		
13.9	The sinks are located on key locations for use of the workers		
13.10	The critical areas contain areas of cleaning such as disinfection		
13.11	There are records of the efficacy of the disinfection machines used		
13.12	There are clear signs that indicate one must wash their hands after using the bathroom		
			QUALIFICATION
14	WATER SUPPLY	(Art. 7-I)	POND (1-3) (N/A, 0-3)
14.1	The supply of water for the plantation is	Municipal Network of deep pit	
14.2	The well is near the area of production		
14.3	It is protected		
14.4	Water controls are done	Chemical Physical	
		microbiological	

14.5	There are records of these controls		
14.6	The water used for production is in agreement with the NTE		
14.7	The instalations that contain the water are well kept in order to prevent contamination		
14.8	The chemical treatment of water is controlled		
14.9	The system of distribution to the different areas is controlled		
14.10	The volume and pressure of the water is adequate		
14.11	The systems of water that can be used and water that can not are well labelled		
14.12	There are no connections bewteen the water that can be used and the water that can not		
14.13	The water system is in perfect hygienic conditions		
14.14	The cleaning of the systems are done regularly		
14.15	There are records of these controls		
			QUALIFICATION
15	STEAM SUPPLY (Art. 7-II)	POND (1-3)	(N/A, 0-3)
15.1	Vapor is used in the production sites		
15.2	For its generation the following is used clean water chemical products for eating availability		
15.3	If the second case is applied, what foods are part of this		
15.4	If the food needs vapor, is the required machinery available for the passing of the vapor		
15.5	There are systems that control the filters		
15.6	describe which ones		
15.7	There are recrods of these controls		
			QUALIFICATION
16	DISPOSAL OF WASTE (Art. 7-III)	POND (1-3)	(N/A, 0-3)
16.1	Machinery is available for the disposal of waste Liquids Solids Gases		
16.2	The disposal of damaged water follows proper guidelines		
16.3	The drains and system of evacuation follow proper guidelines		

16.4	There are specific areas available for the disposal of waste that agree with national standards		
16.5	Sewage and waste disposal system meet current national rules		
16.6	Solid waste is disposed in a correct manner		
16.7	The plantation possesses instalations for the disposal of all type of waste		
16.8	These isntalations are designed for the prevention of contamination		
16.9	The containers used for the disposal of waste and non-edible material is clearly identified		
16.10	There is a particular system for the collection and disposal of toxic substances		
16.11	The containers are regularly cleaned in order to prevent major contamination		
16.12	The waste area is far away from the production area		
16.13	A proper system of recollection, storage, protection and elimination of waste is used		
16.14	The recollection, storage, protection and elimination of waste reduces odors and collection of wastes		
	TOTAL SCORE		
	% OF COMPLIANCE		
OBSERVATIONS:			

Annex 14

C.- EQUIPMENT AND UTENSILS		(Art. 8)		QUALIFICATION
1 REQUIREMENTS			POND (1-3)	(N/A, 0-3)
1.1	The equipment corresponds to the type of process for production			
1.2	They are designed, constructed and installed in a way that they will satisfy the requirements for production			
1.3	They are located in a way that helps the production go forward			
1.4	The equipment is exclusive to each area			
1.5	The materials that the equipment are made of are the following:	Atóxicos		
		resistant		
		Inertes		
		Do not allow particles to fall		
		Easy to clean		
1.6	They are designed, constructed and installed to prevent contamination during processes (not safe conditions can lead to dirty conditions (for example formation of condensation			
	If its needed, there is venting available to prevent too much condensation			
1.7	The operations have instructions for the procedures behind every material			
1.8	Next to any machine			
1.9	There are instructions that specify the dangers behind all machines			
1.10	The utensils used to manage non-edible products are not the same for the edible products			
1.11	They are clearly identified			
1.12	There is a preventive method to help with any problematic situations			
1.13	The inspection of machinery and the replacement of the pieces are based on a manual used for fabrication			
1.14	The machinery is kept in a state where it helps prevent contamination	Physical		
		Chemical		
		Biological		
1.15	For the calibration of machinery reference norms are used			
1.16	The service used for the calibration	Own		
		Through others		
1.17	In this second case, a written case is used			
1.18	The frequency of calibration is recorded			
				QUALIFICATION
2 CLEANING, SANITATION AND MAINTENANCE			POND (1-3)	(N/A, 0-3)
2.1	There are written programs for	Cleaning		
		Desinfection		
		Mantenimiento de equipos y utensilios		

2.2	The effectiveness of the programs is tested		
2.3	Describe the substances that are used for the disinfection of	Equipment	
		Utensils	
2.4	The effectiveness of these substances is valid		
2.5	There are written records of the effectiveness		
2.6	The incompatibility of these substances are tested against the products that are processed		
2.7	The concentration used and the time of exposition are adequate		
2.8	Frequency with which this is used	Cleaning Desinfection	
2.9	There are written programs for the maintenance of the machinery		
2.10	Frequency with which this is done		
2.11	There are records of the maintenance of the machinery		
2.12	The substances used for the lubrication of machinery		
2.13	The lubricants are all edible		
2.14	The procedures of lubrication are recorded		
3	OTHER ACCESORIES		QUALIFICATION
		POND (1-3)	(N/A, 0-3)
3.1	The surfaces in direct contact with the food are located in way that prevent an offsent in the productive process		
		They resist exposure to cleaning products	
		Non-corrosive	
		Non-absorbent	
3.2	The materials they are fabricated from are:	Don't allow the falling of particles	
		Atóxicos	
		Easy to clean	
		Easy to disinfect	
3.3	Sistems used for:	Cleaning Desinfection Maintenance	
3.4	Frequency that this procedures are done:	Cleaning Desinfection Maintenance	
3.5	Substances used for:	Cleaning Desinfection Maintenance	
3.6	The efficacy of this procedures are valid		
3.7	Their efficacy is tested		
3.8	The tubes used for the conduction of raw materials, intermediate products and final products are:	Of resistant materials Inert Non-porous Waterproof Easily removable for its cleaning	

3.9	System used for the cleaning of the fixed tuberries		
3.10	The efficacy of this procedure is tested		
3.11	Substances used for the cleaning and disinfection		
3.12	The efficacy of these substances is tested		
3.13	The incompatibility of these substances are tested against the products that go through the tubes are tested		
	TOTAL SCORE		
	% DE COMPLIANCE		

OBSERVATIONS

Annex 15

OFFICIAL FOOD SYSTEM

D.- PERSONEEL (TITLE IV-CHAPTER I)

1 GENERALITIES

1.1	Total of employees:		Men		Women	
1.2	Personal de planta:		Men		Women	
1.3	Personal administrative:		Men		Women	

2 EDUCATION (Art. 11)		POND (1-3)	QUALIFICATION (N/A, 0-3)
2.1	The requirements the workers have to complete are clearly stated for each area		
2.2	There are training programs for BPM	Own	
		External	
2.3	There are programs for the evaluation of		
2.4	There is an specific program or procedure in place for the hiring of new works in relation to the work and responsibilities they have to complete		
	The initial training is reinforced periodically		
3 HEALTH STATUS (Art. 12)		POND (1-3)	QUALIFICATION (N/A, 0-3)
3.1	The workers at the plantation can proof their health status with a personal card		
3.2	There are medical procedures in place to prevent sickness		
3.3	With what frequency		
3.4	Records of the reinforcement of these programs and procedures		
3.5	There is a record for the amount of accidents		
3.6	There are specific groups in place to help in emergency situations		
3.7	Groups against fires		
3.8	Groups for first aid		

3.9	The workers that have any sort of contagious disease are isolated for a period of time						
3.10	A record of these situations is taken						
3.11	If another breakout occurs, the causes are investigated						
3.12	The causes are registered						
							QUALIFICATION
4	HYGIENE AND MEASURES OF PROTECTION (Art. 13)					POND (1-3)	(N/A, 0-3)
4.1	There are norms in place for the hygiene of the workers						
4.2	The workers are aware of these norms						
4.3	The workers have appropriate uniforms						
4.4	Of colors that allow their hygiene to be shown						
4.5	They are washable		They are disposable				
4.6	The uniforms are in a perfect state of						
4.7	The cleaning of the uniform is		In the plantation itself An outside service				
4.8	This type of process requires the use of gloves from the workers						
4.9	The material of the uniforms don't create any sort of contamination						
4.10	The workers can't use their uniforms outside of the workplace						
4.11	The type of shoes the workers use is adequate						
4.12	There are visible signs for the workers to see						
4.13	The necessity of washing ones hands is shown by the workers before the day starts						
4.14	Everytime one exists and comes back to their designed work area						
4.15	Everytime a worker uses the hygiene services						
4.16	After manipulating any product of substance that could cause contamination						
4.17	The necessity of washing ones hands is shown before one puts their gloves on						
4.18	The type of process makes it necessary for one to wash their hands						
4.19	What substances are used for		Washing of hands Desinfection of hands				
4.20	The efficacy of these substances is tested						
4.21	The workers use		Hats Masks				
4.22			Washables		Disposable		
4.23	Clean						

4.24	In good conditions		
			QUALIFICATION
5	BEHAVIOR OF THE PERSONNEL	(Art. 14)	POND (1-3)
			(N/A, 0-3)
5.1	There are clear and visible signs that indicate the prohibition of	Smoking or eating the work areas Taking unknown people to the work areas Using street clothing Showing ones hair, mustache in the work place Using jewelry Using makeup	
5.2	There are systems for the use of signaling		
5.3	For the evacuation of the workers		
5.4	For the moving of materials		
5.5	To differentiate bewteen procedures		
5.6	There are written norms for security purposes		
5.7	The workers are aware of these norms		
5.8	Secure and complete machinery are available (aprooved by firemen)	Extintores fire hydrants Exhaust ports Others (alarms, valves)	
5.9	In optimal conditions for use		
5.10	Distributed accordingly		
5.11	The workers are training for the control of the machinery		
		TOTAL SCORE	
		% OF COMPLIANCE	

OBSERVATIONS: _____

Annex 16

OFFICIAL FOOD SYSTEM

E.- ROW MATERIALS AND SUPPLIES		(CHAPTER II)	QUALIFICATION
1 REQUIREMENTS		POND (1-3)	(N/A, 0-3)
1.1	The suppliers are certified about the raw materials		
1.2	There are records of this		
1.3	The suppliers are certified about the raw materials		
1.4	There are specifications for every raw material		
1.5	These specifications become part of the norms		
1.6	Inspect and classify raw materials during reception		
1.7	There is an analysis of the quality of the raw materials		
1.8	With what frequency		
1.9	There are records of these analyses		
1.10	There are records for the accomplishment of these specifications		
	There is a change in the supplier		
	There is a change in the origin of an ingredient		
	The verification proposes a contradiction with the analysis done		
1.11	All raw materials are analysed accordingly		
1.12	The results of the analysis are recorded		
1.13	For the storage of raw material nature is taken in consideration		
1.14	The specific requirements the raw materials need are recorded		
1.15	Classify the raw materials according to their use		
1,16	They are appropriately distributed	External packages	
		Internal packages	
1.17	The expiration dates are correct		
1.18	There is a lack of non appropriate raw materials for the use of human beings		
1.19	The containers	Not susceptible to deterioration	
		Don't let particles get close to raw materials	
		Easy to destruct and clean	
1.20	An applied system for the rotation of the lots		
1.21	The conditions of the environment in the storage units are recorded	Cleaning	
		Temperature	
		Humidity	

	Ventilation		
	Lighting		
1.22	This areas are separated from the areas of production		
1.23	There is a policy in place for the return of raw materials		
1.24	There is a record of the return policy and the returns made		
1.25	There is an specific procedure for taking raw materials to risk areas of high contamination		
1.26	The defrosting of the raw material is done through	Time	
		Temperature	
		Others	
1.27	The raw materials defrosted won't frost again		
1.28	The food addivites are appropriate for the food they are being added to		
1.29	They are appropriately named		
1.30	Their expiration date is labelled		
2 WATER (Chapter II-Art. 26)		POND (1-3)	QUALIFICACION (N/A, 0-3)
2.1	The water for the raw materials is drinkable?		
2.2	Their specifications agree with the norms in the INEN		
2.3	Evaluate the parameters:	Physics chemical	
		Microbiological	
2.4	With what frequency		
2.5	The assesments are evaluated		
2.6	System used to clean the water		
2.7	The treatment done to the water is monitored		
2.8	With what frequency		
2.9	The monitoring is recorded		
2.10	The ice is fabricated with drinkable water		
2.11	The ice is fabricated, kept and stored in aseptic ways		
2.12	Verify the safety of the ice		
2.13	Controls that are applied		
2.14	Record these control procedures		
2.15	The vapor that comes into contact with the food comes from drinkable water		
2.16	The chemical substances used INEN		

	comes from	Other organisms internationally known		
2.17	The cleaning of the raw materials comes from water:	Drinkable		
		Treated		
2.18	Water is reused from the procedures to make products			
2.19	There is a process of storage for this water			
2.20	There are biological and chemical controls done on this water			
2.21	With what frequency			
2.22	There are records of these controls			
2.23	The results of the assessments verify the quality fo the water			
2.24	The system of distribution of these is appropriate			
	TOTAL SCORE			
	% OF COMPLIANCE			
OBSERVATIONS:				

Annex 17

OFFICIAL FOOD SYSTEM

F.- PRODUCTION OPERATIONS		(CHAPTER III)	POND (1-3)	QUALIFICATION (N/A, 0-3)
1	There is a system for the planning of the fabrication of products			
2	There are specific rules written for the fabrication of products			
3	The procedures for fabrication are tested			
4	They are accomplished			
5	How do you verify its accomplishment			
6	The areas are appropriate for the production of products			
7	The efficacy and hygiene of the products is tested before any fabrication is done			
8	The documents regarding production are clearly identified			
9	They are regularly used by the workers			
10	There is a written procedure for all the steps of the fabrication			
11	The workers are aware of any problems, warnings and errors that could occur			
12	The design of the different areas is appropriate			
13	The areas of production have enough space			
14	They are perfectly distributed:	All type of machinery		
		The raw materials to use		
		The helping materials		
15	The areas are delimited based on the nature of the processed products			
16	The necessary precautions are taken to avoid cross contamination			
17	The critical points in any process of production are determined			
18	The critical points are avoided			
19	The cables that form part of the processes are well controlled and placed			
20	The systems for liquids possess a filtration mechanism			
21	They are used regularly			
22	The windows in the production areas are closed			
23	The windows exposed to hallways are clearly protected			
24	With protection against insects			
25	The following environment conditions are shown:	Hygiene based on standards		
		Order		
		Ventilation		

	Humidity		
	Temperature		
	Over pressure		
	Control machinery in good conditions		
26	In the areas of production, during the process of fabrication:	They procedures for products are available They are used with efficacy They are recorded and tested Precautions are taken to avoid any damage And contamination	
27	Protection methods are used for susceptible raw materials		
28	There are written procedures for the fabrication of all products		
29	Every operation is evaluated with the signature of the person that did it		
30	A document records all the important steps realized		
31	The workers are warned to inform of any wrong procedure		
32	The abnormalities detected are reported	To the technic responsible for the operation In the records of the lots Corrective actions are taken when necessary These corrective actions are recorded	
33	There are procedures and precautions to prevent any sort of damage		
		TOTAL SCORE	
		% OF COMPLIANCE	

OBSERVATIONS: _____

Annex 18

OFFICIAL FOOD SYSTEM

G.- PACKAGING, LABELED AND SEALED (CHAPTER IV)		POND (1-3)	QUALIFICATION (N/A, 0-3)
1	The areas destined for the packaging and labelling are separated between each other		
2	They are clearly identified		
3	The workers in all these areas are aware of the possible contaminations		
4	The packaging of the products is done in the shortest time possible to avoid contamination		
5	The packaging of the products accomplishes all of the norms		
6	There is a written procedure for the packaging of the products		
7	The packaging products are labelled according to quality		
8	The approbation of these are recorded		
9	Labels are placed stating approbation		
10	There is a record of the packages and labels used		
11	There are procedures for the cleaning of the products that will be used		
12	These procedures are tested		
13	There are procedures that will test the efficacy of these		
14	The results of the tests are recorded		
15	These records form part of the history of the lots		
16	There are suppliers labelled for the packaging and labelling		
17	The safety of the labels and packaging is stated		
18	Of what way		
19	The containers have the required conditions		
20	The final products already packaged verify the following:	Quarantine	
		Approved	
		Rejected	
21	The information on the labels agrees with the products themselves		
22	What is the destiny for the _____ Without marking a number or expiration date		

	labels that are not used: Marked with a number and expiration date		
23	The final orders for labelling are consolidated		
24	This operation is recorded		
25	Forms part of the history of the lots		
	TOTAL SCORE		
	% OF COMPLIANCE		

OBSERVATIONS: _____

Annex 19

OFFICIAL FOOD SYSTEM

H.- STORAGE, DISTRIBUTION AND TRANSPORT (CHAPTER V)		POND (1-3)	QUALIFICATIONS (N/A, 0-3)
1	The cellars that contain the final products hold the correct hygiene standards		
2	There are written programs for Cleaning of the cellars Control of plagues		
2.1			
2.2	These programs are applied		
2.3	With what frequency		
3	The environmental conditions are appropriate for the products		
4	They are kept in the right temperature and humidity conditions		
4.1	These conditions are verified		
4.2	With what frequency		
4.3	The verifications are recorded		
5	The cellars contain instructions on how to manage the products		
6	There are specific areas for: Quarantine Approved products Rejected products Refunds of product		
7	Every area has shelves for the storage of products		
8	They are separated conveniently: Floor (minimum 10cm) The walls Between them		
8.1			
9	There is a procedure that states that the first thing that comes in will go out (F.I.F.O)		
10	Food is stored properly identified indicating their condition		
11	There is an specific area for the refund of products		
12	There are written procedures for the refunds		
13	The transportation of raw material and finished material follow hygiene standards		
13.1	They are built of products that don't risk the quality of the products		
13.2	These materials allow for an easy cleaning of the car		
13.3	The conditions of temperature and humidity keep the hygiene standards of the products		
14	There are specific cars assigned to the transportation of raw materials and edible products		
15	There are written procedures for the cleaning of these vehicles		
16	With what frequency is cleaning made		
16.1	The frequency of the cleaning is recorded		
TOTAL SCORE			
% OF COMPLIANCE			
OBSERVATIONS:			

Annex 20

OFFICIAL FOOD SYSTEM

		(Title V- Unique Chapter)	POND (1-3)	QUALIFICATIONS (N/A, 0-3)
I.-	QUALITY ASSURANCE AND CONTROL			
1	The plantation has a department for the control of quality			
2	The laboratory that analyzes the quality of the products has the necessary machinery to analyze			
3	All the equipment is calibrated			
3.1	With what frequency is the equipment calibrated			
3.2	The calibration of the equipment is recorded			
3.3	This service is:	Done by themselves	Done by others	
3.4	There is a contract that states the calibration is done by others			
4	The analytical methods are accepted			
5	There are written procedures for:			
5.1	Raw materials			
5.2	Materials for packaging and storage			
5.3	Products in process			
5.4	Final products			
6	They are applied regularly			
7	There is a record of the products done			
7.1	Of physics chemics			
7.2	Of microbiological			
8	There are records of the procedures done to change the quality of the products			
9	An analysis is done to determine the quality of the water			
10	The changes done to the water are recorded			
10.1	There is a procedure of this monitoring			
11	Control of the quality:			
11.1	Guaranteed that the quality system will be kept			
11.2	Permanent communication with suppliers			
11.3	Every lot produced is controlled			
11.4	There are samples of the products			
11.5	The conditions of storage are safe			
11.6	There are essays done on the stability of final products			
11.7	Supervises countersamples			
11.8	Products that are refunded are examined			
11.9	Inform to production of abnormal operations			
11.10	Approves/rejects products, materials, procedures, etc. According to specifications			
12	Production is informed of any abnormalities			
13	The department that controls quality assures that:			
13.1	Specifications of raw material			
13.2	Specifications of material for storage and packaging			

13.3	Procedure for sample taking		
13.4	Procedures and manuals for the use of equipment		
13.5	Protocols for the control of		
13.6	Raw materials		
13.7	Materials for storage and packaging		
13.8	Products in the processing stage		
13.9	Final products		
13.10	Control of the wáter		
13.11	Areas that need control of the atmosphere		
13.12	Security measures		
13.13	Program and records of calibration of equipment		
13.14	Records of essays of these calibration		
13.15	Records of suppliers		
13.16	Dates of storage and packaging of raw materials		
13.17	Dates of storage and manipulation of final products		
13.18	Procedures of validation		
13.19	Procedures of attention to refunds		
13.20	Procedures for the gathering of products		
14	The products have labels for their acceptance or rejectment		
15	The documents of work are filed		
16	The raw products are labelled and filed		
17	There are records of the results of the analysis made	Raw material	
17.1		Final product	
18	There are protocols done on the different areas of the plantatation that unite partial records		
19	The protocols and records are filed		
19.1	For what time?		
20	The areas are adequate for their purposes:		
20.1		Phisics and chemical	
20.2		Microbiological	
20.3		In process	
20.4		Others	
21	There is a procedure for the process of getting rid of waste		
22	The equipment used fulfills the requirements of the products		
23	The equipment posses:	Technical manuals	
23.1		Papers with references to technical measures	
23.2		Instructions for its maintenance	
23.3		Records of maintenance	
24	The activities are recorded in paper		
24.1	They are conveniently supervised		
25	The reactives are:	Properly located	

25.1		Conveniently labeled		
25.2		Prepared through written methods		
25.3		Controlled in quality and efficacy		
25.4		Stored appropriately		
26	The control techniques:		Appropriately established	
26.1			Written in an understandable manner	
26.2			Used regularly	
26.3			Filed properly	
26.4			Written without any special fix	
25	They are controlled regularly			
25.1	The raw materials			
25.2	The materials of packaging and storage			
25.3	The products in process			
25.4	The final products:	Determining the organoleptic characteristics		
		Physics and chemical parameters		
		Microbiological parameters		
26	All of these controls form part of the lot history			
27	Periodically the sistem of safety is proved correct			
28	Through insepections			
29	Through insepections done by others			
30	Evaluations are done repeatedly		Raw materials	
30.1			Materials for packaging and storage	
30.2			Reactives	
31	The reference substances			
31.1	Managed through specific rules			
31.2	Properly conserved			
31.3	Prepared through written procedures			
31.4	Their used is registered			
			TOTAL SCORE	
			% OF COMPLIANCE	

OBSERVATIONS:

Annex 21

GMP AUDIT FOOD

COMPANY: _____

DATE: _____

PRODUCTION LINES: _____

AUDITED: _____

AUDITORS: _____

Documented
NE
DM
AD
EX

Application
NE
DM
AD
EX

b. – What degree of decline do the floors have in wet areas?

Application
NE ---
DM ---
AD --
EX --

c. – What is the floors slope in areas of refrigeration?

Application
NE ---
DM ---
AD --
EX --

d. – What is the condition of the floor drain?

Application
NE ---
DM ---
AD --
EX --

Art. 8.3 Walls

12. – What material are the walls, are they smooth, impervious, easily cleaned and disinfected?

Documented
NE ---
DM --
AD --
EX --

Application

b. – Are the horizontal and vertical corners of the walls concave?

Application
NE ---
DM --
AD --
EX --

c. – Is there no walls attached to the roof and end up on top?

Application

NE ---
DM ---
AD ---
EX ---

Section 8.4 Ceilings

12. – How are they designed, easy cleaning and disinfection?

Application

NE --
DM --
AD --
EX --

b. – Are not splintering windows? If there are glasses, do you take precautions?

Documented

Application

NE --
DM --
AD --
EX --

c. – How are the frames of the windows, are there hollow?

Application

NE --
DM --
AD --
EX --

d. – Are there windows that connect with pest proof systems outside?

Documented

Application

NE --
DM --
AD --
EX --

Section 8.6 Doors

a. – What are they? Can your width move freely? Are they closing? Are the hollow doors airtight?

Application

NE --
DM --
AD --
EX --

12. – How big is the gap between the outer door and the floor?

Application

NE	---
DM	---
AD	---
EX	---

12. – Where are the doors of the areas most at risk?

Application

NE	---
DM	---
AD	---
EX	---

Article 8.7 Stairs, Elevators and complementary structures (ramps, platforms)

12. – Where are the used stairs? How do you ensure that you do not contribute to pollution or impede the flow of materials? How are they easy to clean and maintain?

Documented

Application

NE	---
DM	---
AD	---
EX	---

12. – The design prevents accumulation of dirt, mold growth and shedding of particles

Application

NE	---
DM	---
AD	---
EX	---

12. – Are the design of critical support facilities prevent accumulation of dirt and pest harborage?

Application

DM	---
AD	---
EX	---

d. – How is the network of electrical installations, are they open or closed, are its terminals attached to walls or ceilings? If they are closed, they are clean?

Documented

Application

NE	---
DM	---
AD	---
EX	---

8.8 Lighting

a. – What type of lighting is available? Does it provide comfort?

Documented	Application
NE	--
DM	---
AD	---
EX	--

b.- How do you protect the lamps and fixtures that are above the processing and packaging lines

Application	
NE	---
DM	---
AD	---
EX	--

c.- Does the lighting interfere with the appreciation of the natural color of food?

Application	
NE	---
DM	---
AD	---
EX	--

8.9 Air quality and ventilation

a. – Is there ventilation? How does it renew the heat in the areas that require it?

Application	
NE	--
DM	---
AD	---
EX	--

12. – How is the cleaning of the air injection systems in the production areas?

Documented	Application
NE	--
DM	---
AD	---
EX	--

12. – What is the flow of air currents between these areas and is there a lay out of circulation?

Documented	Application
NE	--
DM	---
AD	---
EX	--

d. – Is the air from the fans, or air refurbished? What is the pressure flow and is there or not a program of maintenance, cleaning and filter changes?

Documented Application

NE --
DM --
AD --
EX --

8.10 Temperature Control

a. – Are there facilities for heating, cooling, cooking, refrigerate or freeze food?

Documented Application

NE --
DM --
AD --
EX --

12. – How is the temperature control and how does it maintain the environment in the areas necessary?

Documented Application

NE --
DM --
AD --
EX --

8.11 Storehouse – Warehouse

Allow warehouse

NE --
DM --
AD --
EX --

a.- Do they maintain and clean the premises?

Yes_ No_

12. – Do they avoid pest access and protected from contamination and food spoilage?

Yes_ No_

12. – Where does they store the cleaning chemicals products, lubricants and fuels?

Documented Application

NE --
DM --
AD --
EX --

d. – Where do they store the deteriorate food by effect of temperature and humidity?

Documented Application

NE	--
DM	--
AD	--
EX	--

8.12 Sanitary

12. – Are there sanitary facilities with toilets, showers and dressing rooms sufficient and independent for men and women?

Application

NE	--
DM	--
AD	--
EX	--

12. – Are the dressing rooms and toilets separate from the manufacturing areas?

Application

NE	--
DM	--
AD	--
EX	--

12. – Is the access to the bathrooms to the production areas direct or indirect?

Application

NE	--
DM	--
AD	--
EX	--

d. – What are the conditions of the sinks?

Application

NE	--
DM	--
AD	--
EX	--

e. – Are there sanitizer dispensers in critical areas?

Application

NE	--
DM	--
AD	--
EX	--

f. – Are they clean and ventilated toilet facilities?

Documented

Application

NE	--
DM	---
AD	---
EX	--

Article 9 Plant Services – Facilities

9.1. Water supply

a. – What is the condition of the water distribution system?

Application

NE	---
DM	--
AD	---
EX	--

12. – What type of water is used in operations, fire control, steam generation, cooling hint?

Documented

Application

NE	--
DM	---
AD	---
EX	--

12. – Are the pipes, identified according to which standard or code?

Documented

Application

NE	--
DM	---
AD	---
EX	--

9.2. - Steam supply

a. – How is the steam that is in contact with food?

Documented

Application

NE	--
DM	---
AD	---
EX	--

9.3.- Disposition of rights liquids

12. – How is the wastewater and industrial tributaries treated? Are there separated systems?

Documented

Application

NE	--
DM	---
AD	---
EX	--

- b. – Does the design of drains prevent contamination of food, water or drinking water sources?

Application

NE	--
DM	--
AD	--
EX	--

12. – Do you know how to handle liquid waste? Does this prevent contamination of food?

Documented

Application

NE	--
DM	--
AD	--
EX	--

9.4.- Solid waste disposal

- a. – What system of collection, storage, production and disposal of garbage is handled?

Documented

Application

NE	--
DM	--
AD	--
EX	--

- b.- Do the waste collection containers have lids and are they identified?

Documented

Application

NE	--
DM	--
AD	--
EX	--

- c.- Are there security systems to prevent contamination?

Documented

Application

NE	--
DM	--
AD	--
EX	--

d.- Are the food contact surfaces removable?

Application

NE ---
DM ---
AD ---
EX ---

e. – Are there covered surfaces with food contact with any other painting material?

Documented

Application

NE ---
DM ---
AD ---
EX ---

f. – Are the pipes that carry foods inert, non-porous, waterproof and removable?

Documented

Application

NE ---
DM ---
AD ---
EX ---

g. – Does it allow the installation of equipment, continuous flow and sound equipment and personnel?

Documented

Application

NE ---
DM ---
AD ---
EX ---

Section 11 Are there vacuum equipments that prevent the spread of dust in the environment?

YES __

NO __

Is there a program for cleaning and pre-filters and filter change?

Documented

Application

NE ---
DM ---
AD ---
EX ---

Does it prevent the return of dust, the injectors and air extractor?

Documented

Application

NE ---
DM ---
AD ---
EX ---

Art. 12 Monitoring Equipment

12.1. – What policy is taken for the installation of equipment?

Documented	Application
NE	---
DM	---
AD	---
EX	---

12.2. – Does the machinery or equipment of appropriate instrumentation for operation, control and maintenance?

Documented	Application
NE	---
DM	---
AD	---
EX	---

12.3.- What is the system calibration of the instruments of control in critical processes?

Documented	Application
NE	---
DM	---
AD	---
EX	---

12.4.- There are:

12. – List of equipment and instruments that require calibration, control and maintenance

Documented	Application
NE	---
DM	---
AD	---
EX	---

b.- Plans and programs for verifying calibration of equipment and instruments

Documented	Application
NE	---
DM	---
AD	---
EX	---

c.- List of responsible for the calibrations

Documented	Application
NE	---
DM	---
AD	---
EX	---

d.- A list of qualified contractors

Documented

Application

NE --
DM --
AD --
EX --

e.- Methods of calibration and reference standards

Documented

Application

NE --
DM --
AD --
EX --

f.- Calibration records, identifying the instruments needed , working range, resulting from the calibration of instruments and responsible signatures

Documented

Application

NE --
DM --
AD --
EX --

12.5.- How plans, implements, monitors and recording the preventive and connective maintenance? Is there a procedure? Are the activities documented and recorded?

Documented

Application

NE --
DM --
AD --
EX --

Annex 23

CHAPTER II

HYGIENE REQUIREMENTS FOR MANUFACTURING OPERATIONS

Art. 14 Commodities and Materials

14.1.- How is the sampling and testing of raw materials and packaging materials? Is it documented?

Documented		Application
NE	---	
DM	---	
AD	---	
EX	---	

14.2 .- How can one ensure the use of only raw independent materials that hold acceptable health standards?

Documented		Application
NE	---	
DM	---	
AD	---	
EX	---	

14.3.- a. – What is the process behind the control of raw materials, independent and packaging materials – packaging work?

Documented		Application
NE	---	
DM	---	
AD	---	
EX	---	

b. Is the quality of accepted levels specified?

Documented		Application
NE	---	
DM	---	
AD	---	
EX	---	

14.4.- How does one control the receipt of raw materials? Where are they received?

Documented		Application
NE	---	
DM	---	
AD	---	
EX	---	

- 14.5.- Where are the raw materials and inputs stored? How often do these rotate?
- | Documented | Application |
|------------|-------------|
| NE | -- |
| DM | --- |
| AD | --- |
| EX | -- |
- 14.6.- What is the condition of the containers, or packaging of raw materials or inputs?
- | Application | |
|-------------|-----|
| NE | -- |
| DM | --- |
| AD | --- |
| EX | -- |
- 14.7.- Are there documented procedures implemented that ensure and minimize contamination, when one has to introduce new raw materials in susceptible areas of contamination?
- | Documented | Application |
|------------|-------------|
| NE | -- |
| DM | --- |
| AD | --- |
| EX | -- |
- 14.8.- How does one control the defrosting speed of raw materials in need?
- | Documented | Application |
|------------|-------------|
| NE | -- |
| DM | --- |
| AD | --- |
| EX | -- |
- 14.9.- How does one ensure they are not refreezing?
- | Documented | Application |
|------------|-------------|
| NE | -- |
| DM | --- |
| AD | --- |
| EX | -- |
- 14.10.- Do you know the established limits set by the Codex or national standards on the use of raw materials or supplies of controlled use?
- | Documented | Application |
|------------|-------------|
| NE | -- |
| DM | --- |
| AD | --- |
| EX | -- |

Article 15 Packaging

15.1.- Are the supplier certificates that describe the characteristics of the packing material and its approval by FDA available? Are the specifications of the packing material perfectly known?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

15.2.- How is one guaranteed to have clean and suitable containers for final use?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

15.3.- Where are the packages / containers stored?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

15.4.- What mechanisms are used to protect the containers from flying glass when the packaging of this material is broken in the production line?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

Art.16 Water

16.1.- a. – What kind of water is used for the processes?

Documentation		Application
NE	--	
DM	--	
AD	--	
EX	--	

b.- How does one ensure the type of water will be used for the chosen processes?

Documented		Application
NE	--	
DM	--	
AD	--	

EX --

16.2.- a. – What type of water is used for the cleaning and washing of raw material, equipment and objects?

Documented	Application
NE --	
DM --	
AD --	
EX --	

b.- How does one ensure that the recovered water through evaporation or drying, when reused will not become contaminated in the recovery process?

Documented	Application
NE --	
DM --	
AD --	
EX --	

Art.17 Manufacturing Operations

17.1.- a. – What rules govern the organization of production?

Documented	Application
NE --	
DM --	
AD --	
EX --	

17.2.- The development of a product considers:

- | | | |
|---|------|-----|
| a. – This procedure is valid | Yes_ | No_ |
| b. – Use of appropriate locals | Yes_ | No_ |
| c. – Clean and appropriate areas and equipment | Yes_ | No_ |
| d. – Competent staff | Yes_ | No_ |
| e. – Raw materials and materials under specifications | Yes_ | No_ |
| f. – Records of performed operation | Yes_ | No_ |
| g. – Records of critical control points | Yes_ | No_ |
| h. – Comments and Warnings | Yes_ | No_ |

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

17.3.- The manufacturing process is carried based on:

– Cleaning & Order
 Yes_ No_

b.- Use of cleaning agents for cleaning and disinfection approved by regulatory codes
 Yes_ No_

c.- Cleaning and validation procedures periodically validated
 Yes_ No_

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

17.4.- Procedures and records

a. – For the different manufacturing stages Yes_ No_

b- Check – list of cleaning areas and presence of equipment and utensils

Yes_ No_

c. – Control of temperature and humidity over pressure

Yes_ No_

d.- Operation of instruments and control equipment

Yes_ No_

e. – Control of raw materials

Yes_ No_
 Application

Documented	
NE	--
DM	--
AD	--
EX	--

f. – How does one control the use of lethal or dangerous substances?

Documented		Application
NE	--	
DM	--	
AD	--	

EX --

g. – How does one identify the production status of products?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

17.5. – Is there a record or log of production?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

17.6. a. – How to identify and control the parameters and critical processes such as time, temperature, humidity, activity, Ph, pressure, flow rate?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

b. – How does one control the manufacturing conditions such as freezing, distillation, heat treatment, acidification and cooling?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

17.7. – How does one prevent the contamination of food by the other foreign material methods?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

17.8. – Where are the corrective actions taken?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

17.9. – How does one ensure that the air or gas used does not become a source of contamination?

Documented		Application
NE	--	
DM	---	
AD	---	
EX	--	

17.10. – How are the operations managed?

Documented		Application
NE	--	
DM	---	
AD	---	
EX	---	

17.11. – What is the policy for the disposal of altered-of-date products or of products that have fallen to the ground?

Documented		Application
NE	--	
DM	---	
AD	---	
EX	---	

17.12. – What is the policy used for the file control records of production and distribution?

Documented		Application
NE	--	
DM	---	
AD	---	
EX	---	

Article 18 POLLUTION PREVENTION OF CROSS CONTAMINATION

18.1.- What steps are taken to prevent the contamination of food with raw materials that are in the early stages of the process?

Documented		Application
NE	--	
DM	---	
AD	---	
EX	--	

18.2. – What steps are taken to prevent that the staff in contact with the raw materials at an early stage do not come into contact with the product in the final stage.

Documented		Application
NE	--	
DM	---	
AD	---	

Annex 24

CHAPTER III

QUALITY CONTROL SYSTEM: ASSURANCE AND QUALITY CONTROL

Art. 20 QUALITY CONTROL

Are there control procedures available for the prevention and reduction of avoidable and unavoidable effects such as natural ones?

Documented	Application
NE --	
DM --	
AD --	
EX --	

Art. 21 Section 21

21.1. Consider the control system and quality assurance of the following:

a. - Specification of materials?	Yes_	No_
b. - Criteria for acceptance, release, retention and rejection?	Yes_	No_
c. - Manuals and instructions for the equipment, processes, procedures?	Yes_	No_
d. - Protocol of manufacture?	Yes_	No_
e. - Authorizations and responsibilities for decision making?	Yes_	No_
f. - Record and technical history of the production lot?	Yes_	No_
g. - Records of cleaning, calibration and preventive maintenance?	Yes_	No_
Documented	Application	
NE --		
DM --		
AD --		
EX --		

21.2.- How does one ensure that the plans for sampling, laboratory procedures, specifications and test results produce reliable results?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

21.3.- Has the quality of health assurance or safety used through the HACCP been developed? Is it documented? Is it available for review?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

21.4. Where does the quality control of raw materials work in process and end products occur?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

Section 22 MAINTENANCE AND CLEANING

22.1.- Do the facilities and equipment have a suitable system of maintenance and operating conditions?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

22.2. a. - Are there procedures for the cleaning and disinfection that include the agents and substances used, concentration, forms of use, deployment requirements, frequency of cleaning?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

b.- How to ensure effective disinfection with agents or substances normally used?

Documented		Application
NE	--	
DM	--	
AD	--	

EX	--	
c. - Do the recorded verification inspections occur after cleaning?		
Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

Article 23 SANITATION PLAN

a. - Is it written? Does it contain at least:

a. - Cleaning and disinfection program	Yes_	No_
b. - Program available for the deposition of solids	Yes_	No_
c. - Pest Control System	Yes_	No_

b.- What security measures does the company put in place for the use of chemicals to control pests? Where is the pest control done?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

Annex 25

CHAPTER IV

PERSONAL FOOD HANDLER

Section 24 How does one ensure that the staff maintains personal hygiene?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

How does one show that staff is fully trained for their jobs?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

Art.25 Are there health certificates of staff who handle food?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

How often are medical checkups performed?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

What evidence of preventive health actions are shown?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

How does one ensure that no employee with a potential health condition, comes into direct contact with exposed food?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

Article 26 PERSONAL HYGIENE AND PROTECTION

26.1.- Are there written policies and advanced personnel that ensure product safety and pollution prevention?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

26.2.- How many are available? How often are changes placed? What is their design?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

26.3.- Where is the procedure of washable garments being done?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

26.4.- How does one ensure the adequate washing of the hands of the operators who are in contact with the food, and how often do they do this?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

26.5.- Do they have masks for critical operations?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

26.6.- What is the condition of the gloves?

Documented
NE --
DM --
AD --
EX --

Application

26.7 What is the condition of the shoes?

Documented
NE --
DM --
AD --
EX --

Application

Article 27 STAFF BEHAVIOR

27.1 Are the hair, beards or feet protected in critical areas?

Documented
NE --
DM --
AD --
EX --

Application

27.2 Are the nails short, clean, and unpolished?

Application
NE
DM --
AD --
EX --

27.3 Is the lack of jewelry, watches, or ornaments, and excessive makeup and perfume easily shown?

Application
NE
DM --
AD --
EX --

27.4 Are the lenses used made of plastic?

Application
NE
DM --
AD --
EX --

Are they insured?
 Documented Application
 NE --
 DM --
 AD --
 EX --

27.5 Is it clear that there is no indicatives of eating, drinking, smoking or chewing of any object or products?

Documented Application
 NE --
 DM --
 AD --
 EX --

Art. 28 Does the staff and visits meet which states the importance of the health protection standards? Are they identified?

Documented Application
 NE --
 DM --
 AD --
 EX --

Section 29 EDUCATION AND TRAINING

29.1.- Is there a training plan over health standards, hygiene and food handling?

Documented Application
 NE --
 DM --
 AD --
 EX --

29.2.- Are there training exercises for the new staff? Of old?

Documented Application
 NE --
 DM --
 AD --
 EX --

29.4.- The training of the plant personnel and maintenance involves at least:

a.- Designation of areas Yes_ No_

b.- Types of uniforms and accessories allowed and not allowed Yes_ No_

c. - Standards of behavior in the areas, including sanitary	Yes_	No_
d.- Caution to be taken to avoid cross contamination and risks	Yes_	No_
e. - Control and management of critical points	Yes_	No_
Yes_	No_	
f. - Surveillance and Monitoring of operations	Yes_	No_
g.- Critical Limits	Yes_	No_
h.- Connective actions	Yes_	No_
Documented	Application	
NE	---	
DM	---	
AD	---	
EX	---	
29.6.- Are the alluding ads that point to their necessity?	Application	
Documented		
NE	---	
DM	---	
AD	---	
EX	---	

Annex 26

CHAPTER V

STORAGE, DISTRIBUTION, TRANSPORTATION AND MARKETING

Art.31 Storage operations, take into account the following considerations:

- a. - The stores and warehouses contain appropriate health and environmental conditions Yes_ No_
- b.- – Are pallets used for storage? Yes_ No_
- c.- Is there a control system for rodents and pests? Yes_ No_
- d. - Is there a separation of at least 30cm between walls? Yes_ No_

- e. – Is there a use for the identification and condition of a product? Yes_ No_
- f.- Record temperature and relative humidity walk-in refrigerator or freezer? Yes_ No_

- g.- Is the execution of the FIFO system shown? Yes_ No_
Documented Application
NE ---
DM ---
AD ---
EX ---

Art. 32 CONSIDER TRANSPORT

- a. – Are the food and raw materials transported under hygienic conditions and a safe temperature? Yes_ No_
- b.- Appropriate speeds Yes_ No_
- c.- Where is a cold chain required? Yes_ No_

- d.- Is the area of the vehicle used for transporting food easily washable? Yes_ No_
- e. - Policies for the transportig of food and other substances Yes_ No_
- f.- Records for the verification of the suitability of the vehicles before the loading of food. Yes_ No_
Documented Application
NE ---
DM ---
AD ---
EX ---

Section 33 DISTRIBUTION

Is the FIFO system used in the activities and areas of distribution?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

34 MARKETING OR FOOD PRESERVATION

a. - How does one ensure the marketing and sale of food preservation?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

b. - Are the cabinets, furniture and shelves easy to clean?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

c. - Do you have the necessary equipment?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

d. - Do you use the FIFO system?

Documented		Application
NE	--	
DM	--	
AD	--	
EX	--	

SIGNATURES:

AUDITED:

AUDITORS:

Annex 27





EMBUTIDOS
G PIGGIS





ahumados



navideños