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Action plan to meet the FDA's quality standard for juice 21 CFR 120 HACCP for the business PROALVA, before exportation of fruit pulp to the United States.

Thesis to graduate with a diploma in

International Studies with a Bilingual Mention in Foreign Commerce

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Dedication

To those passionate about commerce, an exchange of cultures and ideals that are immersed through interaction; to those who wish to study in order to share a service, offering quality and safety with international standards of quality.

Acknowledgments

To God, for the guidance of every step I have taken, to my parents who have been my pillar of support to achieve all of my goals, to my sister to has been my second mother who has supported me always and to my boyfriend who has motivated me throughout to make all my dreams come true.

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Summary

This work analyzes the FDA's quality standard "21 CFR 120 HACCP" for juices in order to carry out an action plan on which the company PROALVA will base itself before entering into the United States market. This study of the company will determine which processes it will maintain and which need to be improved or implemented in order to comply with the quality standard and receive Prior Notice, which is the last step before the exportation of products.

Introduction

Traditionally, Ecuadorian companies have been characterized by being presented with a series of complications when expanding their markets, above all when it comes to products with added value, since they need to meet quality standards of which many of them are unaware. In this sense, the purpose of this project is to create an action plan, a road map, of the necessary steps to be taken to meet the quality standards required by the United States for the entrance of foodstuffs according to the current legal regulation specifically in the company PROALVA, fruit pulp manufacturer, that seeks to export internationally.

Consequently for PROALVA expansion into foreign markets, the necessity has emerged to meet all the requirements demanded by the United States; in order to do this, the company must follow regulations and comply with everything required to meet this goal, keeping in mind that this is a company that is currently undertaking the process of internationalization. Therefore, the main problem is the owners' lack of knowledge of the quality standards in the United States and how to meet them. Hence, this graduation work will generate an understandable road map applicable to this specific case.

The idea of this action plan comes from the need to find the necessary means to help us meet the standards required by the United States prior to the exportation of fruit pulps. PROALVA has already been 10 years in the national market, notably improving and implementing quality standards that make it competitive and attractive, both nationally and internationally.

Within the development of the action plan, a market investigation was carried out to determine the target market for the international commercialization of fruit pulps. As a result, the United States was selected as the destination country, and then the import standards of that country were identified. Afterwards, the operative function of the

company was determined and the currently recognized standards in order to outline what the company lacks to comply with the FDA standard for Juices 21 CFR 120 HACCP.

Through the study of the FDA standard for Juices 21 CFR 120 HACCP, the principles that PROALVA currently adhere to can be compared with the requirements of the standard, in order to implement a road map that indicates what has to be done by the company to meet the requirements and comply with the standard that will help it to introduce itself into the United States market and be competitive with other Ecuadorian producers of fruit pulp.

CHAPTER 1: HISTORY OF THE COMPANY PROALVA, BASIC CONCEPTS OF QUALITY AND SAFETY, GOOD MANUFACTURING PRACTICES AND EXECUTIVE ORDER 3253

1.1 History of the company

The company PROALVA, located in Quito, has been in the Ecuadorian market since 2006. PROALVA is a company dedicated to the production and commercialization of fruit pulps that meet with national quality standards, which is why they can satisfy the demands of Ecuadorian clients, offering products safe for consumption.

The mission of PROALVA is the production and commercialization of fruit pulps. The vision is to be a competitive company in the production and commercialization and ready to satisfy market needs, form a work team that is capable of developing skills in fruit management and to grow according to the needs that present themselves.

The company currently holds the following certifications: BPM certification, number BPMA-003 PROALVA, awarded by ICONTEC and endorsed by ARCSA.

1.2 Machinery

To transform fruit into pulp, PROALVA has several machines, among which are:

- Cauldrons for cooking and packaging
- Blenders
- Citrus extractors
- Citrus slicers
- De-pulping machines
- Packaging machines
- Sealing machines

1.3 Nutritional composition of the product

Among the flavors most desired by consumers are: blackberry, tree tomato, naranjilla, strawberry, mango, and tamarind. See Annex 1. The presentations currently produced are of: 100g, 500g and 1kg.

The information of each product varies, according to the fruit, because they can be sweeter or sourer or need to use different components to get a greater variety of product. See Annex 2 and 3.

The product can be offered all year round since Ecuador has a varied climate, which makes it easy to get fruit from different regions at affordable prices to the benefit of the end consumer.

1.4 Quality

"The concept of quality takes on a complex range of attributes that influence value or acceptability to the consumer. These characteristics include: nutritional value; sensorial properties, such as appearance, color, aroma, texture and taste; as well as the methods of elaboration and functional properties. Many of the characteristics considered of quality can be subject to regulatory, standard, or contractual conditions." (Arispe and Tapia)

The philosophy of the system of quality supposes that, if activities are planned, programmed and documented, it is easier to repeat over and over again the operative processes that achieve desired standards of quality. In this way, the problems that affect quality both directly and indirectly can be controlled, evaluated and resolved. (Secretary of Economy of México)

By assuring quality the company complies with a process that implies: planning, production, presentation, inspection, distribution, post-sale services and statistical techniques of process control and, of course, personnel training. This is how they provide enough trust in that a product or service satisfies client expectations. (Secretary of Economy of México)

Through a quality assurance system it is possible to offer products or services to clients. To be in competitive conditions, in regards to other providers, it is necessary to give greater guarantees to potential clients, in terms of costs as well as in delivery time and post-sale services; accordingly, relying on the elements of a system of quality is an indicator of being on the path of quality and depending on a trustworthy provider.

According to the Secretary of Economy: "the companies that implement systems of quality possess the following characteristics:

- Definition of a policy of quality. - The senior management of each company should clearly establish its objectives and make them known to all personnel, and the general guidelines for achieving them. This obliges them to promote and develop, at all level of consciousness, the meaning of quality and constantly indicate the importance it has to the company's clients. It is indispensable to inform the personnel that the products or services provided or manufactured in bad quality lead to high costs economically and to the company's image.

- Quality execution. - Senior management should establish the corresponding control and management functions in order that, at each level of the company, workers apply the quality policy that has been determined.

- Design the company's quality assurance model.- Even if there are already existing models or general outlines that signal work sequences, responsibilities, and procedures, it is important to take care that their selection be considered from the senior management down to the last of the employees.

- Certification. - After meeting all the previously mentioned requirements, the company should seek the certification of some accredited organization. This will show clients that their products or services meet conditions of trust that any consumer needs."

1.5 Safety

According to the World Health Organization (WHO), food safety is a fundamental matter of public health for all countries and one of the issues of greatest priority for consumers, producers and governments. (Arispe and Tapia)

Safety is defined by the Royal Academy of Spanish Language as the nature of not causing harm. (Spanish Royal Academy)

The purpose of food safety is to prevent all the risks that can present themselves due to bacteria, microbes, chemical or physical contaminants that can affect the health of consumers.

Food safety in public health emphasizes the following:

- The growing range of illnesses transmitted through food and the appearance of new hazards with food origins.
- Fast changes in food production, elaboration and commercialization technology.
- Advances and developments of new and better analysis and identification techniques of microorganisms.
- The international commerce of foodstuffs and the need to synchronize standards of food safety and quality.
- Lifestyle changes, including rapid urbanization.
- Gradual consumer requirements relating to safety and a greater demand of information on quality.

In developing countries trying to improve the safety and quality of foodstuffs, the health of the population must be protected by reducing the risk of illnesses transmitted by food and facilitating the globalization of the economy and the opening of new markets; transparency and openness in all aspects, as well as the application of tools such as Good Agricultural Practices and Good Manufacturing Practices.

Food manufacturers should ensure the healthiness of their products to protect the health of the consumer. In order to do this, they must implement a quality control system that can identify, evaluate and control potential hazards associated with prime materials, ingredients, processes and manipulation of the finished products.

The high demands of industrialized countries require trust and to satisfy the nutritional needs of consumers in order to maintain a healthy lifestyle. With the opening of new markets there has been an enormous increase in world commerce and also in the large risk of the transmission of illness from foods. This has led to consciousness of the efficient application of safety controls throughout the food chain, from production and elaboration to commercialization and consumption of the product.

The lack of the correct application of a safety system can result in rejection by and unattractiveness to international markets, which is why it is indispensable to eliminate barriers to competition. To do so, the company has to ensure the health of consumers, which is why it is important to audit and obtain accredited certifications in order to export.

1.6 Good Manufacturing Practices

It is important to mention that in Ecuador, Good Manufacturing Practices are the principles to maintain hygiene in the manipulation, preparation, elaboration, packaging and storage of foods for human consumption. Their objective is to guarantee that foods be manufactured in adequately sanitary conditions and decrease the inherent risks of production (PRO ECUADOR). Thus, all the manufacturing processes where the final product has contact with humans should guarantee that they are manufactured in adequately sanitary conditions and that the inherent risks of production are reduced.

1.7 Executive Order 3253

Furthermore, since 2002, in the Executive Order 3253 - Regulations of Good Manufacturing Practices for Processed Foods, with which must complied in all the applicable points, depending on the product - allowing ARCSA to dictate the technical sanitary standards in a time period of no more than 90 days, even though by that time the new Substitutive Technical Regulation of Good Manufacturing Practices for Processed Foods ARCSA-DE-042-2015-GGG R.O (Official Record 555) already existed.

In effect, the National Agency for the Regulation, Control, and Sanitation Vigilance (ARCSA), issued the substitute technical regulation of good manufacturing practices for processed foods that applies to all the companies that process, package, store and distribute foodstuffs, with the end of guaranteeing the safety of all foods, their safety, and their competitiveness at a national and international level. (Official Record 555)

CHAPTER 2: MARKET SELECTION

2.1 Concepts of the market and market selection

To begin the current chapter, it is necessary to explain the fundamental concept of a market. According to Patricio Bonta and Mario Farber, authors of the book *199 Questions on Marketing and Publicity*, a market is "where offer and demand converge. In a smaller sense, the market is the combination of all the real and potential buyers of a product. For example: the auto market is formed not only by those who possess an automobile but also by those who would buy one and have the means to pay their cost" (Bonta and Farber). And for Allan L. Reid, in his book *Modern Sales Techniques and their Applications*, the market is like "a group of people that can buy a product or service if they wish it" (Reid).

Market selection, on the other hand, refers to markets of interest. The selection becomes an act of crucial relevance to companies that decide to carry out their activities in foreign markets (Yeoh, Ojala and Tyrvainen).

Such a decision requires information on the possible destination markets and the value of that information is going to determine, in great part, the level of success or failure reached in an international market (Anderson and Strandskov). These concepts allow for the clear identification and understanding of the following analysis.

2.2 The world market and high production line standards

Today, the world market is demanding due to concerns about different illnesses derived from products of daily consumption. Therefore, what is demanded are products that favor people's wellbeing, so countries producing different foodstuffs have seen the need to improve their production techniques and implement new and innovative practices in order to be competitive in a market that is concerned about the wellbeing of the people who are going to consume their products of preference.

In addition to the demands of the production line, to ensure safety it is also imperative to understand the answers to the following questions by the market: Why do people buy a certain product? What influences supply and demand? Which season sees more demand? These are some of the questions that companies should ask since they are a key tool when entering a new market and, furthermore, allow them to get to know and adjust to the different tastes being demanded. The goal is a progressive growth of rising sales numbers and that the competition not turn out to be an obstacle to success.

2.3 Introduction into a new market

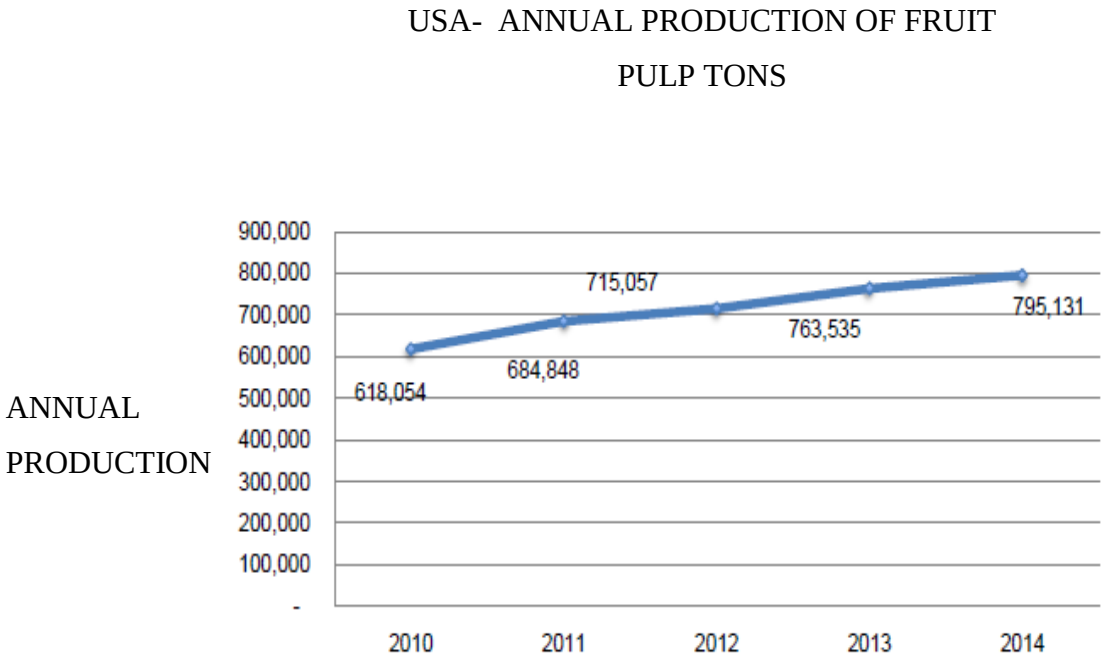
Prior to the introduction into a new market it is essential to carry out an analysis through a rigorous investigation with reliable sources, in order to generate an adequate decision-making process. The analysis reduces uncertainty and minimizes risks of the productive activity to be carried out. To generate this information, with the Ecuadorian state, it is necessary consult to an institution specialized in the subject: the Institute of Promotion of Exportation and Investment (PRO ECUADOR). Through it, Ecuadorian companies can find out about the principles and potential commercial partners, as well as receive an analysis on consumption, costs, points of sale, distribution channels, and the demands with certain demographical characteristics of the products to be exported.

2.4 Commercialization of fruit pulps in the United States

In this particular case, the product is fruit pulps, but before its exportation the different information that PRO ECUADOR has gathered on the commercialization of fruit pulps in the United States should be reviewed. That country is a potential destination country according to the intention of the company and the analysis done through the information obtained (PRO ECUADOR).

Currently, the market for natural fruit pulps is rapidly increasing in the majority of industrialized countries. Due to the accelerated rate of life, people have less time to quickly prepare nutritious food and that constitutes one of the primary motives to consider the United States as a preferred country. It is enough to know that in the last few years there has been a growing tendency to consume fruit pulp, according to the following:

Graph 1: Annual production of fruit pulp in the United States 2010-2014



Source: PRO ECUADOR

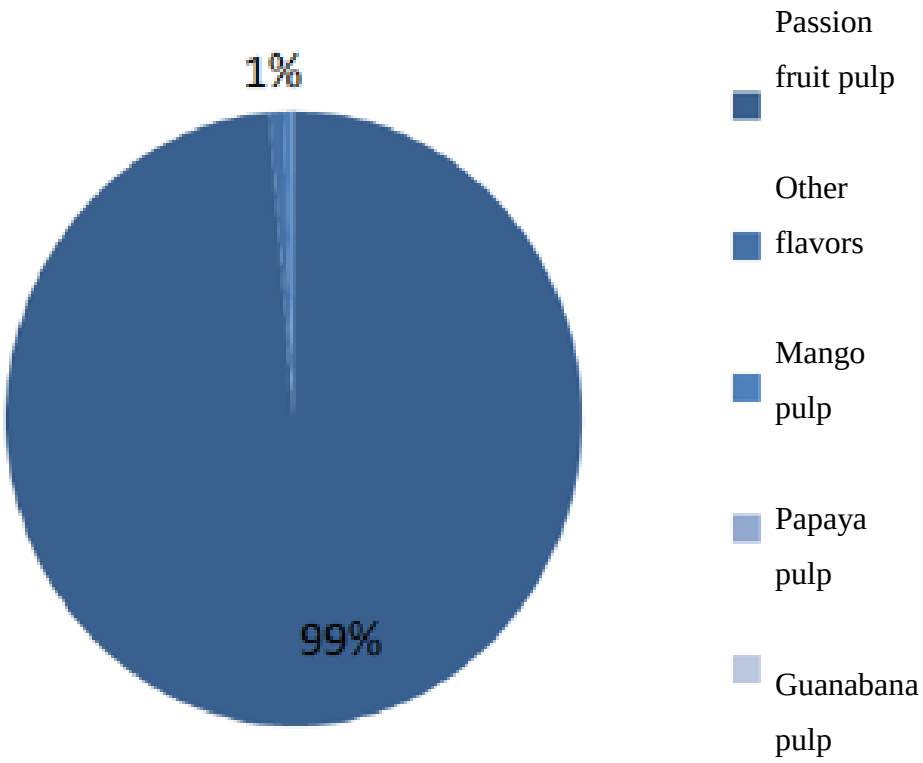
As can be seen in the graph, from 2010 to 2014 the annual production of fruit pulp in the United States grew from 618,054 to 795,131 tons. It can be seen that the market has demand, which is why PROALVA sees it as an attractive market to enter, with healthy

ingredients with a minimal use of sugar that does not affect people's health and the introduction of non-traditional flavors.

It could be inferred that by exporting to the United States the product will be amply distributed, not only because of the size of the country but also because of the differentiation from competition, both internal and international, that PROALVA would achieve through the diversity of the product, considering the following:

Ecuador is one of the countries with the greatest diversity in the world, due to its geographical position that generates a singular variety of climates conducive to the cultivation and production of fruits - and its derivatives - with incomparable flavors, quality and characteristics than other places of origin. Therefore, this plus, and in order to stop being a primary exportation country, other alternatives have been sought out to change what for a long time has not been able to be achieved. Seeking new products, with added value, the result was fruit pulp that are highly sought after in foreign markets for being practical, affordable, high-yielding, and quick to prepare.

Graph 2: Average percentage of fruit pulp exports

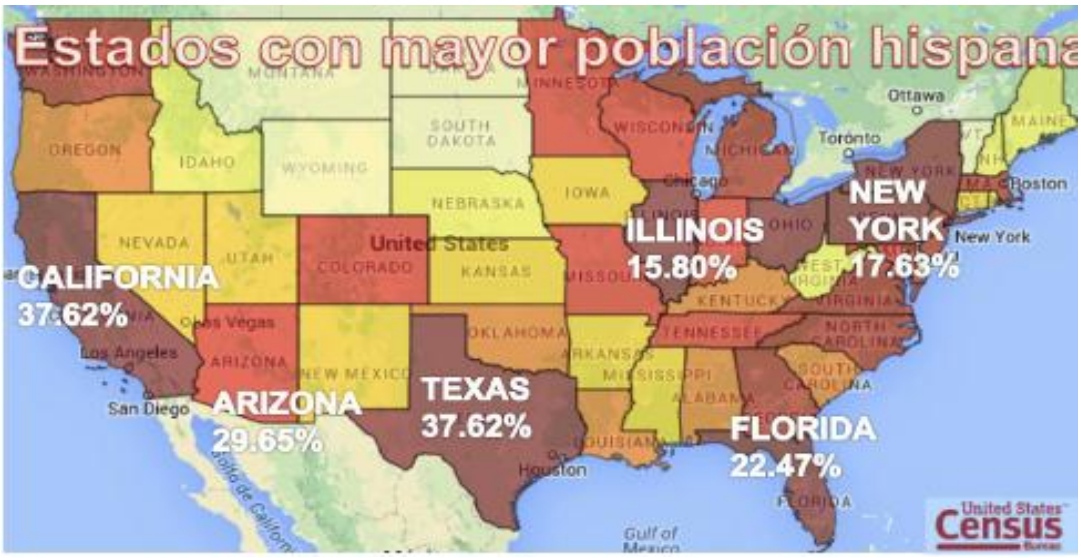


Source: PRO ECUADOR

As can be seen in the graph, maracuyá (passion fruit) pulp is the most sought after in the United States market, with 99% consumption. PROALVA, with different flavors highly sold in national territory, such as tomate de árbol (tree tomato) or tamarind, could introduce the product to different states with a large Ecuadorian population, like New York, New Jersey, Connecticut, etc., potential consumers. This would generate higher income to Ecuador from exports with added value through innovation.

Although the United States is considered one of the largest and most consumerist countries in the world, it must be taken into account that not all of the states behave similarly. It is indispensable, therefore, to target the cities where there are higher concentrations of Hispanics to direct the product to a nostalgic market, where consumers prefer a traditional fruit juice from their region of origin that cannot be found in the United States.

Graph 3: Percentage of the Hispanic population in the United States



Source: PRO ECUADOR

As can be seen in the graph, the large percentage of Hispanics in various states of the United States represent a market of interest since a large percentage of this group are Ecuadorians that maintain a sense of belonging and nationalism.

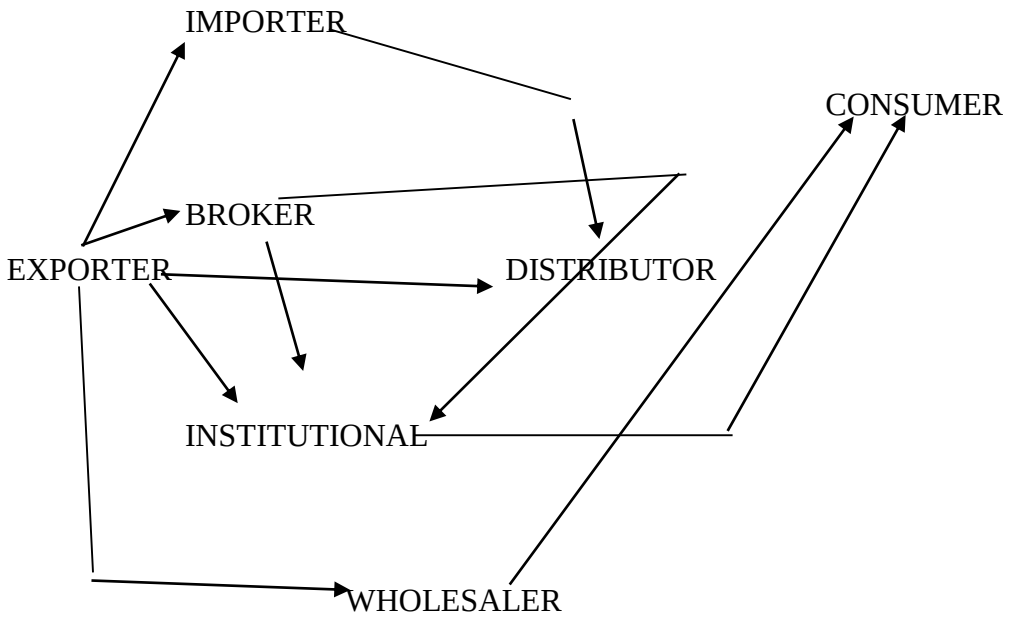
According to the data from PRO ECUADOR, the profile of the consumer of fruit pulp in the United States is in a rage of 20-50 years old. This represents a great opportunity to introduce other flavors, offering a healthy product that is easy to prepare, which is a positive result if taken into account the fast-paced lifestyle in this country.

Additionally, the presentation of the pulps will vary according to consumer preferences. As indicated in the first chapter, there are presentations of 100g, for quick consumption,

applicable in restaurants since this presentation renders approximately 14oz. Then there is the 500g presentation for sales to self-service establishments, such as small, medium and large markets, and the 1 kilogram presentation to be preferably sold wholesale.

Finally, to enter into the international market a distribution channel is necessary. This channel is going to be the necessary tool for the product to reach the hands of the consumer, so the best channel for the exporter must be selected in order to avoid unnecessary costs.

Graph 4: Distribution chain



Source: PRO ECUADOR

As can be seen in the graph, there are different ways to get from the exporter to the consumer. To know which channel is the most appropriate the distributors must be analyzed. If they are wholesale or if they need a broker to reach the consumer, the

appropriate logistics must be acted upon when exporting. Once the market has been identified, an analysis of the specific regulations to enter this product into the United States market will be carried out.

CHAPTER 3: FOOD SAFETY MODERNIZATION ACT, INTERNATIONAL EXPORTATION CERTIFICATIONS, STANDARD 21 CFR 120 HACCP AND NOTICE BEFORE EXPORTING

3.1 Food Safety Modernization Act

The Food Safety Modernization Act (FSMA) was signed into law by the President of the United States Barack Obama, on January 4, 2012. This law is an important development and update on the subject of food safety. Its objective is to protect public health by focusing more on preventing food safety problems, instead of limiting itself to reacting to problems after they occur (U.S. Food & Drug Administration).

This law gives the Food and Drug Administration (FDA) new executive authority to achieve higher rates of compliance with food safety standards based on prevention and possible risks. In regards to prevention, for the first time the FDA will have a legislative mandate to require comprehensive controls at all levels of food supply. (PRO ECUADOR, Analysis of International Markets Bulletin).

According to the Exporter Service Desk at PRO ECUADOR new regulations stand out that the FSMA gives new authority to the FDA (U.S. Food & Drug Administration):

- Legal framework and relevant sources of information
- Production Control System: this new regulation will establish that each stage of food production must have a monitoring system that shows different errors and immediately corrects them.
- Furthermore, the FDA together with the Ministry of Agriculture of each country, will inspect producers at their place of planting, in order to provide guides to not contaminate crops, not use contaminated water that affects crops.
- Required standards related to food safety.

3.2 Guide to international certifications

According to PRO ECUADOR, certifications are the system established to identify a product with specific characteristics. There are governmental, international and business agencies dedicated solely to certifying that the practices and processes of production meet the particular standards of each one of them: in quality, origin, fair trade, sustainability, organic, biodynamic, relation, etc. (PRO ECUADOR)

Furthermore, there are international certifications that are required to prove that the product meets the necessary standards to leave the country or enter into a new market with its own regulations. This adjusts to the regulations of each country, for example: Certification of health registration, Certificate of Good Manufacturing Practices, HACCP. (PRO ECUADOR)

Likewise, there are voluntary certifications, those that are required by the consumer because it provides a written guarantee that the product, process or service meets the specified requirements. In our medium, certifications become fundamental for both the buyer and the seller, because both parties seek to be socially and economically responsible, and above all to create new markets and inspire consumer confidence. (PRO ECUADOR)

According to the PRO ECUADOR website, updated in 2016, there are 3 essential steps to obtaining certification:

1. Implementation: based on embodying technical standards of certification within the company's processes.
2. Inspection: makes reference to a review by a technician sent by the certifying organization, which verifies that the company meets all the standards included in the certification.

3. Certification: After the technician sends the final report with the implemented corrections, a certification request is sent by the company to the certifying organization's head office.

Graph 5: Inspection and certification process

Source: Comprehensive Exporter Assessment Service Department

As PRO ECUADOR shows in its International Certifications guide, Graph 5, there are 10 steps to better understanding the inspection and certification process:

Step 1: Contact between the company and the certifying organization can take place electronically, physically, or by telephone.

Step 2: The certifying organization sends the appropriate request form for the required certification, the introduction of the certifying organization and the Information Packet about the certification process.

Step 3: The company fills out the forms, signs them with the day's date; the documents are sent to the certifying organization.

Step 4: The certifying organization sends a quote for the cost of the certification process selected.

Step 5: The company receives the information with the contracts, analyzes the proposal and agrees by signing. Later, it signs the contract and sends the documents to the certifying organization.

Step 6: The certifying organization sends the technical documents to be completed by the operator according to references. The client responds sending the documents and the requested information.

Step 7: The certifying organization sends a bill to the company, which pays off the bill within the required time frame.

Step 8: The certifying organization plans an inspection with the operator. In the case of a certification renewal, an inspection will be made by the auditor before a year passes since the previous inspection, and a report will be issued. The report will be sent by the auditor to the person responsible for the certification.

Step 9: The person responsible for the certification will study the report and the annexed information. He or she will send the Certification Decision to the client with the incompliances found.

Step 10: The client returns the signed Certification Decision to the certifying organization. The company responds to the incompliances found by implementing corrective actions. The maximum time to respond is 2 months.

After being approved, the certifying organization sends the CERTIFICATE, or requests it from the main office and then sends it.

3.3 Important certifications and private seals

It is indispensable to PROALVA to have HACCP certifications, which stands for Hazard Analysis Critical Control Points. This is a systematic preventative process to guarantee food safety, in a logical and objective way (Secretary of Joint Programming FAO/WHO, 1999).

The HACCP is not a quality management system but a food safety management system that should be defined as a prerequisite to the implementation of a quality management system, as a legal obligatory requirement applicable to all food establishments and is necessary for acquiring certification. (PRO ECUADOR, HACCP Guide) Furthermore, it is a recognized and internationally accepted method to help organizations identify, evaluate, and systematically control the hazards that can affect food security and hygiene. To do this, control mechanisms are implemented to not surpass the critical limits associated with each control point established throughout the food production process (PRO ECUADOR).

3.4 Requirements to obtain HACCP certification

To obtain HACCP certification, the company must implement 7 basic principles:

- Principle 1: Identify hazards
- Principle 2: Identify Critical Control Points (CCP)
- Principle 3: Establish critical limits
- Principle 4: Establish a monitoring system of the CCP
- Principle 5: Establish corrective actions
- Principle 6: Establish a verification system
- Principle 7: Create a documentation system

1. Identify hazards

The first principle prepares a list of all the operative processes, primarily where most significant hazards occur. For each hazard there is a corrective preventative measure or immediate solution.

To identify the hazard points throughout the entire procedure used for food production, it is considered from the starting point. That is, from harvesting, to elaboration, manufacture and distribution, to the purchase point; at which point it is necessary to identify prime materials, ingredients and all the foods used because they can contain some kind of contaminant be it physical, chemical or biological. This prevents the multiplication of germs that can cause errors (PRO ECUADOR, HACCP certification requirements).

Furthermore, the HACCP team must detail all of the biological, chemical or physical hazards that can be produced in each stage, and describe the preventative measures to be applied to control hazards or errors, which will be analyzed and will have to eliminate or reduce to very low levels acceptable to the production of a safe food product.

2. Identify Critical Control Points (CCP)

With all the information obtained previously, from the different stages of the elaboration process of a product, contamination points are identified through an analysis of prime material to the elaborated product. This will determine the critical control points, taking into account that hazards can surface at each stage and if it is necessary, training should be provided to those responsible for the chain of decision-making (PRO ECUADOR, HACCP certification requirements).

If it is determined that there is a risk or hazard in a stage in which control is necessary to maintain safety, and if there is no existing preventative measure that can be adopted, the product or process must be modified at any stage: before or after.

3. Establish critical limits

"This principle imposes the specification of critical limits for each preventative measure; these critical limits are the levels or tolerance prescribed that should not be exceeded to ensure that the CCP is effectively controlled" (PRO ECUADOR, HACCP certification requirements).

If any of the parameters regarding the control points is beyond the critical limit, the process will be out of control, which is why the preventative measures are associated with the critical limits that act as a safety limit.

In some cases, there can be more than one critical limit for a certain stage, to define the limit and status for a product or process. Measures of temperature and time tend to be used, humidity level, pH, aqueous activity, chlorine available, microbiological

specifications, among others, such as organoleptic parameters like appearance, smell, color, taste and texture (PRO ECUADOR, HACCP certification requirements).

4. Establish a monitoring system of the CCP

Through a monitoring system programmed by a responsible, trained person with the ability to make corrective decisions at a critical control point in relation to its critical limits. The ideal is to detect a loss of control at the CCP, at which information is quickly provided on physical and chemical measures as well as microbiological tests, so that everything occurs faster and, in general, are indicators of the microbiobial state of the product to take corrective measures before the product that is being elaborated has to be rejected. (PRO ECUADOR, HACCP certification requirements).

5. Establish corrective actions

With the goal of correcting potential deviations, corrective action plans should be formed, established and clearly defined in order for them to be carried out by a responsible person who understands the process and the measures that must be taken at each CCP, considering the HCCP system. These measures should assure that the CCP is under control and that includes making decisions related to the affected product.

The procedures related to the deviations and the product's destination should be documented in HACCP records. This prevents the monitoring results from showing a loss of control at a CCP and allows the re-establishment of control before the deviation results in a loss of safety.

When a deviation from the established critical limits is inevitable, the corrective action plans should respond objectively to:

- Define beforehand where the rejected product will go
- Correct the cause of rejection to regain control of the CCP
- Keep a record of corrective measures that have been taken in response to a deviation at the CCP.

The use of control sheets that identify CCPs and corrective measure to be taken when a deviation occurs will permit adequate documentation when it is necessary to repeat them, which is also recommended to keep on file for a prudent amount of time.

6. Establish a verification system

Procedures must be established to allow for verification that the HACCP Program functions correctly. Methods, procedures, monitoring tests and confirmation must be used, including random testing and analysis. The frequency of verification should be enough to validate the HACCP Program.

Verification activities can include the following:

- HACCP test (system and responsibilities) and of its records
- Test of deviations and product destination
- Operations to determine if CCPs are under control
- Validation of the critical limits established

7. Create a documentation system

Establish a documentation system of procedures and appropriate records of these and their application. For this is it necessary to have an efficient and exact record-keeping system through the HACCP program, which can be combined into a manual since it applies to all stages.

According to PRO ECUADOR in the HACCP certification requirement guide, the records can be kept in the following manner:

- Responsibilities of the HACCP team
- Modifications introduced to the HACCP Program
- Description of the product throughout processing
- Use of product
- Flow chart with CCPs indicated
- Hazards and preventative measures for each CCP
- Critical limits and deviations
- Corrective actions

After defining the above points, it can be determined that for the HACCP system to work correctly, the personnel are the main protagonist in making sure the HACCP plan works, because every facet of production is their responsibility, in addition to maintenance, and the provision of indispensable prime material and supplies.
This makes their understanding of extreme importance to high performance levels, less waste, fewer hazards, and no errors to correct, with the goal always being a safe product.

In regards to the benefits of the implementation of the HACCP system, in the first place it ensures food safety and the consequent reduction of costs due to minor complaints from consumers; the brand's positioning improves, offering a product that meets the needs demanded, in a privileged position with its consumers.

3.5 FDA Standard 21 CFR 120 HACCP for Juices and Pulps

According to the U.S. Health and Human Services Department website, updated on April 1, 2016, the most important points of the regulation are synthesized into an analysis according to the product to be exported, such as fruit pulps. PROALVA has obtained a minute study of everything it needs to implement regulation 21 CFR 120 prior to exporting to the United States.

3.5.1. Applicability

Any juice sold as such or used as an ingredient in drinks should be processed according to the requirements as defined in the Federal Law for Food, Medicine and Cosmetics, 21. Processors must apply the existing FDA provisions to minimize microbiotic hazards to food safety of fresh fruit and vegetables in the management of raw agricultural products.

3.5.2 Definitions of 120 within the Standard 21 CFR

The following definitions also apply, of which are described those most used in PROALVA's action plan:

- Cleaning. Means washing with water of adequate sanitary quality.
- Means of control. To prevent, eliminate or reduce.
- Control methods. Means any action or activity to prevent, reduce to acceptable levels or eliminate a hazard.
- Critical control point. Means a point, step or procedure in a food process in which a control method can be applied and in which that control is essential to reducing an identified food hazard to an acceptable level.
- Critical limit. Means the maximum or minimum value at which a physical, biological or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of identified food hazards.
- Importer. Means the owner or consignee in the United States at the time the food product enters the United States, or the agent or U.S. representative of the foreign owner or consignee at the time of entrance into the United States. The importer is responsible for ensuring that the goods entering the U.S meet all applicable laws.
- Monitoring. Means carrying out a planned sequence of observations or measurements to evaluate if a process, step or procedure is under control and to keep a precise record for verification purposes.
- Airtight product. Means a product that is hermetically sealed and, when stored at room temperature, will not show any microbiotic growth.
- Validation. Means that the element of verification focused on the gathering and evaluation of scientific and technical information to determine if the HACCP plan, when adequately applied, will effectively control identified food safety hazards. (FDA)

3.5.3 Standard Sanitation Operating Procedure (SSOP)

At sanitary controls, each processor should have or implement a standard sanitation operating procedure that covers sanitation practices before, during and after processing (SSOP).

According to the U.S. Health and Human Services Department, the SSOP will address:

- Water security.- water that is in contact with food or surfaces used in the making of ice;
- Condition and cleaning of surfaces or in direct contact with foods, such as: utensils, gloves and outward clothing, and raw and processed products;
- Prevention and cross-contamination of unsanitary objects, food packaging materials;
- Keeping hands washed, disinfection of hands and sanitary facilities;
- Protection of foods, food packing materials and surfaces that come into contact with foods from the adulteration of lubricants, combustibles, pesticides, cleaning compounds, disinfectants, and other chemical, physical and biological contaminants;
- Labeling, storage and appropriate use of toxic compounds;
- Control of employee health conditions that could result in microbiological contamination of food, food packaging materials and surfaces in contact with foods;
- Elimination of plagues from food processing plants;
- Monitoring, the processor will monitor the conditions and practices during processing with enough frequency to ensure, at minimum, conformity with conditions and practices; in which the processor should correct, in a timely manner, those conditions and practices that do not comply;

- Records, the processor should maintain SSOP records that, at minimum, document the monitoring and prescribed corrections.

3.5.4 Hazard analysis

A hazard analysis will be done in writing to determine if there are any existing potential food hazards for each kind of juice processed which identifies control methods that the processor can apply to control and stop these hazards. The written hazard analysis will consist of the following:

- An evaluation of each identified food hazard to determine if the possibility of the hazard occurring is reasonable and therefore constitutes a food hazard that should be dealt with in the HACCP.
- A food hazard that is likely to occur, for which a prudent processor will establish controls such as: data about illnesses, scientific reports and other information provide a base to conclude that there is a likelihood of a hazard occurring.

This evaluation will include an evaluation of the seriousness of the illness or injury if the food hazard occurs.

3.5.5 Legal background

If a processor does not have and implement a Hazard Analysis Critical Control Points (HACCP) system that complies with requirements. Whether or not the actions of a processor are consistent with ensuring the security of the juice will be determined through an evaluation of the processor's general implementation of its HACCP system.

3.5.6 Records

Each processor should maintain the following records that document its Hazard Analysis Critical Control Points (HACCP) system:

1. Records that document the implementation of the standard sanitation operating procedures (SSOP);
2. A required written analysis of hazards;
3. The required HACCP plan in writing;
4. Records that document the current application of the HACCP plan that includes:
    a. Monitoring the critical control points and their critical limits, including registering in real time the temperatures and other measurements, according to what is laid out in the HACCP plan; and
    b. Corrective actions, including all the actions taken in response to a deviation; and
    c. Furthermore, documents that register the verification of the HACCP system and the validation of the HACCP plan or hazard analysis, as the case may be.

Likewise, all the required records should include:

1. The name of the processor or importer and the location of the processor or importer, if the processor or importer has more than one location;
2. The date and time of the activity reflected in the report;
3. The signature or initials of the person in charge of operation or creating the record; and
4. The identity of the product and production code, as the case may be. The processing information and other information will be recorded in the records at the time of observance. The records will contain the values and real observations during the control.

3.5.7 Record retention

1. All required records will be kept at the processing plant or in the place of business of the importer in the United States for, in the case of perishable or refrigerated

juices, at least a year after the date on which said products were prepared, and in the case of frozen, preserved products or products in storage, for 2 years or the shelf life of the product, whichever is greater, after the date of preparation of the products.

2. Storage is permitted outside the place of the required processing records after 6 months after the date of 24 hour monitoring of the official revision request, and the electronic records are considered accessible, as well.
3. If the transformation facility closes during a prolonged period of time among stationary packaging, the records can be transferred to another reasonably accessible place at the end of the stationary packaging, but will be immediately returned to the transformation facility for official revision upon request.

3.5.8 Documentation

The reports will be signed and dated by a higher-level individual within the processing plant or by a high-level administrator of the processor. These signatures should mean that the records have been accepted by signing.

- After initial acceptance;
- Upon any modification; and
- After the verification and validation of agreement.

3.5.9 Public disclosure

- All of the required records should not be available for public disclosure or commercial secrets or commercial information or confidential financial information.
- The required records to be maintained are subject to disclosure once they are publicly available, if they do not cause competitive difficulties, such as generic HACCP plans that reflect standard industry practices.

3.5.10 Training

The person who has met the requirements can be responsible for the following functions:

a. Developing risk analyses, including the outline of control measures, as required.
b. Developing a Hazard Analysis Critical Control Points (HACCP) plan that is appropriate to a specific processor, to meet requirements;
c. Verifying and modifying the HACCP plan according to the corrective action procedures and specified validation activities;
d. Review required records.

The person who carries out the listed functions in letter "a" of this section will have successfully completed the training on applying HACCP principles to processing juices at least the equivalent of that received in the standard curriculum recognized by the FDA, or will be qualified in other ways through work experience for these functions.

3.5.11 Application of requirements on imported products

There are 2 requirements that every importer of juice must meet:

1. Obtain the juice from a country that has an active memorandum of understanding (MOU) or a similar agreement with the Food and Drug Administration that covers food and documents the equivalent or the compliance with the inspection system of the foreign country with the U.S., in order to precisely reflect the relationship between the signing parties and is completely functioning and applicable.
2. Have and put in practice written procedures to ensure that the juice that the importer receives for importation to the United States was processed according to the requirements. The procedures should prevent, at minimum:
    a. The specifications of the product that are designed to ensure that the juice is not adulterated under the Federal Food, Drug and Cosmetics Act because it could be damaging to ones health or because it could have been processed under unsanitary conditions; and

b. Positive measures to guarantee that the products offered for importation were processed under controls that meet these requirements. These steps can include any of the following:
    i. Obtaining from the foreign processor the Hazard Analysis Critical Control Points (HACCP) plan and the program of requirements before required standard operating procedure records that are related to a specific lot of food offered for importation;
    ii. Obtaining a continual or specific certificate from an appropriate foreign governmental inspection authority or third party that certifies that the imported food has been processed according to requirements;
    iii. Regularly inspecting the foreign processor's facilities to ensure that the imported food is processed according to requirements;
    iv. Maintaining and copy on file, in English, of the risk analysis of the foreign processor and the HACCP plan, and the foreign processor's written guarantee that the imported food meets requirements;
    v. Periodically test the imported foods and keep on file a copy in English of the foreign processor's written guarantee that the imported product is processed according to requirements; or
    vi. Other appropriate verification measures that provide an equal level of guarantee of compliance with requirements.

3.5.12 Competent authority

An importer can contract a third party to help or carry out any or all of the verification activities, including writing the verification procedures of the importer in the name of the importer. The importer should also keep records, in English, that document performance and the results of the positive measures.

3.5.13 Determination of compliance

The importer should provide proof that all the juices offered for import to the United States have been processed under conditions that meet requirements. If there are no guarantees that an imported juice has been processed under conditions equal to those required for national elaboration under the same requirements, the product will appear adulterated and will not be allowed to enter.

3.5.14 Pathogen reduction

To comply with requirements, juice product processors should include in their Hazard Analysis Critical Control Points (HACCP) plans, measures that remain constant during a period of time, as least as long as the conservation period of the product when it is stored in normal conditions and subject to moderate mistreatment.

The following juice processors are exempt from this paragraph:

A juice processor that uses on stage of thermal treatment enough to achieve stability in storage of the juice or a thermal concentration process that include thermal treatment of all the ingredients, as long as the processor includes a copy of the thermal process used to achieve storage, stability or concentration.

1. If these conditions or practices are not met, correct those that do not meet the HACCP plan; or
2. If the conditions and practices are met, the processor should validate the HACCP plan in regards to the 5 log reduction standard; and
3. Take corrective measures as established in 120.10. The corrective actions should include the guarantee that no product enters the market that is harmful to ones health as established in 120.10. (FDA)

3.6 Labeling

To be exported to the United States, the product must meet the current standards of the U.S. Department of Agriculture and the FDA, agencies that regulate food and drugs.

Fruit pulp should have an efficient packaging and shipping system during exportation to the United States that protects the product from any possible risks, that adds value and that meets the requirements of the consumer and current regulation and legislation to not meet with any inconveniences when importing to the destination country.
The primary objective of packaging being to contain, protect, and conserve the product during its storage and distribution; PROALVA's fruit packaging has to have the following characteristics:

The first requirement is for the importer to register with the FDA, who will send instructions on how to label the product, and later assign a registration number that will identify it as a "food packager or processor". The general requirements for labeling food products are:

- Identify the food.
- List the ingredients.
- Name and direction of the manufacturer.
- Nutritional information.
- Net weight.
- Allergen information.
- Relevant information.

3.6.1 Manufacturer's declaration

The declaration of the country of origin should be noted. If the name and address of a national firm declares itself as part of the firm responsible for the distribution of the product, the declaration of the country of origin will appear close to the name and the address, in a comparable font size.

The declaration of identity is the name of the food, which should appear on the front label. Prominent type or print should be used for the declaration of identity in black lettering. The font size should be proportional to the most prominent printed material on the front label and should be one of the most important characteristics.

The name to be used should be that established by law or regulation. If there is no existing law or regulation, the declaration of identity should be the common or usual name of the food, if it has one. If it does not have a common name, a descriptive and appropriate name that does not cause confusion should be used.

3.6.2 Net weight

The declaration of net weight (the net quantity of the contents) is placed distinctively on the bottom area that occupies 30% of the display paper, generally at a level parallel with the base of the packaging.
Printed food labels should show net weight in the metric system of measurement (grams, kilograms, milliliters, liters) and in the measurement system of the United States (ounces, pounds, liquid ounces). The declaration in the metric system can be placed before or after the declaration in the U.S. measurement system, or above or below it. Each one of the following examples is correct (additional examples are included in the regulations):

- Net weight 1lb 8oz (680g)
- Net weight 1lb 8oz (680g)
- 500ml (1 pt 0.9 fl oz)
- Net weight 1 gal (3.79L)

For net weight declarations, the minimum size of the font is the smallest possible according to the available space for the labeling of the primary display paper (PDP). The following is a table of the minimum size according to the PDP area.

Table 1: Area of primary display paper

Area of primary display paper	**Minimum font size**
≤ 5 in² (< 32 cm²)	1/16 in (1.6mm)
5 in² a 25 in² (32- 161 cm²)	1/8 in (3.2 mm)
25 in² a 100 in² (161- 645 cm²)	3/16 in (4.8 mm)
100 in² a 400 in² (645-2.580 cm²)	1/4 in (6.4 mm)
>400 in² (> 2.580 cm²)	1/2 in (12.7 mm)

Source: U.S. FDA Food Regulations

3.6.3 List of ingredients

The list of ingredients is placed on the same label panel as the name and address of the manufacturer, the packager or the distributor. This can be the information panel or the PDP. It can be placed before or after the nutritional information label and the name and address of the manufacturer, packager or distributor.

The water added to prepare a food product is considered an ingredient and should be mentioned in descending order of predominance according to weight. Always mention the common or usual name for ingredients, unless there is a regulation that establishes a different term.

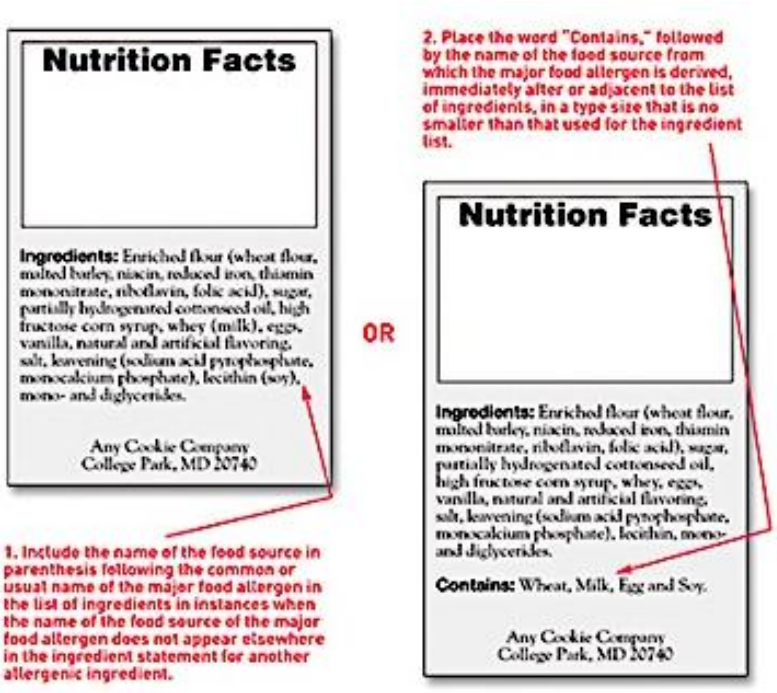
3.6.4 Allergy information

This refers to the ingredient that forms part of the following eight foods or food groups, or an ingredient that contains proteins derived from one of these groups:

- Milk
- Eggs
- Fish
- Crustaceans
- Tree nuts
- Wheat
- Peanuts
- Soy

Allergens should be declared on the label as shown:

Graph 6: Allergens

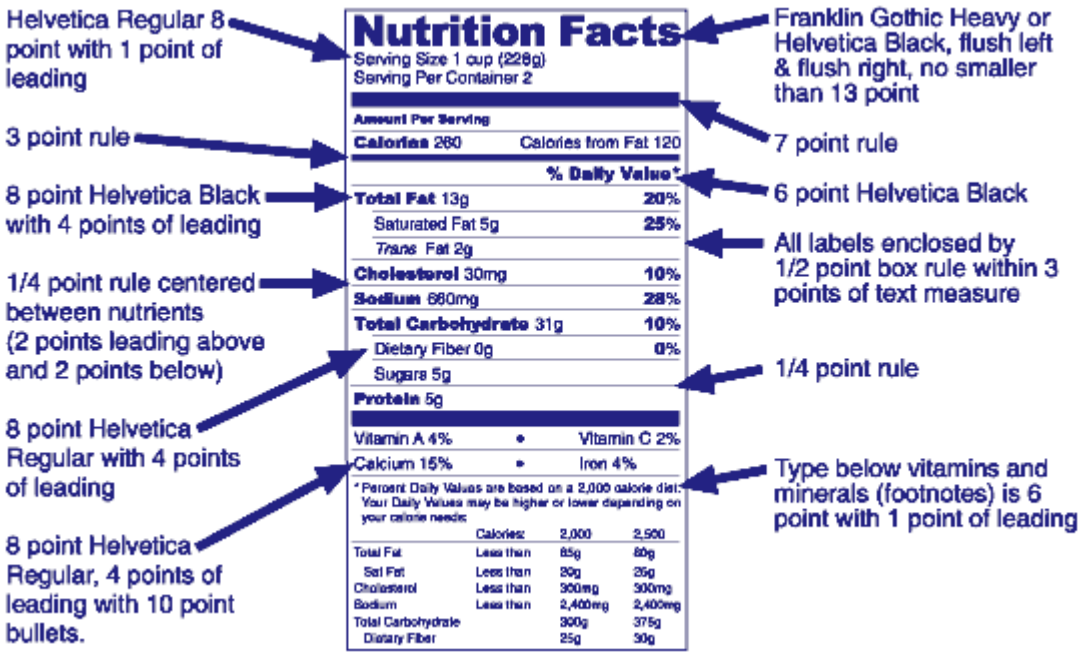


Source: U.S. FDA Food Regulations

3.6.5 Nutritional label

The nutritional information label can be placed together with the list of ingredients, the name and address (of the manufacturer, packager or distributor) on the primary display paper (PDP). These three label declarations can also be placed on the information panel (the label panel to the right of the PDP or, if there is not enough space on the side panel, in the next panel to the right). On packages with insufficient space on the PDP and the information panel, the nutritional information label can be place on an alternative panel that can be seen by the consumer.

Graph 7: Nutritional Label



Source: U.S. FDA Food Regulations

In Graph 7 an example can be seen of the graphs used by the FDA to show the nutritional information label, all the formatting requirements are specified in the Federal Regulations Code. Furthermore, the nutritional information label includes a black rectangle or a color printed on a white or neutral background.

If the nutritional information label must be presented in a second language, the nutritional information can be presented on separate labels for each language or on a label with the second language and the translation of all the required information, after the English version (Registrar Corp).

CHAPTER 4: ACTION PLAN, CONCLUSIONS AND RECOMMENDATIONS

4.1 Prior notice

Registrar Corp assists in the compliance with the requirements of Prior Notice of the U.S. Food and Drug Administration (FDA), in which the following three steps must be completed:

1. Fill out the prior notice form
2. Provide billing information
3. Send the completed forms to the U.S. fax: +1-757-244-0179

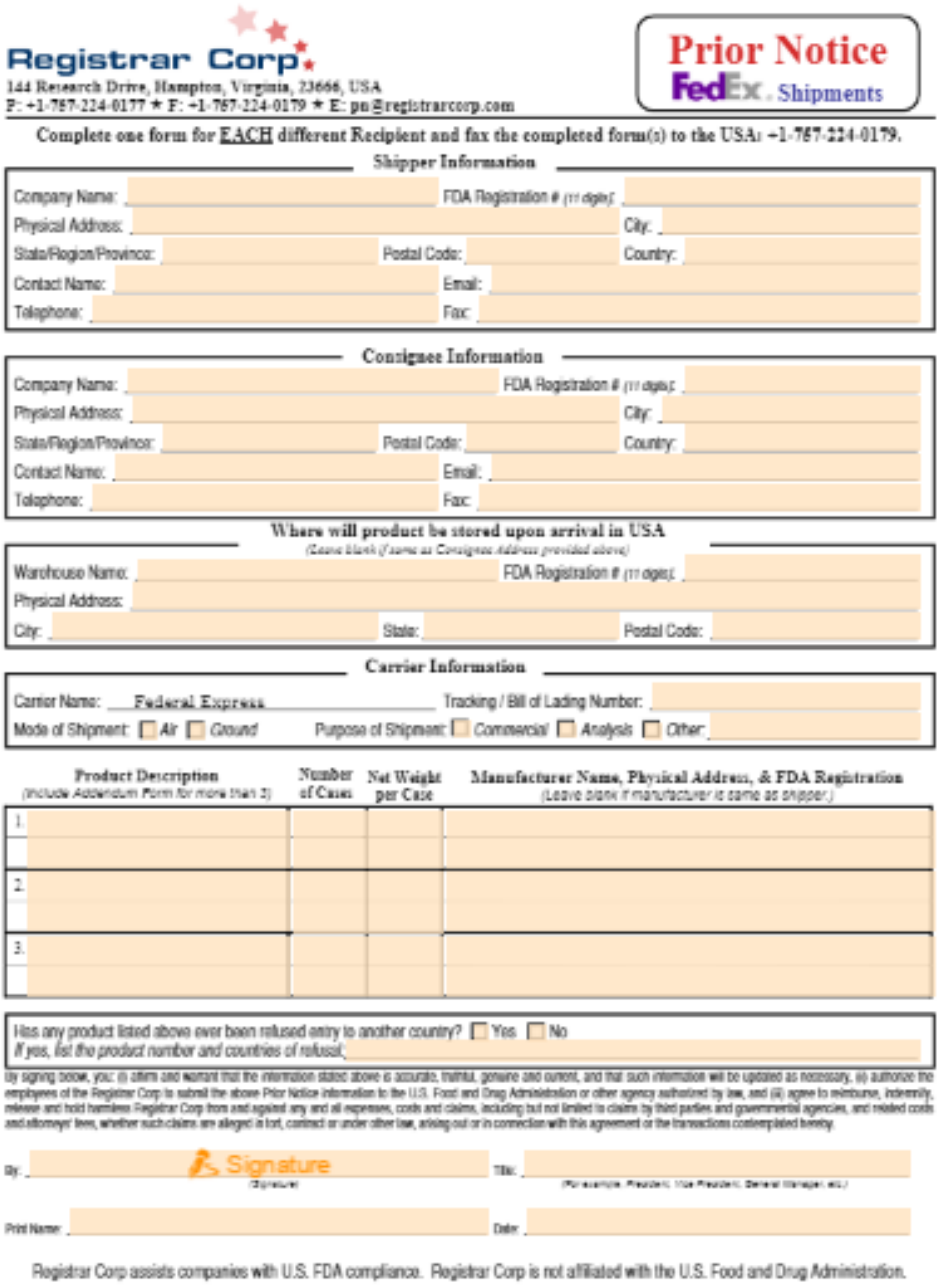
Upon receiving the diligently completed forms, Registrar Corp:

- Will manage the Prior Notice process with the U.S. Food and Drug Administration (FDA) and U.S. Customs, and
- Border Protection Service (CBP), and
- Provide in a matter of hours the confirmation page with the corresponding bar code. (U.S. Food and Drug Administration)

In addition, a photocopy of the Confirmation Page with the Bar Code must be made and send together with the shipment or package; the Prior Notice is expected to be received to comply with United States Regulations.

PROALVA has decided to export its product by sea, for which it must fill out the Prior Notice for sea freight, as a primary requirement. The following graph shows all the requirements that must be fill in.

Graph 8: Previous Notice



Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
P: +1-757-224-0177 ★ F: +1-757-224-0179 ★ E: pn@registrarcorp.com

Prior Notice
FedEx Shipments

Complete one form for EACH different Recipient and fax the completed form(s) to the USA: +1-757-224-0179.

Shipper Information

Company Name: FDA Registration # (11 digits):
Physical Address: City:
State/Region/Province: Postal Code: Country:
Contact Name: Email:
Telephone: Fax:

Consignee Information

Company Name: FDA Registration # (11 digits):
Physical Address: City:
State/Region/Province: Postal Code: Country:
Contact Name: Email:
Telephone: Fax:

Where will product be stored upon arrival in USA
(Leave blank if same as Consignee Address provided above)

Warehouse Name: FDA Registration # (11 digits):
Physical Address:
City: State: Postal Code:

Carrier Information

Carrier Name: Federal Express Tracking / Bill of Lading Number:
Mode of Shipment: ☐ Air ☐ Ground Purpose of Shipment: ☐ Commercial ☐ Analysis ☐ Other:

	Product Description (Include Addendum Form for more than 3)	Number of Cases	Net Weight per Case	Manufacturer Name, Physical Address, & FDA Registration (Leave blank if manufacturer is same as shipper.)
1.				
2.				
3.				

Has any product listed above ever been refused entry to another country? ☐ Yes ☐ No
If yes, list the product number and countries of refusal:

By signing below, you: (i) affirm and warrant that the information stated above is accurate, truthful, genuine and current, and that such information will be updated as necessary, (ii) authorize the employees of the Registrar Corp to submit the above Prior Notice information to the U.S. Food and Drug Administration or other agency authorized by law, and (iii) agree to reimburse, indemnify, release and hold harmless Registrar Corp from and against any and all expenses, costs and claims, including but not limited to claims by third parties and governmental agencies, and related costs and attorneys' fees, whether such claims are alleged in tort, contract or under other law, arising out of in connection with this agreement or the transactions contemplated hereby.

By: Signature Title:
(Signature) (For example, President, Vice President, General Manager, etc.)

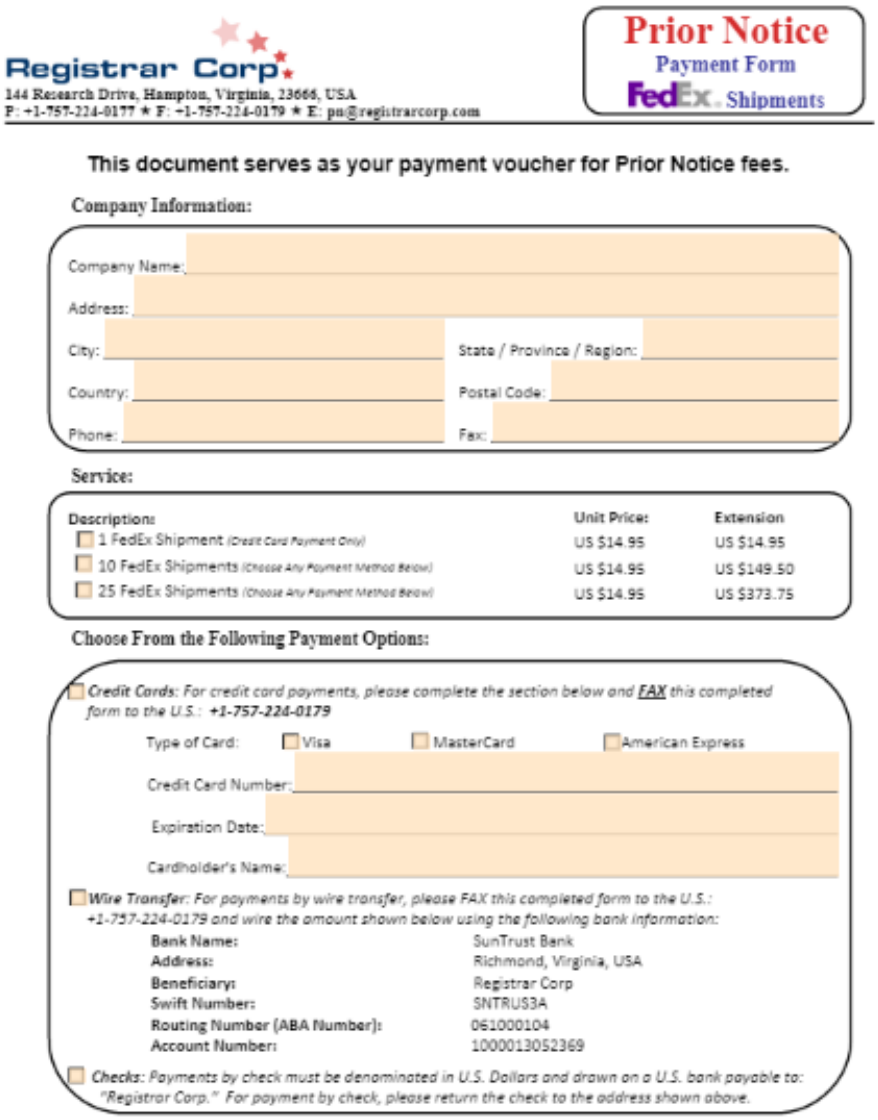
Print Name: Date:

Registrar Corp assists companies with U.S. FDA compliance. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Source: Registrar Corp

Moreover, it is obligatory to fill out the billing form. This document serves as a voucher of the payment of Prior Notice.

Graph 9: Billing



Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
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Prior Notice
Payment Form
FedEx Shipments

This document serves as your payment voucher for Prior Notice fees.

Company Information:

Company Name:
Address:
City:
State / Province / Region:
Country:
Postal Code:
Phone:
Fax:

Service:

Description:	Unit Price:	Extension
1 FedEx Shipment (Credit Card Payment Only)	US $14.95	US $14.95
10 FedEx Shipments (Choose Any Payment Method Below)	US $14.95	US $149.50
25 FedEx Shipments (Choose Any Payment Method Below)	US $14.95	US $373.75

Choose From the Following Payment Options:

Credit Cards: For credit card payments, please complete the section below and FAX this completed form to the U.S.: +1-757-224-0179

Type of Card: Visa MasterCard American Express
Credit Card Number:
Expiration Date:
Cardholder's Name:

Wire Transfer: For payments by wire transfer, please FAX this completed form to the U.S.: +1-757-224-0179 and wire the amount shown below using the following bank information:

Bank Name:	SunTrust Bank
Address:	Richmond, Virginia, USA
Beneficiary:	Registrar Corp
Swift Number:	SNTRUS3A
Routing Number (ABA Number):	061000104
Account Number:	1000013052369

Checks: Payments by check must be denominated in U.S. Dollars and drawn on a U.S. bank payable to: "Registrar Corp." For payment by check, please return the check to the address shown above.

Source: Registrar Corp

4.2 Conclusions

After carrying out this methodological proposal, the status of the company was can be analyzed in each of the three chapters, the market selected, as well as become familiarized with the guides for exportation of fruit pulps to the United States, regulation 21 CFR 120 HACCP that the FDA indicates is specifically what PROALVA must comply with in order to export to the United States, and finally, after the last step of registering on the Registrar Corp website, what is the action plan after completing all the prior steps.

- The situational analysis of PROALVA shows that the national industry of Ecuador meets the international standards for quality and good manufacturing practice.
- The U.S. market demand in regards to compliance with the regulation 21 CFR 120 HACCP for juice, market parameters and conditions, can be met satisfactorily.
- An adequately design action plan will help overcome obstacles the company will face whose goal is to enter into the field of exporting a national juice product.
- The processes followed by PROALVA, applying to regulations, are directed correctly and the defined road map permits it to legitimately place itself for confidently offering its product internationally.

4.3 Recommendations

- Knowing that the objective is to increase commercial offerings to markets in other countries means complying with complex arrangements that involve even international agreements. The companies involved in this process must be stimulated by the corresponding national institutions.

- Part of the stimulus of this effort, accepting that it is done from a developing country, should be the recognition of its management and the ease of paperwork, both official and private, which almost always slow down certain processes.

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Annex

Annex 1

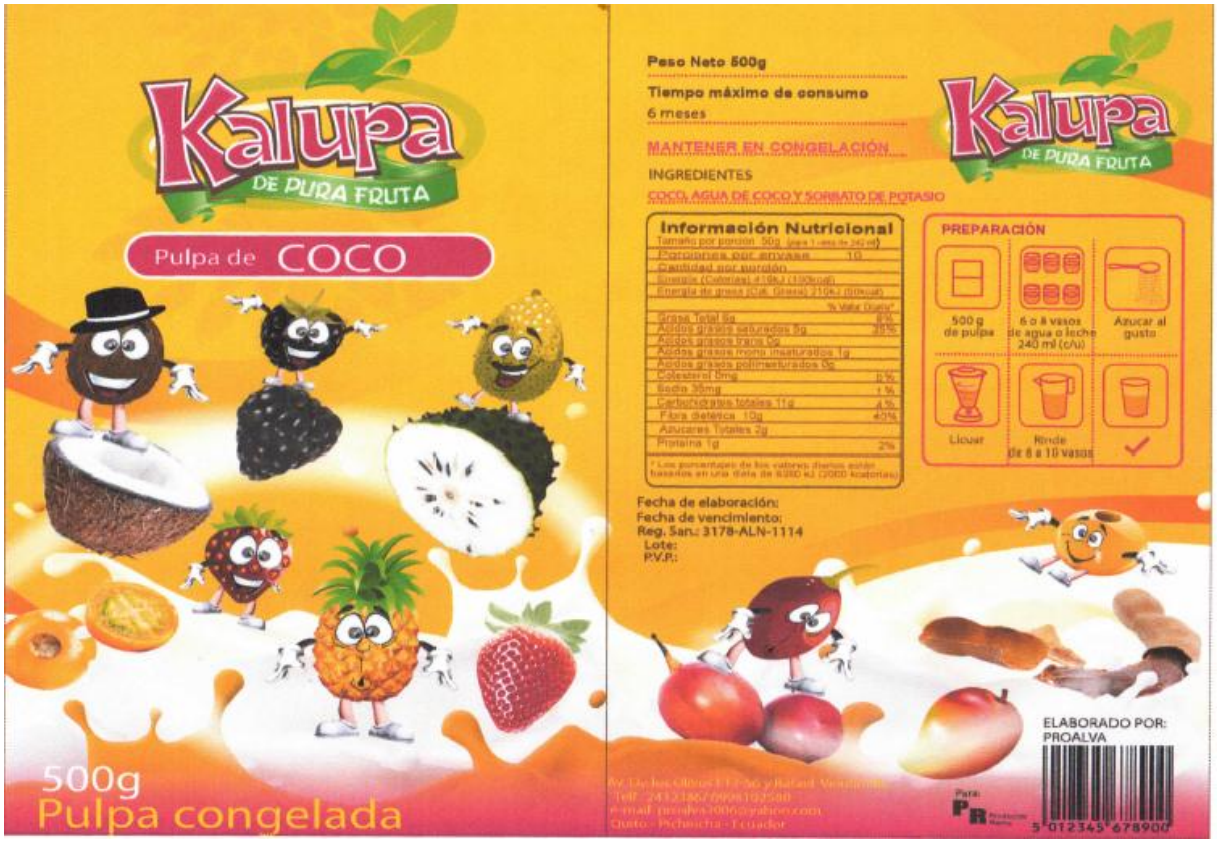
Ingredients and Recommended Retail Price for wholesales of juice in Ecuador

Name of pulp	Ingredients	RRP
Arazá	All pulps are 100% fruit.	1.62
Babaco		1.70
Coconut		2.15
Peach		2.16
Strawberry		1.66
Soursop		2.84
Guava		1.50
Lime		1.60
Mango		1.60
Apple		1.45
Passion fruit		2.60
Cantaloupe		1.55
Blackberry		2.52
Orange		1.58
Naranjilla		1.53
Papaya		1.40
Pineapple		1.55
Watermelon		1.40
Tamarind		1.70
Taxo		1.63
Tree tomato		1.60

Source: PROALVA

Annex 2

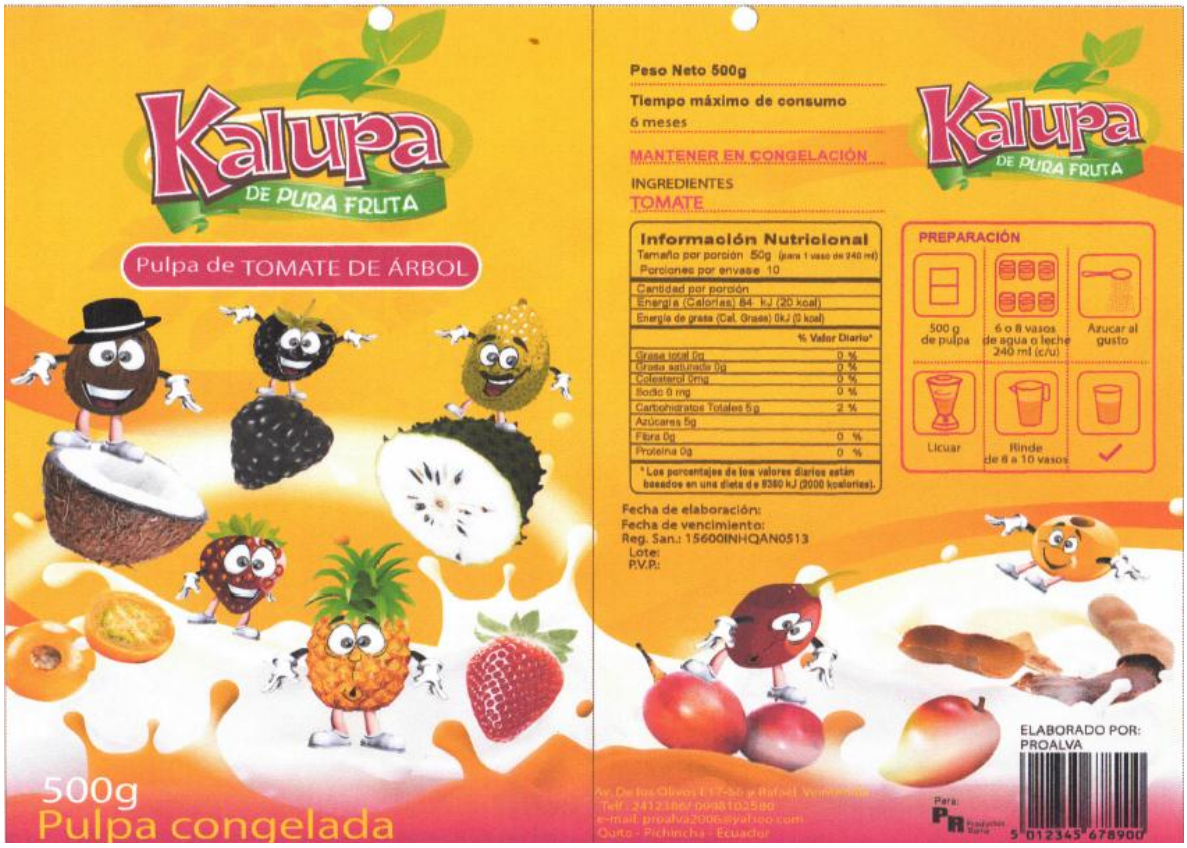
Coconut pulp label



Source: PROALVA

Annex 3

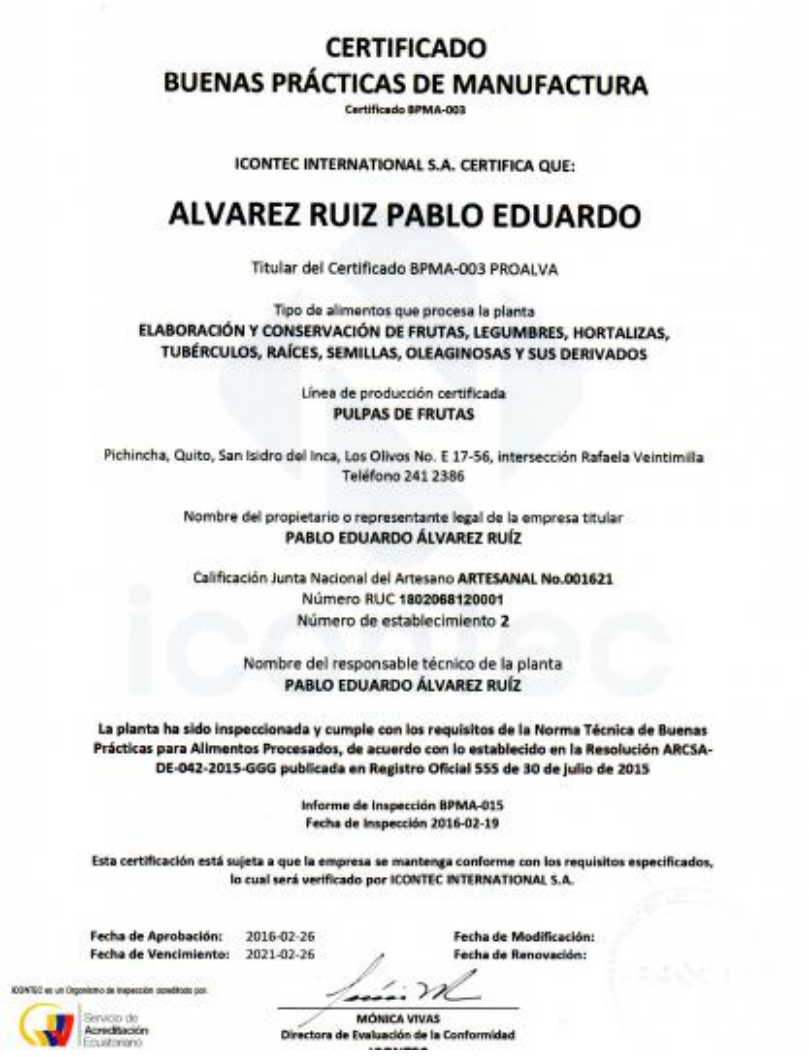
Tree tomato pulp label



Source: PROALVA

Annex 4

Certification of Good Manufacturing Practices



CERTIFICADO
BUENAS PRÁCTICAS DE MANUFACTURA
Certificado BPMA-003

ICONTEC INTERNATIONAL S.A. CERTIFICA QUE:

ALVAREZ RUIZ PABLO EDUARDO

Titular del Certificado BPMA-003 PROALVA

Tipo de alimentos que procesa la planta
ELABORACIÓN Y CONSERVACIÓN DE FRUTAS, LEGUMBRES, HORTALIZAS, TUBÉRCULOS, RAÍCES, SEMILLAS, OLEAGINOSAS Y SUS DERIVADOS

Línea de producción certificada
PULPAS DE FRUTAS

Pichincha, Quito, San Isidro del Inca, Los Olivos No. E 17-56, intersección Rafaela Veintimilla
Teléfono 241 2386

Nombre del propietario o representante legal de la empresa titular
PABLO EDUARDO ÁLVAREZ RUÍZ

Calificación Junta Nacional del Artesano **ARTESANAL No.001621**
Número RUC **1802068120001**
Número de establecimiento **2**

Nombre del responsable técnico de la planta
PABLO EDUARDO ÁLVAREZ RUÍZ

La planta ha sido inspeccionada y cumple con los requisitos de la Norma Técnica de Buenas Prácticas para Alimentos Procesados, de acuerdo con lo establecido en la Resolución ARCSA-DE-042-2015-GGG publicada en Registro Oficial 555 de 30 de julio de 2015

Informe de Inspección BPMA-015
Fecha de Inspección 2016-02-19

Esta certificación está sujeta a que la empresa se mantenga conforme con los requisitos especificados, lo cual será verificado por ICONTEC INTERNATIONAL S.A.

Fecha de Aprobación: 2016-02-26
Fecha de Vencimiento: 2021-02-26
Fecha de Modificación:
Fecha de Renovación:

ICONTEC es un Organismo de Inspección acreditado por:
Servicio de Acreditación Ecuatoriano

MÓNICA VIVAS
Directora de Evaluación de la Conformidad

Source: PROALVA