UNIVERSIDAD DEL AZUAY

Faculty of Legal Sciences

School of International Studies

Proposal for a Certification Model for NUNA Food Company

Authors:
Karla Sofía Auquilla Herrera
Mateo Sebastián Sarmiento Gavilanes

Director:
Juan Maldonado Matute

Cuenca – Ecuador
2026

DEDICATION

To my grandfather Luis Antonio for being part of this beautiful process, for teaching me through his actions, for being my greatest example of overcoming difficulties and fighting back, and for never letting me be defeated. Thank you, Grandpa, for so much love, so much patience. Thank you for filling me with life. This work is definitely for you.

To my mom, Johanna, and dad, Luis Eduardo, who are my daily source of motivation. I owe them not only my life, but also all my gifts and talents. Thank you so much for being the best parents life could have given me.

To my siblings, who inspire me to excel, who are my best friends, my life partners, my teachers, with whom I've shared laughter, mischief, tears, and countless anecdotes. I dedicate my entire life to you for teaching me to be a better person every day.

Finally, I also dedicate this achievement to myself. For a moment, I thought I wouldn't make it, and honestly, it hasn't been an easy process, but it was 100% worth it. Behind every text lies the whole context of years of effort. This work is dedicated to all the people who believed in me and in Nuna .

ACKNOWLEDGMENTS

To my parents, Elba and Mauricio, for their guidance and example. Their hard work, their values, and their support have been the guiding light of every step of my development.

To my siblings, Paulo and Sharon, for their words of encouragement, for their motivating conversations, and for being there for me at all times.

To my girlfriend, Thalía, for her love, patience, and constant encouragement. Thank you for believing in me even when I doubted myself.

To Falcor, my faithful companion, whose presence has been a relief and a comfort on the most demanding days.

Thank you all for being there, for supporting me, and for encouraging me to complete this important chapter of my life.

ABSTRACT

The ISO 22000 standard ensures both quality and food safety within the food industry. Nuna Sabores del Alma, a company engaged in the production of dairy products, aims to enhance its operational processes through the implementation of this standard. To this end, a comprehensive review of existing literature was conducted, along with a situational diagnosis of the company using a checklist based on the ISO 22000 requirements. Each parameter was evaluated and classified according to its level of compliance, followed by the development of an action plan to address the identified gaps. The situational analysis revealed partial compliance with the standard, with the most critical deficiencies observed in areas such as procedure validation, monitoring, auditing, and continuous improvement. Moreover, the analysis highlighted the need for the company to formally structure and implement the standard in order to ensure product safety and strengthen consumer trust. Consequently, an improvement plan was proposed to address each of the nonconforming requirements.

Keywords: Food safety, Food safety management, Good manufacturing practices, ISO 22000:2018, Quality management.

RESUMEN

La norma ISO 22000 garantiza tanto la calidad como la inocuidad en la industria de alimentos. Nuna Sabores del Alma es una empresa que se dedica a la producción de derivados lácteos y busca fortalecer sus procesos mediante la implementación de dicha norma, para ello, se realizó una búsqueda de la literatura existente, además de un diagnóstico situacional de la empresa, haciendo uso de una lista de verificación con base en la norma, cada parámetro se alineó de acuerdo con su nivel de cumplimiento, después de lo cual se realizó un plan de acción para disminuir brechas. El análisis situacional demostró un cumplimiento parcial de los requerimientos de la norma, siendo las deficiencias más importantes aquellas relacionadas con la validación de procedimientos, monitoreo, auditoria y finalmente mejora continua. Así mismo, se observó la necesidad de la empresa de estructurar e implementar la norma para asegurar la inocuidad del producto y fortalecer la confianza del consumidor, para lo cual se propone un plan de mejora de acuerdo a cada requisito que no se ha podido cumplir.

Palabras clave: Buenas prácticas de manufactura, Gestión de calidad, Inocuidad alimentaria, ISO 22000:2018, Seguridad alimentaria

INDEX

LIST OF FIGURES

LIST OF TABLES

INTRODUCTION

Today, the food industry must meet increasingly high standards in terms of quality, safety, sustainability, and corporate social responsibility. To address the challenges of local, national, and international markets, companies must adopt continuous improvement measures in their processes, incorporate quality management systems, and pursue certifications that guarantee the safety and quality of their products. Three key levels should be considered in process implementation: improvement, quality, and certification, as these strengthen public confidence in products.

ISO 22000 is one of the most robust certifications, ensuring compliance with the technical requirements essential for production and food safety. Its main components address production, trade, occupational health, the environment, animal welfare, and fair trade. In this context, continuous improvement serves as a relevant tool for systematizing processes and methodologies, such as the PDCA (Plan–Do–Check–Act) cycle, which supports compliance with the requirements established by the standard.

This study evaluates the Ecuadorian company Nuna Sabores del Alma, dedicated to producing natural dairy products with an emphasis on sustainability and corporate social responsibility, in pursuit of ISO 22000:2018 certification. The evaluation is based on a rigorous analysis of its management, value chain, and internal processes. Accordingly, the study examines both the company's strengths and the challenges it faces during implementation. It should be noted that the standard not only ensures legal compliance but also provides a comprehensive approach to public health protection, while significantly enhancing brand reputation and institutional image.

CHAPTER 1
INTEGRATION OF CONTINUOUS IMPROVEMENT AND CERTIFICATIONS IN FOOD PRODUCTION

1.1 Introduction

This chapter focuses on three main aspects of the food industry: (1) continuous improvement, (2) quality management, and (3) certification systems. These elements are essential for ensuring both the safety and quality of food production, as well as protecting public well-being. A deeper understanding of these concepts makes it possible to improve food quality while also enabling organizations to comply with increasingly stringent regulations that reflect global market standards. In particular, certifications are fundamental instruments for verifying compliance with requirements in areas such as trade, production, safety, occupational health, environmental protection, and ethical practices such as cruelty-free and fair trade.

Continuous improvement refers to an approach that promotes the ongoing optimization of both processes and products within organizations. This concept, widely applied in different fields, relies on tools such as the Deming cycle (Plan–Do–Check–Act, PDCA), which plays a central role in achieving operational efficiency improvements in the food industry and beyond. However, continuous improvement is not limited to food production; it also provides the foundation for progress in workplace safety and environmental stewardship (Grados & Obregón, 2018).

Quality management, in turn, addresses practices and standards that demonstrate compliance with consumer expectations and international requirements. For example, ISO 9001 establishes a framework for implementing continuous improvement and ensuring customer satisfaction across diverse sectors such as manufacturing, commerce, and environmental management. These requirements ensure consistency and uniformity, which are vital for achieving and maintaining market trust (Palacios, 2021). Certifications extend to compliance in fields such as occupational health, environmental protection, fair trade, and animal welfare.

Organic certifications and standards such as ISO 22000, GlobalG.A.P., and the BRC Global Standard for Food Safety constitute proven models applicable to the food industry. Beyond ensuring product quality and safety, they also facilitate access to international markets and enhance consumer confidence. It is therefore crucial not to limit the scope to

food certifications alone, but to select those most appropriate for the organization's needs and competencies, particularly those linked to sustainability and ethical practices. Within this framework, the chapter highlights how continuous improvement, quality management, and certifications interrelate to raise industry standards and provide greater assurance of safety, quality, and sustainability in food production.

1.2 Continuous Improvement

Continuous improvement is an approach that seeks to consistently implement enhancements in processes, services, and products within an organization. It is based on the notion that there is always room for improvement (Arriarán, 2023). Generally, changes do not occur abruptly; rather, they involve incremental adjustments that, when combined, yield significant long-term benefits. This process helps companies adapt more effectively to global market standards and respond to rising consumer expectations.

In quality management, continuous improvement is grounded in principles such as leadership commitment, full employee participation, and a customer-oriented focus. It also relies on data collection and analysis for informed decision-making. This approach supports the implementation, maintenance, and evolution of improvements over time (Enríquez et al., 2020). One of its most valuable tools is the PDCA cycle, also known as the Deming cycle, which offers a structured framework: it identifies specific areas for improvement, implements necessary changes, evaluates results, and manages adjustments according to the most urgent needs (Centro Europeo de Posgrado, 2024). This process fosters a culture of continuous learning and adaptation, which is essential for long-term success.

1.3. Quality management

Quality management relates to consumer expectations and ensures that products and services consistently meet them. It is not limited to the final product but also encompasses organizational processes, from the purchase of raw materials to delivery to the intended audience (Inquilla et al., 2017). Within the framework of continuous improvement, quality management provides the tools and methodologies needed to identify and address areas requiring enhancement. Quality standards such as ISO 9001, for example, offer a model for implementing a management system that is functional, robust, and efficient (Chacón & Rugel, 2018). These standards emphasize customer focus, leadership commitment, employee engagement, process orientation, and perseverance in establishing continuous improvement.

The successful implementation of a quality management system requires commitment from the entire organization. Leaders must foster an environment that prioritizes quality and continuous improvement while motivating staff to participate actively. It is also necessary to implement systems for evaluating, measuring, and monitoring quality performance. Such mechanisms make it possible to demonstrate progress, as well as to identify and apply appropriate adjustments.

Quality management is inherently linked to customer satisfaction. Addressing quality involves conducting studies and implementing actions aimed at anticipating both the needs and expectations of consumers. This enables organizations to design products and services that not only meet but also exceed expectations, thereby achieving greater acceptance, customer retention, and strengthening the company's reputation and competitiveness in the market.

1.4 Continuous improvement cycle

It is a structured methodology designed to assist companies in implementing incremental improvements, relying on the PDCA cycle as a vital tool throughout the process. Below, we review the conceptual approaches to the different stages of the cycle and their application in continuous improvement, as described by Pons et al. (2018):

- *Plan:* In this phase, potential opportunities for improvement are identified, and detailed plans are developed to address them in a timely manner. This requires defining specific objectives, allocating resources, and establishing a schedule. Key Performance Indicators (KPIs), essential for verifying the success or failure of improvements, are also determined.
- *Do:* Once planning is complete, the next step is to implement the planned actions. This stage highlights the need for a careful and coordinated process to ensure effectiveness. Clear and ongoing communication among all stakeholders is essential to guarantee a shared understanding of roles and responsibilities.
- *Check:* After the improvements have been implemented, results must be reviewed to determine whether the established objectives were met. This involves collecting and analyzing data to compare actual performance with planned objectives. Verification enables the identification and resolution of deviations or problems that may have arisen during implementation.

- *Act:* Based on the results of the verification, decisions are made regarding future actions. If the improvements were successful, they are standardized and formalized as part of the organization's regular operations. If the results were unsatisfactory, adjustments and corrections are made before repeating the PDCA cycle. This stage ensures that lessons learned during the process are integrated into future improvement initiatives.

The PDCA cycle fosters a culture of continuous learning and adaptation within organizations and the global marketplace. By repeating the cycle regularly, companies can systematically address challenges and seize opportunities for improvement. This methodology not only enhances quality and process efficiency but also strengthens organizational resilience by enabling proactive responses to market variations and customer expectations through planned decision-making. In short, continuous improvement, quality management, and the PDCA cycle are interrelated and mutually reinforcing, ensuring long-term productivity and success. Adopting continuous improvement with a systematic and structured approach allows organizations to optimize processes, satisfy customers, and maintain a competitive advantage.

1.5 Certification systems

Certification is a structured mechanism that provides assurance regarding the products or services offered by a company. It evaluates compliance with specific standards that enhance a brand's positioning in international markets by addressing aspects such as quality, safety, and commercial transparency. Certification enables companies to remain competitive by obtaining international validation. In essence, it is a procedure through which an entity, independent of both the producer and the buyer, formally verifies in writing that a product, process, or service meets established requirements.

1.5.1 Commercial certifications

Certifications are structured to ensure that both products and services comply with the standards required by international markets in terms of quality, safety, and commercial transparency. They also enable companies to strengthen their competitiveness in global markets and to comply with international trade regulations.

- ISO 9001: The most widely recognized international standard for quality management systems. It is applicable to any type of organization, including

manufacturing and service companies, and ensures that products and services meet customer expectations as well as international regulations.

- Certificate of Origin: Confirms the place of production or manufacturing of a specific product, which is essential for accessing certain markets and for compliance with trade agreements.

Application: Certifications can be implemented across diverse industries, including manufacturing, export, and dairy, among others.

1.5.2 Productive certifications

These certifications ensure that companies comply with and maintain quality and efficiency standards in their production processes, guaranteeing product consistency and minimizing errors.

- ISO 22000: This standard focuses on food safety, ensuring that products are safe for human consumption. It integrates the principles of the ISO 9001 quality management system with Hazard Analysis and Critical Control Points (HACCP) (Espinosa Ugarte, 2025).
- GlobalG.A.P.: A certification centered on responsible agricultural production. It ensures compliance with standards related to food safety, sustainability, and worker welfare. It is particularly relevant for producers aiming to access international markets.

Application: Applicable to sectors such as agriculture, food manufacturing, and the consumer goods industry.

1.5.3 Security certifications

This type of certification guarantees that a company's operations are carried out safely, minimizing risks for both workers and products.

- **OHSAS 18001 / ISO 45001:** These certifications ensure occupational health and safety within companies. They facilitate the detection and control of workplace risks, help reduce accidents, and promote improvements in working conditions (Carrasquilla & Villarreal, 2022).

- **BRC Global Standard for Food Safety:** Provides a framework of specific requirements for managing safety in food production companies. It ensures compliance with international standards of food quality and safety.

Application: Adaptable across industries, particularly those with high operational risks such as construction, heavy manufacturing, and the food sector.

1.5.4 Occupational health certifications

These certifications protect the health and well-being of all employees within a company.

- **ISO 45001:** An international standard for occupational health and safety management systems. It focuses on improving worker safety, reducing risks in the workplace, and fostering better working conditions.

Application: Applicable across diverse sectors such as industry, construction, manufacturing, mining, and any other field where potential occupational hazards exist.

1.5.5 Environmental certifications

These certifications contribute to reducing the environmental impact of companies' operations, promoting sustainability and responsible resource use.

ISO 14001: An international standard for environmental management systems. It helps organizations monitor and continuously improve their environmental performance in a systematic manner.

Community Eco-Management and Audit Scheme (EMAS): Focuses on continuous improvement and environmental management within organizations.

Application: Applicable to any company with a significant environmental impact.

1.5.6 Cruelty Free Certifications

These certifications ensure that companies do not engage in animal testing, guaranteeing that products are not tested on animals at any stage of the production process.

- **Leaping Bunny:** Widely recognized in the cosmetics and personal care industry, it certifies that both products and their ingredients have not been tested on animals.
- **PETA Cruelty-Free:** Similar to Leaping Bunny, this certification confirms that companies do not use animals in any phase of product testing.

Application: Applicable in industries such as cosmetics, personal care, and pharmaceuticals.

1.5.7 Fair Certifications Trade (Fair Trade)

These certifications ensure that products are produced using fair and ethical practices, providing decent wages and improved working conditions for producers and workers.

- **Fair Trade International:** Awarded to products such as coffee, cocoa, sugar, tea, textiles, and others that comply with fair trade standards. It promotes better working conditions and fair wages for producers in developing countries.
- **Fair for Life:** Covers both agricultural and manufactured products, guaranteeing fair trade and responsible practices throughout the entire production chain.

Application: Applicable to agriculture, textiles, food products, and other sectors related to exports from developing countries.

These certifications provide a foundation for improving quality, safety, employee well-being, and environmental impact within companies. They also facilitate access to global markets and contribute to sustainability. Depending on the specific needs and characteristics of each organization, the most suitable certification should be selected to align with operational objectives and strategic goals.

1.5.8 Certification systems for food and management

Food certifications play a crucial role in ensuring consumer safety, promoting quality, and supporting sustainable production. They establish specific standards to guarantee safety, ethical practices, and responsible production, while also fostering transparency between producers and consumers. The main certification systems for food and management include:

- **ISO 22000 – Food Safety Standard**

ISO 22000 establishes the requirements for implementing a food safety management system applicable to all companies in the food chain (Cordero Carmiol, 2016). It integrates key aspects of quality management and food safety principles, such as prerequisite programs, hazard analysis, critical control points, and interactive communication throughout the supply chain. Introduced by the International Organization for Standardization (ISO) in 2005, it has become a benchmark for food safety management.

ISO 22000 was designed as a comprehensive model applicable to any company in the food chain, regardless of size or type. It emphasizes risk analysis, identification of critical control areas, and proactive measures to anticipate, detect, and respond to potential food safety hazards. The standard also includes communication and resource management elements, ensuring that food products meet regulatory safety and quality requirements, thereby improving industry practices and alleviating consumer concerns.

- **GlobalG.A.P.**

GlobalG.A.P. (Good Agricultural Practices) is an internationally recognized collection of standards for the agricultural sector, covering production from field to point of sale. Its objective is to guarantee safe and sustainable agricultural practices while minimizing environmental impact and reducing chemical use, ensuring safe and fair conditions for workers and producers (Figueredo et al., 2018).

The certification addresses food safety, traceability, environmental management, and working conditions. It promotes responsible practices such as minimizing pesticide and fertilizer use, managing water resources efficiently, and safeguarding the well-being of producers. GlobalG.A.P. has been widely adopted internationally, reflecting its alignment with global consumer expectations and sustainable production practices.

- **BRC Global Standard for Food Safety**

Established in 1998 by the British Retail Consortium, the BRC Global Standard for Food Safety provides a framework for ensuring food safety, integrity, legality, and quality (Escobar et al., 2023). It was created to address the lack of a retailer-recognized certification that tackles food safety challenges in retail.

The standard requires strict compliance with food safety management systems, HACCP-based procedures, quality management, staff training, facility design, and equipment maintenance. Implementation by manufacturers and suppliers ensures compliance with retailer requirements, promotes continuous improvement, and strengthens consumer confidence.

- **Organic Certification**

Organic certification ensures that food is produced using renewable resources, without synthetic pesticides, chemical fertilizers, or genetically modified organisms (GMOs) (Dilas et al., 2020). It also emphasizes soil and water conservation and ethical treatment of animals.

Originating from early 20th-century agricultural movements, these standards now provide formal verification for products meeting organic principles. Organic certification has gained popularity due to rising consumer demand for natural and sustainable products, reflecting interest in health, environmental responsibility, and fair labor practices.

- **Impact of Certification Systems on Quality Management**

Implementing these certification systems significantly enhances quality management in the food industry by providing a structured framework for monitoring and improving production processes. Benefits include:

- **Improved Food Safety:** Standards such as ISO 22000 and BRC ensure strict food safety practices, reducing contamination risks and protecting public health.
- **Increased Operational Efficiency:** Well-documented processes reduce waste and serve as guides for future improvements.
- **Access to New Markets:** Internationally recognized certifications facilitate entry into new markets, meeting customer and regulatory requirements.
- **Strengthened Consumer Confidence:** Certifications provide a guarantee of quality and safety, reinforcing trust in the brand.
- **Promotion of Social Responsibility and Sustainability:** Certifications like GlobalG.A.P. and Organic support sustainable and responsible practices, benefiting consumers, the environment, and local communities.

Food certification systems are essential tools for quality management in the industry. They provide a framework to ensure safety, quality, sustainability, and ethical practices. Implementation improves operational efficiency, enhances food safety, builds customer loyalty, and opens opportunities in global markets. Therefore, companies should consider adopting and maintaining internationally recognized certifications as part of their strategic quality management initiatives.

1.6 Regulatory requirements

1.6.1 ISO 22000

The ISO 22000 standard was designed to ensure that food products are safe throughout the supply chain. Its main requirements include:

- **System Management:** Maintain a documented food safety management system (Instituto para la Calidad Pontificia Universidad Católica del Perú, 2023). Companies must implement clear policies and procedures that ensure food safety at all stages, from production to delivery. Proper documentation allows for effective monitoring, evaluation, and updating of the system.
- **Management Responsibility:** Senior management commitment and leadership (Centro Europeo de Posgrado, 2022). Top management must be actively involved, demonstrating strong commitment and providing the necessary resources for the system to operate effectively. Management must prioritize food safety and ensure that all staff understand its importance.
- **Resource Management:** Providing the necessary resources to implement and maintain the system (Instituto para la Calidad Pontificia Universidad Católica del Perú, 2023). The success of the system depends on the availability of trained personnel, appropriate infrastructure, and relevant technology. Companies must ensure that equipment and technology are adequate for managing food safety risks (Centro Europeo de Posgrado, 2022).
- **Planning and Producing Safe Products:** Identifying and controlling hazards that may affect food safety (Centro Europeo de Posgrado, 2022). This involves conducting detailed risk analyses to propose preventive and corrective measures, ensuring that potential hazards are effectively managed.
- **Validation, Verification, and Improvement:** Continuous evaluation and improvement of the food safety management system (Centro Europeo de Posgrado, 2024). Companies must validate the effectiveness of controls, verify that procedures are followed, and identify opportunities for improvement. Internal audits and periodic reviews help maintain an up-to-date and functional system.

The ISO 22000 standard provides a solid conceptual foundation for companies to access global markets by meeting food safety requirements. Its implementation strengthens consumer confidence in the products offered (Centro Europeo de Posgrado, 2022).

1.6.2 GlobalG.AP .

GlobalG.A.P. certification is widely recognized in the agricultural sector, as it establishes standards for implementing responsible and sustainable practices. Its main requirements include:

- **Food Safety and Traceability:** Producers must implement systems to track and ensure the safety of agricultural products from the field to the market. Traceability is essential for identifying and addressing safety issues promptly.
- **Environment:** Producers must adopt sustainable practices to minimize environmental impact, including proper waste management and responsible water use (Figueredo et al., 2018). These measures help conserve natural resources and protect the environment for future generations.
- **Worker Health, Safety, and Well-Being:** Certification ensures fair and safe working conditions. Labor practices must comply with national laws and international standards, providing a safe and equitable work environment for all employees.
- **Animal Welfare:** When animals are involved in production, certification requires that their basic needs are met and that they are provided with a suitable environment (Figueredo et al., 2018).

GlobalG.A.P. helps producers demonstrate their commitment to responsible agricultural practices and meet the expectations of consumers who prioritize sustainability.

1.6.3 BRC Global Standard for Food Safety

The BRC Global Standard provides guidelines for managing food safety. Its main requirements include:

- **Leadership Commitment:** Senior management must actively participate in and demonstrate commitment to food safety management. Leaders are responsible for spearheading the implementation of standards and allocating the necessary resources, establishing food safety as a top organizational priority.
- **Food Safety Management System:** Companies must implement a management system based on HACCP principles (Postgraduate European Center, 2024). This preventive approach helps identify and mitigate potential food safety risks at all stages of production. The system must be thoroughly and consistently documented.
- **Food Quality and Safety Management:** Procedures for managing quality and food safety must be documented, regularly evaluated, and updated to reflect changes in regulations and best practices. All staff should be informed of these procedures to ensure consistent implementation.

- **Human Resource Management:** Employees must receive adequate and relevant training to achieve competency in their food safety roles. Ongoing training ensures that staff understand and implement procedures necessary to maintain certification standards.
- **Facility Management:** Facilities must be designed, maintained, and organized to meet hygiene requirements, preventing product contamination and ensuring a safe production environment.

The BRC standard helps suppliers meet retailer expectations while strengthening their food safety management systems. Its implementation ensures compliance with the high safety and quality standards demanded by customers.

1.6.4 Organic Certification

Organic certification focuses on sustainable agricultural practices and food production without the use of genetically modified organisms (GMOs). Its main requirements include:

- **Soil and Crop Management:** Organic certification promotes sustainable practices such as crop rotation and the use of organic fertilizers to maintain soil health and avoid synthetic chemicals (Carranza et al., 2024). These practices benefit the environment and ensure high product quality.
- **Animal Welfare:** For products involving animals, certification requires ethical treatment, including access to suitable environments, pasture, and veterinary care. Animal welfare practices must ensure health and humane treatment.
- **Pest and Disease Management:** Biological and mechanical methods must be used for pest and disease control (FAO, 2021). Synthetic pesticides are prohibited, and natural methods such as biological predators and integrated pest management are encouraged to minimize environmental impact and prevent product contamination.
- **GMO Ban:** All certified products must be free from genetically modified organisms. This strict prohibition applies throughout the production process, from planting to processing, addressing environmental and safety concerns associated with GMOs. Organic certification emphasizes sustainability and the production of natural, environmentally friendly products.

CHAPTER 2

SITUATIONAL ANALYSIS

2.1 Introduction

This chapter addresses the business management of Nuna, an Ecuadorian company dedicated to producing natural dairy products with a focus on sustainability and corporate social responsibility. Nuna collaborates with local micro-producers to offer products free of additives, colorings, and preservatives, consolidating its reputation in the healthy food market (Nuna Sabores del Alma, 2022).

This study employs a SWOT analysis to identify the company's strengths, weaknesses, opportunities, and threats. Strengths include its commitment to quality standards and sustainability, while opportunities are evident in potential expansion into international markets and the growing demand for healthy foods. Weaknesses include limited production capacity and dependence on micro-producers, which could affect raw material quality. Threats encompass intense competition and price fluctuations.

Another key aspect is the value chain, which ensures that all activities, from raw material procurement to distribution, align with Nuna's values. Primary activities, such as production and logistics, are complemented by support activities, including human resource management and technological development, optimizing company operations. The process map illustrates Nuna's various departments and their interactions to ensure operational efficiency (Torres et al., 2021). It breaks down strategic, operational, and support processes so that all employees work in a coordinated environment that facilitates achieving business objectives (Sánchez, 2020).

Finally, the process interaction matrix highlights interrelationships between key areas of the company. It identifies synergies and opportunities for improvement, allowing Nuna to optimize resources, enhance product quality, and maintain competitiveness in a dynamic market. The analysis of Nuna's strategy, value chain, and processes demonstrates a company committed to sustainability and innovation, capable of facing daily challenges while continuing to grow in the healthy food sector (Navarro et al., 2024).

2.2 Company History

Nuna Sabores del Alma is an Ecuadorian company led by Karla Auquilla, founded during the 2020 pandemic crisis. Located in Déleg, Cañar, Ecuador, the company specializes

in the production and marketing of natural foods, primarily dairy products such as yogurt, honey, jams, and granola. Despite the challenges posed by the pandemic, Karla and her team transformed this situation into an opportunity, initially reselling food products in May 2020 and, by September of the same year, beginning to produce their own food.

Nuna stands out for its commitment to sustainable production and Fair Trade. All products are 100% natural, free of chemicals, flavorings, and colorings, reflecting the company's focus on providing genuine nutritional balance. The company collaborates closely with local micro-producers, promoting a circular economy in which both producers and Nuna benefit fairly.

Environmental sustainability is also a key focus. Aware of the negative impact of plastics, Nuna prioritizes eco-friendly packaging. Yogurts and other products are offered in recyclable glass containers, while larger Greek yogurt presentations use biodegradable containers made from materials such as corn starch.

Nuna's most notable products include a variety of yogurts—natural yogurt with fruit, yogurt with collagen, and Greek yogurt in different forms and flavors. The company also offers 100% pure honey, processed only by sifting to maintain quality and purity. These products aim not only to satisfy consumer tastes but also to contribute to a healthy and balanced diet.

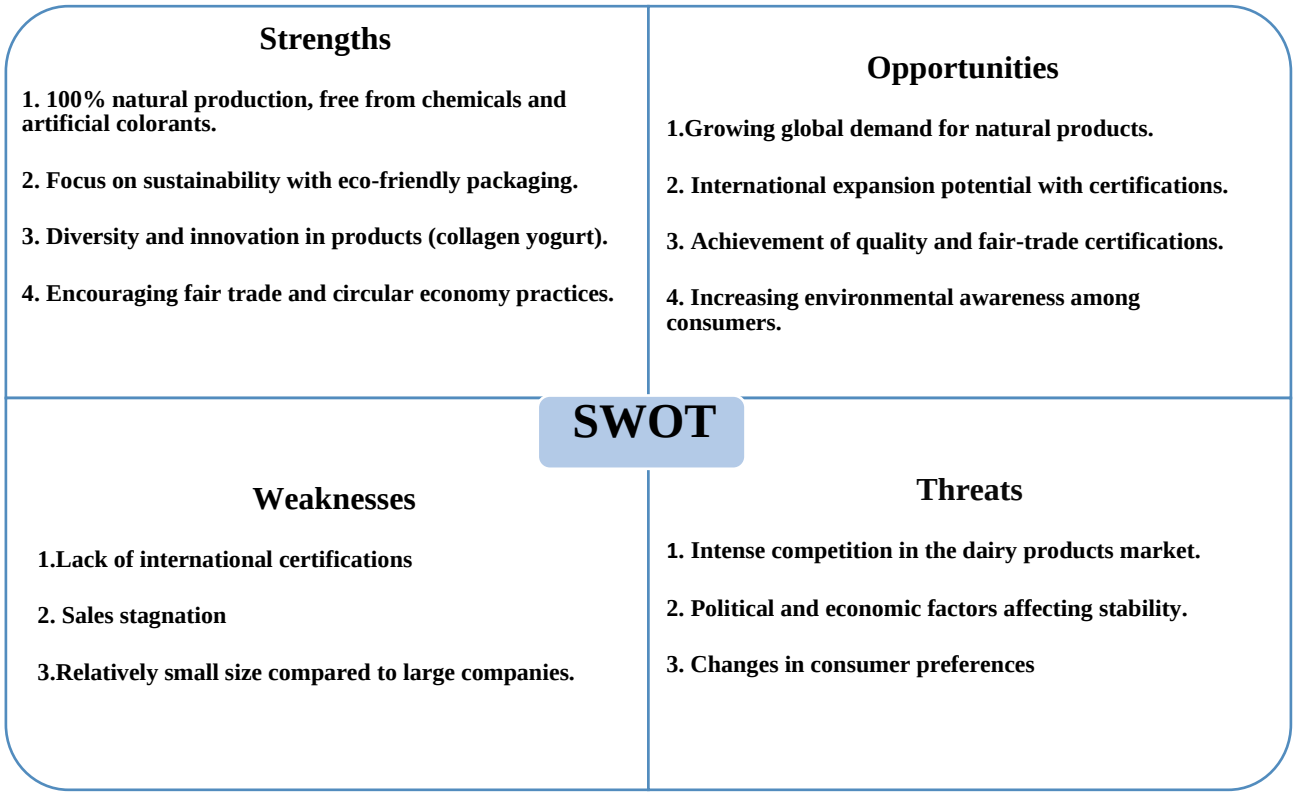
The company's vision, driven by Karla Auquilla, is to innovate within the traditional dairy market, offering unique and unconventional products with high nutritional value. Nuna Sabores del Alma aims for growth and expansion, both domestically and internationally, focusing on strengthening its brand presence and emphasizing product differentiation and quality.

A key challenge is the lack of international certifications that formally validate the quality and sustainability of its processes. While Nuna maintains a clean and eco-friendly production model, certifications such as ISO 22000 (food safety) and Fair Trade seals are necessary to support its practices in competitive international markets.

Nuna Sabores del Alma represents a business model centered on sustainability, health, and consumer well-being, striving to be profitable while remaining responsible toward the environment and the community. Its future growth depends on its ability to meet international market demands, including obtaining certifications that validate its commitment to quality and sustainability.

2.3 SWOT Analysis

Figure 1
SWOT Analysis



Note: Figure created by the authors based on information from Nuna Sabores del Alma (2022).

2.3.1 Strengths

- **Natural Production:** All products are 100% natural, free of chemicals, flavorings, and colorings, ensuring genuine nutritional value.
- **Focus on Sustainability:** Commitment to eco-friendly and recyclable packaging, along with collaboration with local micro-producers.
- **Product Innovation:** Diverse yogurt varieties and other products, offering unique presentations and added benefits, such as collagen-enriched yogurt.
- **Commitment to Fair Trade:** Promotion of a circular economy through fair collaboration with micro-producers.

2.3.2 Opportunities

- **Growing demand for natural products:** a global trend toward natural and organic foods that supports business growth.
- **International expansion:** potential to access international markets if quality and sustainability certifications are obtained.
- **Quality certifications:** implementation of a Quality Management Model and obtaining certifications such as ISO 22000 and *Fair Trade* could increase credibility and expansion.
- **Environmental awareness:** increasing demand for products with responsible environmental practices.

2.3.3 Weaknesses

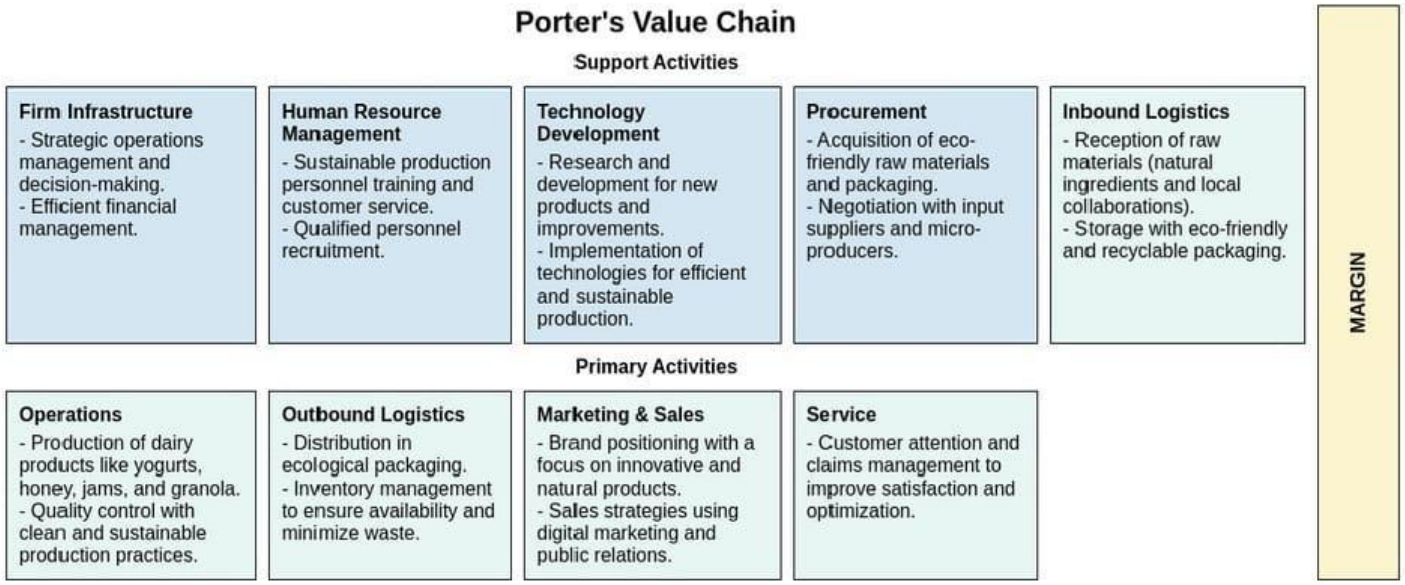
- **Lack of International Certifications:** The absence of recognized certifications may limit the company's ability to compete in international markets.
- **Sales Stagnation:** Nuna has experienced periods of stagnant sales, which could affect its growth and market competitiveness.
- **Relatively Small Size:** As a new micro-enterprise, the company faces challenges compared to larger, well-established competitors in the dairy industry.

2.3.4 Threats

- **Intense Competition:** The dairy market is highly competitive, with large companies capable of rapidly implementing similar quality standards.
- **Political and Economic Factors:** National political and economic events may impact the company's stability and operations.
- **Changing Consumer Preferences:** Shifts in consumer trends can influence demand for specific products.
- **Production or Supply Issues:** Disruptions in the supply chain or production processes may affect product availability and quality.

2.4 Porter's value chain

Figure 2
Porter's value chain



Note: Obtained from Nuna Sabores del Alma (2022).

2.4.1 Primary Activities

Within the value chain, these activities are directly related to the physical creation of the product, its commercialization, and delivery to the customer, as well as the subsequent support provided. According to Riquelme (2020), they are organized into the following sections:

2.4.2 Internal Logistics

This section refers to the internal organization of the company, as it is essential for managing and administering the activities related to receiving and storing raw materials, as well as distributing materials for production. The effectiveness of this segment is reflected in the value generated for the company and its customers (Riquelme, 2020).

- **Receiving raw materials:** purchasing natural ingredients and collaborating with local micro-producers.
- **Storage:** Use of eco-friendly and recyclable packaging to ensure product quality and sustainability. In addition, proper storage of supplies according to their exact refrigeration points.

2.4.3 Operations

The raw material is managed from its entry logistics to the product creation stage. There is a direct relationship: the greater the efficiency, the more resources are saved, which translates into added value at the end of the process (Riquelme, 2020).

- **Production:** In Nuna, this stage focuses on the elaboration of dairy products such as yogurt, honey, jams, and granola. All production follows natural processes, free of chemicals and artificial colorings, to ensure authentic nutritional quality.
- **Quality control:** Although the company applies clean and sustainable production practices, it still lacks formal certifications that validate these processes at an international level.

2.4.4 External logistics

Also known as outbound logistics, this stage involves the delivery of products to wholesalers, distributors, or directly to end consumers, depending on the commercial strategy adopted (Castro et al., 2020).

- Distribution: Products are shipped using eco-friendly packaging, in line with the company's sustainability principles. Current strategies focus on local distribution, with the potential to expand into international markets.
- Inventory management: Efficient inventory control ensures product availability, reduces the risk of shortages, and minimizes waste, contributing to cost savings and customer satisfaction.

2.4.5 Marketing and Sales

This area ensures both growth and market positioning, as it allows for an understanding of the public's needs and preferences, which must be taken into account when developing the product to meet market demands.

- **Brand positioning:** focus on differentiation through innovative and natural products.
- **Sales strategies:** Using digital marketing and public relations to increase visibility and expand brand presence.

2.4.6 After-Sales Service

This activity encompasses aspects such as facility management and customer service. Reinforcing this area generates greater consumer trust, which directly increases the intrinsic value of the product (Riquelme, 2020).

- **Customer Service:** Providing support and gathering feedback to improve customer satisfaction and strengthen loyalty.
- **Complaints Management:** Systematic handling of complaints and suggestions to optimize product quality and service.

2.4.7 Support Activities

According to Porter, these activities support primary activities and maintain a symbiotic relationship, as they provide inputs, technology, human resources, and other essential resources. While some of these resources are directly linked to specific primary activities, others, such as infrastructure, contribute to the proper functioning of the entire value chain (Riquelme, 2020).

2.4.8 Company Infrastructure

It is an essential element for the efficient operation and growth of a company, as it consists of physical spaces, machinery, networks, and other elements that facilitate daily operations and internal communication. Proper implementation optimizes processes and provides security for employees.

- **Management:** Coordination of operations and strategic decision-making to ensure the fulfillment of the mission and vision.
- **Accounting and Finance:** Efficient financial management to support growth and expansion.

2.4.9 Human Resources Management

This activity focuses on attracting, training, and retaining talent, ensuring that employees have the necessary skills and motivation to contribute to the company's objectives. In Nuna, it is directly related to the promotion of sustainability and customer satisfaction.

- **Training and Development:** Staff training in sustainable production practices and customer service.

- **Recruitment:** Hiring qualified personnel to support operations and growth.

2.4.10 Technological Development

- **Product innovation:** Research and development to create new flavors and improve product offerings.
- **Production technology:** implementation of technologies that support efficient and sustainable production.

2.4.11 Purchases

- **Raw material procurement:** selecting suppliers and purchasing natural ingredients and eco-friendly packaging.
- **Negotiation with suppliers:** establishing strong relationships with micro-producers and input suppliers.

2.5 Process map

It serves to measure objectives and responsibilities, as well as to improve coordination between departments and facilitate decision-making based on real workflows. It is an important component of implementing quality management systems.

Table 1
Process map

Process Category	Process	Interaction with other processes
Strategic Processes		
Strategic Planning	Define long-term goals (certification, expansion)	Interacts with operational and support processes to ensure daily operations are aligned with strategic objectives.
Quality Management	Implementation of a quality management system for international certification	Interacts with operational and support processes to ensure that products meet required quality standards.
Operational Processes		
Production	Production of yogurts and other dairy products	It depends on quality management (to ensure that products are natural and chemical-free) and the supply chain (to acquire raw materials from micro-producers).
Marketing and Sales	Product differentiation and innovation strategies	It coordinates with strategic processes (to meet expansion objectives) and with support (marketing and logistics).
Supply Chain	Acquisition of raw materials from micro producers	It interacts with strategic planning and logistics (to ensure that raw materials meet required standards and arrive on time for production).
Support Processes		
Logistics	Distribution of products nationwide	Works closely with production and sales to ensure products reach points of sale efficiently.
Marketing and Advertising	Product promotion and differentiation strategies	Supports marketing and sales, aligning with the company's strategic objectives and values (natural and eco-friendly products).
Human Resources	Personnel management and training	Supports all processes by ensuring that staff are trained to comply with quality and sustainability regulations.
Technology and Systems	Implementation of technological tools for optimization	Supports operational and support processes, improving efficiency and ensuring compliance with quality standards.

Note: Obtained from Nuna Flavors of the Soul (2022)

2.5.1 Strategic Processes

These processes are related to the planning, direction, and control of the company, as well as the definition of long-term objectives (Sánchez, 2020). Their importance lies in

coordinating daily operations with Nuna's mission and vision. In addition, infrastructure helps set growth objectives, such as expanding into new markets or obtaining international certifications to ensure quality and sustainability (Beltrán et al., 2024).

- **Product Innovation**: Nuna seeks to differentiate itself in a traditional dairy market by creating products with unconventional flavors, such as collagen-infused yogurts or Greek yogurt with exotic flavors (Nuna Sabores del Alma, 2022). This requires alignment with production and marketing so that new products reach the market successfully.
- **Expanding the Supplier Network:** To reinforce its commitment to a circular and fair economy, the company aims to include more local micro-producers. This involves close collaboration with the supply chain and quality management to ensure that raw materials meet the company's standards.

2.5.2 Strategic planning

Definition of objectives, mission, vision and growth goals of the company (international expansion, differentiation through organic products, expansion of the supplier network).

2.5.3 Quality Management

Quality is a fundamental pillar for Nuna, as the company produces 100% natural products without chemical additives, flavorings, or colorings (Nuna Sabores del Alma, 2022). Quality management ensures that products meet these standards through the following initiatives:

- **Quality Control of Raw Materials:** Verifies that the products supplied by local micro-producers meet the nutritional and quality requirements established by the company (Villafuerte et al., 2024).
- **Certifications and Regulations:** Implementing a quality management system not only ensures that products are safe and healthy (Añorga & Becerra, 2024) but also allows Nuna to pursue international certifications, thereby strengthening its market reputation.
- **Research and Development (R&D):** Drives innovation in new flavors and natural products (e.g., fruit yogurts, collagen-enriched yogurts, Greek yogurt) and the development of eco-friendly packaging solutions.

2.5.4. Key or Operational Processes

These are processes directly related to the production and delivery of products and services. They are core activities that generate direct value for the customer and form the foundation of Nuna's daily operations (Canizales, 2020).

- **Production Operations:**

Nuna transforms natural ingredients into high-quality dairy products, focusing on:The production of various dairy items, including yogurts, collagen-enriched yogurt, and Greek yogurt. Chemical-free manufacturing processes using only natural raw materials. Quality control measures aimed at meeting domestic and potential international certification standards.

- **Flavor Innovation:** Developing products with unconventional flavors and incorporating ingredients like collagen as part of Nuna's differentiation strategy. Production is coordinated with marketing and sales to ensure new products reach consumers efficiently.
- **Sustainable Production:** Emphasis on eco-friendly packaging and minimizing environmental impact, integrating logistics and supplier management into the sustainability strategy.

2.5.5. Marketing and sales

The marketing objective is to position products in a competitive market through differentiation strategies. This is reflected in:

- **Selling innovative products:** Promoting nutritional benefits and unconventional flavors to attract consumers interested in healthy, natural eating.
- **Promoting eco-friendly products:** Awareness of environmental impact and the use of recyclable packaging are key differentiators that are actively communicated through Nuna's sales and marketing strategies.

2.5.6. Supply Chain

Sourcing raw materials is a critical process for Nuna, given its commitment to natural products and supporting local micro-producers. This process involves:

- **Relationship with micro-producers:** The company sources its raw materials from small producers, promoting a circular economy. Quality management ensures that these products meet nutritional standards.
- **Efficient supply:** Coordination with production and logistics ensures that raw materials arrive on time and in optimal condition for product production.

2.5.7. Logistics and distribution

- **Distribution and development**
    - Distribution of products in different presentations (glass and kraft).
    - Development of distribution chains at both local and national levels.
- **Marketing and sales**
    - Selling products through local stores, direct channels, and differentiation strategies.
    - Adaptation of products to national and international markets (sales expansion).
- **Marketing and positioning**

The marketing department is essential for conveying the unique value of Nuna's products. This support process interacts with several key initiatives:

- **Promoting Healthy and Sustainable Products:** Highlighting that products are 100% natural and organic is a core message that should be reflected consistently across all marketing campaigns.
- **Launching Innovative Products:** Communicating with consumers about new flavors or product innovations, such as collagen-infused yogurt, is crucial for maintaining market interest and differentiation.
- **Emphasizing Organic, Eco-friendly, and Sustainable Products:** Promoting products that are environmentally friendly and sustainably produced strengthens consumer trust and aligns with the values of responsible consumers.

2.5.8. Support Processes

Support activities are crucial for sustaining both operational and strategic processes, ensuring that Nuna operates efficiently and sustainably. These activities comprise the following areas:

- **Human Resources:** Personnel management is key to ensuring that Nuna's team is trained to meet quality and sustainability standards. This includes: quality and sustainability training, ensuring staff are aware of the company's quality regulations and sustainability goals. Organizational culture management: fostering a culture that promotes innovation, environmental responsibility, and a commitment to natural products.
- **Financial Management:** Efficient management of financial resources to support the acquisition of supplies, expansion of operations, and compliance with international certifications.
- **Logistics:** Ensuring that products reach points of sale and end customers efficiently and on time. Key focuses include:
- **National Distribution:** Efficiently managing product distribution nationwide to minimize costs and delivery times.
- **Sustainable Distribution:** Implementing logistics processes that reduce environmental impact, including the use of eco-friendly packaging.
- **Technology and Systems:** The use of technology is essential to optimize production and distribution processes, supporting all areas. This includes quality control systems: implementing technological tools for real-time monitoring of product quality. Logistics Optimization by using technology to improve supply chain efficiency, reducing costs and delivery times.

The interaction between these processes allows Nuna to operate effectively, fulfilling its goals of producing healthy food, supporting local micro-producers, and fostering a sustainable economy.

2.6 Process interaction matrix

Table 2
Process interaction matrix

Processes \ Interaction	Strategic Planning	Quality Management	Production	Accounting	Logistics
Strategic Planning		Quality guidelines and strategic objectives	Production plan and goals	Data for financial analysis	Distribution strategies
Quality Management	Quality requirements for strategies		Specifications and quality supervision	Quality reports for costs	Quality standards in logistics
Production	Production plan report	Compliance with quality standards		Production cost data	Finished products for distribution
Accounting	Financial analysis for decision making	Quality cost evaluation	Evaluation of production costs		Distribution costs
Logistics	Information on strategic distribution	Transportation and storage reports	Feedback on product delivery	Distribution and transportation costs	

Note: table prepared by ourselves with information provided by Nuna Sabores del Alma (2022).

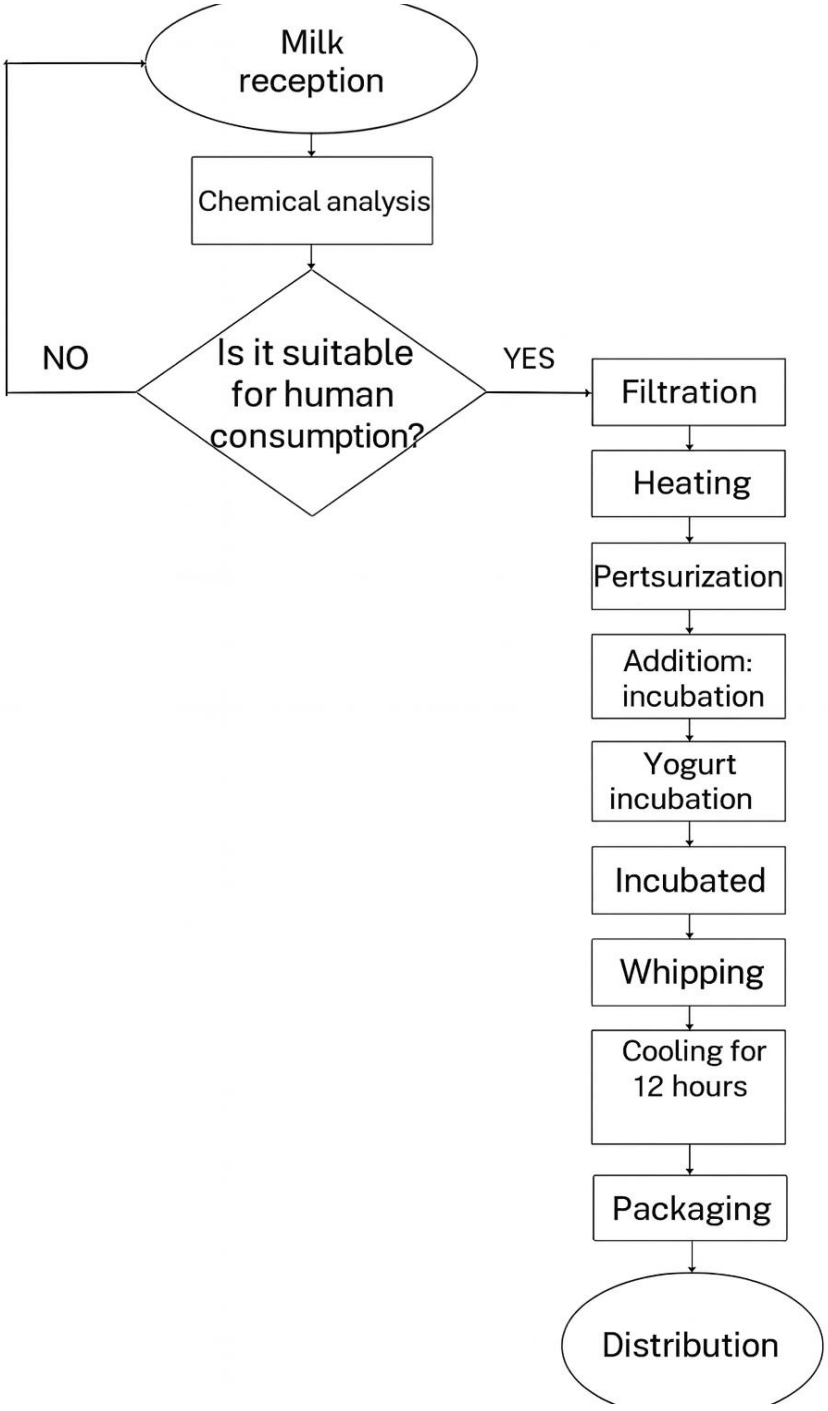
2.7 Nuna Yogurt Production Process

- **Milk Reception:** Fresh milk is received directly from small and medium-sized local producers, with whom Nuna maintains relationships based on trust and quality. This guarantees the freshness of the raw material, supports the regional economy, and promotes sustainable practices in the supply chain (Nuna Sabores del Alma, 2022). An initial inspection ensures that the milk meets quality requirements and is ready for processing.
- **Chemical Analysis:** Milk undergoes laboratory testing to verify composition, quality, and safety. Parameters such as acidity, fat, and protein content are checked to determine suitability for processing.
- **Milk Filtration:** The milk is carefully filtered to remove unwanted particles, ensuring the product remains pure and clean.
- **Heating:** Filtered milk is brought to a specific temperature to prepare it for pasteurization, stabilizing its composition.
- **Pasteurization:** Milk is heated under controlled conditions to eliminate harmful bacteria while preserving essential nutrients, making it safe for consumption.
- **Adding the Yeast:** Live cultures are added to the pasteurized milk. The yeast converts the milk into yogurt, providing texture, flavor, and probiotic benefits.
- **Incubation:** The mixture is kept at a controlled temperature for a set period, allowing the cultures to ferment the milk and develop the yogurt's unique characteristics.
- **Cooling:** After fermentation, the yogurt is rapidly cooled to stop the process, ensuring freshness and preserving flavor.
- **Blending:** Yogurt is blended to achieve a smooth, creamy texture. Fruits or natural flavorings can be added depending on the product type.
- **Refrigeration (12 hours):** Yogurt is stored in cold chambers to stabilize texture and flavor, ensuring optimal quality.
- **Packaging:** The finished product is placed in packaging that maintains freshness and protects it during distribution. Each package contains all necessary consumer information.

- **Distribution:** Products are transported to points of sale under controlled conditions, ensuring they reach consumers fresh and in perfect condition.

This meticulous process ensures that Nuna yogurt maintains high quality, with a flavor and texture that reflects the care taken at every production stage.

Figure 3
Nuna Yogurt Production Process



Note: Figure prepared by the author with information provided by Nuna Sabores del Alma (2022).

2.8. Products

Nuna Sabores del Alma, a Cuenca-based brand led by Karla Auquilla, has established itself as a pioneering enterprise that combines the richness of natural ingredients with

traditional flavors. Its products are valued not only for their quality but also for their focus on nutrition and consumer well-being.

Figure 4
Karla Auquilla, owner of Nuna Sabores del Alma

Note: Image courtesy of Karla Auquilla, owner of Nuna Sabores del Alma (2024).

Featured Products:

- **Parfait:** Made with creamy yogurt, fresh fruit, and granola, this product is a healthy and balanced snack suitable for any occasion.
- **Granola:** A mix of oats, nuts, and honey, providing a nutritious addition to breakfast or as a snack.
- **Fruit Yogurts:** Natural yogurt combined with pieces of fresh fruit, perfect for a quick and healthy snack.
- **Greek Yogurt:** Available in classic and flavored varieties, such as blackberry, pineapple, and mango. It is distinguished by its high protein content and thick texture.
- **Collagen Yogurt:** Enriched with imported collagen, ideal for those seeking additional benefits for skin and joint health.

In addition to these products, Nuna aims to provide a holistic experience of health and enjoyment. Carefully selected ingredients and traditional preparation methods reflect the company's commitment to authenticity, nutrition, and sustainability (Nuna Sabores del Alma, 2022).

Figure 5
Nuna products and their presentations

Note: Image courtesy of Karla Auquilla, owner of Nuna Sabores del Alma (2022).

Table 3
Main products of Nuna Sabores del Alma

Product	Weight/Volume	Unit Price (USD)	Description
Parfait 	250 gr	2.50	Blend of creamy yogurt, fresh fruit and crunchy granola.
Granola 	1 lb	4.50	A mixture of oats, nuts and honey, ideal as a nutritional supplement.
Yogurts with fruit 	450 ml	2.00	Natural yogurt with fresh fruit chunks, perfect for a healthy snack.
Greek yogurt 	450 gr	4.50	Traditional Greek yogurt, rich in protein and creamy texture.
Greek yogurt flavors 	1000 gr	7.00	Greek yogurt with various flavors such as natural, blackberry, pineapple or mango.
Yogurt with collagen 	450 gr.	4.50	Traditional yogurt with collagen imported from Holland.

Note: Table prepared by the author using information and images provided by Karla Auquilla, owner of Nuna Sabores del Alma (2022).

2.9 Prioritization matrix

The prioritization matrix is used to evaluate and score the feasibility of implementing relevant standards, selecting the most suitable one based on the results. It considers factors such as ease of implementation, cost, and availability of resources (Giraldo et al., 2023).

Factors:

- **Ease:** Degree of simplicity in integrating the certification into current processes.
- **Cost:** Expenses associated with certification, including audits and ongoing maintenance.
- **Readiness:** Availability of necessary resources, such as technology, personnel, and access to training.

Certifications Evaluated:

- **ISO 22000 Standard:** Food Safety Management System.
- **GlobalG.A.P.:** Good Agricultural Practices, relevant to agricultural inputs.
- **BRC Global Standard for Food Safety:** Widely recognized certification for food quality and safety.
- **Organic Certification:** Guarantees compliance with organic product standards.

Table 4
Prioritization matrix

Certification	**Factors**			
	Easy	**Price**	**Provision**	**Total**
ISO 22000 Standard	4	3	4	**11**
Global GAP	3	3	3	**9**
BRC Global Standard	2	4	4	**10**
Organic Certification	3	2	3	**8**

Note: table and analysis prepared by the authors.

Analysis:

ISO 22000 stands out as the most feasible option (11 points) due to its high compatibility with existing processes and its comprehensive approach to food safety.

- **The BRC Global Standard for Food Safety** is also a strong choice (10 points), particularly for exports, as it is widely recognized in international markets.
- **Global G.A.P.** is relevant (9 points) if Nuna aims to emphasize the sustainability of its agricultural supply chain.
- **Organic Certification** scored the lowest (8 points), mainly due to its associated costs and the challenges of adapting processes to meet strict standards.

According to the prioritization analysis, ISO 22000 should be implemented as the primary certification, complemented by the BRC Global Standard to enhance international competitiveness. Adoption of GlobalG.A.P. and Organic Certification can be considered in later phases if the company decides to focus on sustainability or target specific market niches.

CHAPTER 3
INTEGRATION OF CONTINUOUS IMPROVEMENT AND CERTIFICATIONS IN FOOD PRODUCTION

3.1 Description of the ISO 22000 Standard

The ISO 22000 Food Safety and Food Management System is an international standard designed to regulate hazards and ensure the creation of safe food products that meet public needs and comply with legal requirements. It was first introduced in 2005 (Correa & Socasi, 2021); however, this proposal adopts the updated 2018 version. Its main objective is to guarantee that food is safe for human consumption throughout the entire supply chain, from production to consumption. The standard applies to all organizations involved in the food chain, including food and beverage production, processing and manufacturing companies, storage and distribution, suppliers of raw materials, additives and packaging, restaurants, hotels, and others (Moreno & Rubel, 2023).

ISO 22000 integrates elements from Food Safety Management (FSM) with fundamental principles of Good Manufacturing Practices (GMP). It also evaluates potential hazards and critical control points (HACCP) and ensures compliance with Quality Management System (QMS) requirements. Its high-level structure is based on the PDCA (Plan, Do, Check, Act) cycle, which facilitates integration with other standards, such as ISO 9001. The standard emphasizes proper and timely communication among all stakeholders in the food chain, enabling early detection and management of potential risks. It includes documented policies, objectives, and procedures aligned with legal and regulatory requirements. To mitigate risks, ISO 22000 requires a mandatory prerequisite program to maintain a hygienic environment throughout the production process. Additionally, it promotes continuous improvement, supporting ongoing evaluation and updating of the food safety system (Correa & Socasi, 2021).

ISO 22000 is generally compatible with other management systems, such as ISO 9001 (quality management), ISO 14001 (environmental management), and FSSC 22000, which combines ISO 22000 with additional international food safety requirements (Moreno & Rubel, 2023). The standard was selected for Nuna due to its comprehensive food safety parameters, which help reduce risks and enhance brand positioning by building consumer trust. By implementing ISO 22000, Nuna aims to guarantee the safety of its products and strengthen its presence in international markets.

3.2 Structure

Integrated Management Systems (IMS) unify quality, environmental, safety, and occupational health standards, optimizing processes and resources. Implementing an IMS offers several benefits, including reduced costs, fewer tasks and audits, improved corporate image, and enhanced regulatory compliance. The PDCA (Plan, Do, Check, Act) cycle is embedded within IMS to ensure continuous improvement. Its implementation requires adequate resource planning and evaluation to guarantee operational effectiveness (Ortiz, 2018). As the International Organization for Standardization (ISO) states, "The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are identified and acted upon" (ISO, 2018, p. 8). Risk-based thinking within IMS provides key indicators, reduces liabilities, and verifies compliance with plans.

ISO 22000 follows the high-level structure of ISO management systems, facilitating integration with other standards such as ISO 9001 (Quality Management) and ISO 14001 (Environmental Management). The standard is divided into ten chapters, covering general requirements through continuous improvement of the Food Safety Management System (FSMS). Its management principles include: customer focus, leadership, people commitment, process approach, improvement, evidence-based decision-making, and relationship management (ISO, 2018, p. 8).

Customer focus is centered on ensuring consumer satisfaction, trust, and loyalty through the identification of needs, strict compliance with legal and regulatory requirements, and the promotion of product safety, supported at all times by transparent communication that fosters continuous improvement. Leadership is reflected in the definition of strategic objectives and the allocation of resources to effectively integrate the FSMS within the organization, while people commitment is demonstrated through engagement at all levels, reinforced by ongoing training, clear guidelines, and effective communication on the importance of compliance. The process approach provides a structured framework for planning and managing processes and their interactions, with methodologies such as PDCA driving efficiency and minimizing risks. Continuous improvement acts as a transversal principle, enabling system enhancement through the detection of nonconformities and the implementation of corrective actions. Evidence-based decision-making further strengthens planning by relying on objective data, reducing uncertainty in risk management, and supporting a proactive organizational culture. Finally, relationship management ensures the

establishment of strategic partnerships with suppliers, customers, and regulatory bodies, contributing to sustainable success.

Structurally, ISO 22000 provides a systematic approach that addresses food safety while ensuring regulatory compliance. Its implementation at Nuna would allow comprehensive control of potential risks within the supply chain, enhancing both competitiveness and reputation in the food industry.

3.3 Scope

ISO 22000 establishes specific parameters for compliance, applicable to the entire food chain—from primary production to the end consumer. Its objective is to guarantee food safety, minimize risks, and strengthen public confidence. The management system encompasses the entire organization, including all relevant functions and sections. To define its scope and applicability, the organization must identify:

> "…the products and services, processes, and production sites included in the FSMS. The scope should include the activities, processes, products, or services that may impact the food safety of their finished products" (ISO, 2018, p. 12).

The information obtained through applicability must be recorded and kept available for future reference. The scope must also be available and maintained as documented information. It should be noted that the standard is applicable to all organizations involved in the food chain, including primary producers (agriculture, livestock, fisheries, and raw material production); processing and manufacturing industries (companies that transform food into final products); storage and distribution companies (logistics centers and transport operators); the food service sector (restaurants, hotels, and catering); as well as input suppliers (manufacturers of packaging, ingredients, and food additives). In the case of Nuna, the application of the standard would cover all of its production processes, ensuring that food complies with quality and safety standards.

Likewise, since it is based on a risk analysis approach, the ISO 22000 standard adopts an integrated system that includes: hazard analysis and critical control points (HACCP); prerequisite programs (PRPs) to minimize cross-contamination; traceability and record control to ensure transparency in the supply chain. Due to its high-level structure, the standard can be integrated with other certifications, such as ISO 9001 (Quality Management), ISO 14001 (Environmental Management), and FSSC 22000 (a specific certification for food safety) (International Organization for Standardization, 2018).

For Nuna, this would enable more efficient resource management, strengthening its competitiveness in national and international markets. Among the benefits of compliance, Nuna would gain strategic advantages such as: reducing the risks of food contamination; meeting international regulations, thereby facilitating exports; increasing consumer confidence by ensuring safe products; and optimizing internal processes, reducing waste and operating costs. The scope of ISO 22000 is broad and adaptable to companies of any size within the food chain. Its adoption by Nuna would reinforce its commitment to food safety, offering high-quality products and improving brand positioning.

3.4 Certification Requirements

To obtain ISO 22000 certification, Nuna must comply with the following requirements:

- **Implementation of a Food Safety Management System (FSMS):** Develop, document, implement, and maintain a FSMS aligned with food safety and quality management principles. Create a food safety manual, establish documented procedures for critical operations, and ensure continuous improvement using the PDCA (Plan, Do, Check, Act) cycle.
- **Senior Management Commitment:** Demonstrate proactive leadership by allocating human, technological, and financial resources. Communicate food safety policies effectively throughout the organization. Establish strategic objectives aligned with food safety and corporate sustainability.
- **Hazard Analysis and Critical Control Points (HACCP):** Identify biological, chemical, and physical hazards throughout the production chain. Determine critical control points (CCPs) and critical limits. Apply preventive and corrective measures when deviations occur.
- **Process Control and Operational Prerequisites:** Ensure compliance with Good Manufacturing Practices (GMPs) across all production stages. Manage suppliers and raw materials, including input validation and supplier certification. Maintain temperature control and traceability using automated systems. Implement strict hygiene and sanitation protocols for facilities and equipment.
- **Communication and Traceability:** Establish communication systems for internal (employees, departments) and external (suppliers, distributors, customers)

stakeholders. Implement a complete traceability system from source to consumer. Develop an incident response plan to manage product recalls efficiently.

- **Performance Evaluation and Internal Audits:** Conduct periodic internal audits to monitor compliance. Track food safety performance indicators. Review documentation and implement corrective actions for detected deviations.
- **Legal and Regulatory Compliance:** Ensure adherence to national and international food safety regulations. Comply with health, environmental, labeling, and certification laws.

3.5 Selection criteria for ISO 22000 certification in Nuna , flavors of the soul

Nuna, Flavors of the Soul, selected the ISO 22000 Food Safety Management System based on strategic and operational criteria designed to meet international food safety standards, optimize production processes, and strengthen market positioning. The main decision-making factors include:

- **Compliance with legal and regulatory requirements.** The first criterion for achieving certification is ensuring strict adherence to legal standards, both local and international. As part of the dairy industry, Nuna must guarantee that its products comply with specific regulations regarding food safety. At the national level, Resolution ARCSA-DE-067-2015-GGG sets forth the requirements for the production, storage, and commercialization of dairy products, enabling even small industries, such as Nuna, to implement rigorous controls throughout their production processes. Internationally, ISO 22000 aligns with the principles of the Codex Alimentarius and with key regulations such as Regulation (EC) 178/2002 of the European Union, which establishes the general principles of food law and sets out traceability requirements across the supply chain.
- **Enhancement of food safety.** The standard ensures a comprehensive approach to food safety throughout the supply chain, from the reception of raw materials to the distribution of yogurt. ISO 22000 provides a solid framework for implementing food safety management systems based on Hazard Analysis and Critical Control Points (HACCP), ensuring that products are free from contaminants and safe for consumption. This commitment not only safeguards consumer health but also strengthens confidence in the brand.

- **Optimization of risk management.** Certification promotes the identification, assessment, and control of risks throughout the production process. For Nuna, the main risks involve microbiological contamination, temperature variations, and the handling of raw materials. ISO 22000 provides guidance on managing these risks through standardized operations, leading to continuous process improvement and the reduction of potential operational failures.
- **Improved traceability and transparency.** The standard requires the implementation of systems that allow for the identification and tracking of products at every stage of the supply chain. For Nuna, traceability is not only a matter of food safety but also a strategic tool for responding promptly to potential incidents or product recalls. It further supports inventory management optimization and reduces operating costs through effective control of production batches.
- **Commitment to quality and continuous improvement.** ISO 22000 fosters a culture of continuous improvement, offering Nuna the opportunity to strengthen its operations, increase efficiency, and maintain high-quality standards over time. This approach not only enhances product quality but also drives innovation, particularly in the development of differentiated products such as probiotic yogurts.
- **Sustainability and corporate social responsibility.** Given the growing demand for products that are both healthy and environmentally responsible, certification provides Nuna with the opportunity to reinforce its commitment to sustainability. The standard promotes the adoption of responsible resource management practices and the reduction of environmental impacts across the supply chain. By aligning with these principles, the company can enhance its market positioning through its commitment to environmental and social responsibility.
- **Competitive advantage in the market.** In an environment increasingly focused on transparency and food safety, holding a globally recognized certification positions Nuna as a leader in quality and food safety. Moreover, it facilitates access to new international markets where certification is a prerequisite for food imports.
- **Strengthening consumer trust.** Finally, one of the most significant impacts of certification lies in building consumer trust. ISO 22000 acts as a seal of assurance,

endorsing the highest standards of quality and food safety. Once achieved, Nuna will be able to consolidate the loyalty of existing customers, attract new market segments, and strengthen its reputation as a brand committed to safety and reliability.

Selecting ISO 22000 enables Nuna Sabores del Alma to consolidate its commitment to food safety, optimize production processes, and achieve sustainable growth. By enhancing traceability, risk management, continuous quality improvement, and corporate social responsibility, this certification positions Nuna for long-term success in both domestic and international markets.

3.6 Preliminary analysis

3.6.1 Initial Diagnosis of Nuna Sabores del Alma

a) Context and Relevance of Certification

Nuna Sabores del Alma produces and markets food from an artisanal and healthy perspective. ISO 22000 certification would allow it to:

- Enter new markets internationally, while complying with global regulations.
- Provide guarantees to ensure consumer confidence by ensuring the safety and security of its products.
- Optimize the supply chain by reducing potential risks and improving traceability.
- Differentiate yourself from the competition by increasing your brand's reputation and prestige.

b) Current situation and gaps compared to ISO 22000

To assess the viability of certification, the company's current strengths and weaknesses in terms of food safety must be identified:

Table 5
Current situation and gaps

Area Evaluated	Current Situation in Nuna	Gap to ISO 22000
Food Safety Management	It has basic quality control processes.	Lack of formalization of a documented SGSA.

Commitment of Senior Management	Management focused on quality, but without specific SGSA policies.	Need for greater leadership in food security.
Control of Raw Materials and Suppliers	Inputs are evaluated, but without formal certifications.	A standardized supplier selection and audit process must be implemented.
Traceability and Data Recording	Partial tracking of batches and products.	A digitalized traceability system is required.
Staff Training	BPM training, but no specific training in ISO 22000.	A structured employee training plan is necessary.
Incident Response Plan	It does not have a product recall plan.	A crisis protocol needs to be developed and implemented.

Note: table and analysis prepared by the authors.

c) Factors for implementation

c.1 Implementation of the food safety management system

To comply with ISO 22000, Nuna must establish a formal SGSA that covers:

- Hazard analysis and establishment of critical control points
- Process monitoring and verification plans.
- Traceability system that allows tracking each product in the supply chain.
- Internal audit program to assess ongoing compliance.

c.2 Necessary resources

To achieve certification, Nuna Sabores del Alma must allocate resources to:

- **Infrastructure and Technology:** Implement traceability systems to track products from raw materials to end consumers. Deploy quality control software to monitor food safety parameters in real time.
- **Staff Training:** Educate employees on food safety management principles. Provide training on ISO 22000 standards, including HACCP, prerequisite programs, and documentation requirements.
- **Improvements in the Production Chain:** Adjust manufacturing processes to comply with ISO 22000 protocols. Enhance storage and handling procedures, including cold chain management and hygiene protocols.

- **External Consulting:** Engage experts for SGSA optimization and system alignment. Conduct pre-certification audits to identify gaps and ensure compliance before formal certification. This allocation ensures that Nuna will meet ISO 22000 requirements efficiently, improving food safety, operational efficiency, and market credibility.

c.3 Certification strategy

Certification can be achieved in progressive phases:

- Diagnosis and establishment of the action plan.
- Staff training and SGSA documentation.
- Implementation of controls and internal audit.
- Correction of findings and request for external audit.
- Obtaining ISO 22000 certification.

c.4 Conclusion and Recommendations

Preliminary analysis indicates that Nuna , Flavors of the Soul, has significant potential to obtain ISO 22000 certification, but faces challenges in formalizing its processes, supplier control, and traceability. To obtain certification, the following should be achieved:

- Establish a dedicated task force for the implementation of the SGSA.
- Concentrate traceability technologies for production control.
- Carry out training programs on an ongoing basis.
- Conduct prior internal audits to assess compliance and address gaps.
- Certification should not only improve food safety, but also seek to strengthen its market position and open up export opportunities.

3.7 Improvement actions

To achieve this goal, Nuna must implement a series of strategic actions focused on improvements in risk mitigation, regulatory compliance, and operational efficiency.

Table 6
Improvement actions

Area for improvement	Strategic actions

Strengthening the Food Safety Management System (FSMS)	- Development of a Food Safety Manual that documents procedures, controls, and responsibilities. - Review and update of internal policies aligned with the principles of Hazard Analysis and Critical Control Points (HACCP). - Implementation of periodic internal audits to assess compliance with ISO 22000.
Optimization of Production and Logistics Processes	- Staff training in GMP and HACCP to ensure compliance with standards. - Automation and digitization of records to improve the traceability of raw materials and finished products. - Supplier control and supply chain auditing to ensure compliance with food safety requirements.
Infrastructure and Risk Control	- Improvement of facilities with separation of work areas to avoid cross-contamination. - Optimization of the waste management system to minimize environmental impacts and improve sustainability. - Inspection and maintenance of equipment with quality standards to prevent failures that affect product safety.
Strengthening the Management System and Continuous Improvement	- Implementation of key performance indicators (KPIs) to measure progress towards certification. - Creation of a food safety committee to monitor compliance with the standard. - Corrective and preventive action plans based on the results of internal and external audits.

Note: table and analysis prepared by the authors.

3.8 Situational analysis based on the norm

3.8.1 Introduction

The ISO 22000 standard provides an internationally recognized framework for food safety management, emphasizing the identification, assessment, and control of risks across the entire food value chain. Beyond ensuring compliance with legal and regulatory requirements, the standard prioritizes public health and consumer confidence—critical factors for dairy companies such as Nuna Sabores del Alma. Its implementation carries significant implications for both strategic and operational management, offering a holistic and integrated approach to food safety that engages all stakeholders, from suppliers to end consumers.

Table 7

Understanding and context of the organization.

HACCP Principle Applied	Requirement	Description	Complies	Partially	Does not comply	Evidence	Observation
Principle 1: Hazard Analysis	**Understanding the organization and its context**	Identify the external and internal activities relevant to the Food Safety Management System (FSMS).		X		Internal SWOT assessment conducted in 2024	Clear identification, but not articulated with food safety management.
Principle 2: Determination of critical control points	**Needs and expectations of stakeholders**	Identify the needs and expectations of stakeholders related to food safety.	X			List of stakeholders	Complete evaluation.
Principle 2: Determination of critical control points	**Scope of the SGIA**	Defines the scope of the SGIA, its limits and applicability.			X	Preliminary Scope Statement	Requires preliminary scope update.
Principle 2: Determination of critical control points	**Food safety management system**	Establishes, implements, maintains and continuously improves the SGIA.			X	-	It requires a system manual and fundamental processes.

Note: table prepared by the author with information from the ISO 22000 standard (2018).

Table 8
Leadership

HACCP Principle Applied	Requirement	Description	Complies	Partially	Does not comply	Evidence	Observation
Principle 1: Hazard Analysis	**Management commitment**	Senior management demonstrates leadership and commitment to food safety.		X		Policy statements	More active monitoring is required.
Principle 2: Determination of critical control points	**Food safety policy**	The organization establishes and communicates a food safety policy.			X	-	A signed and communicated document is required.
Principle 2: Determination of critical control points	**Roles, responsibilities and authorities**	The organization assigns clear roles and responsibilities for food safety.			X	-	It requires training for those responsible, as well as a functional organizational chart.

Note: table prepared by the author with information from the ISO 22000 standard (2018).

Table 9
Planning

HACCP Principle Applied	Requirement	Description	Complies	Partially	Does not comply	Evidence	Observation
Principle 1: Hazard Analysis	**Actions to address risks and opportunities**	Identify risks and opportunities related to food safety.			X	-	Mitigation actions are required, in addition to organizational risk analysis.
Principle 1: Hazard Analysis	**Objectives of the SGIA**	Establishes measurable food safety objectives aligned with policy.			X	-	You need a well-formulated and measurable 2025 goals plan.
Principle 1: Hazard Analysis	**Planning for changes**	Plan changes to the SGIA so that they do not compromise food safety.			X	-	It requires a definition of formal procedures, in addition to a change log.

Note: table prepared by the author with information from the ISO 22000 standard (2018).

Table 10
Support

HACCP Principle Applied	Requirement	Description	Complies	Partially	Does not comply	Evidence	Observation
Principle 1: Hazard Analysis **Principle 6:** Verification	**Resources**	It has adequate resources to implement and maintain the SGIA.	X			Inventory and resource allocation	Suitable
Principle 6: Verification	**Competence**	Ensures that personnel involved in food safety are properly trained.			X	-	Pending effectiveness evaluation, in addition to the respective training records.
Principle 7: Verification	**Awareness**	Promotes awareness about food safety.		X		Internal communications	Requires constant reinforcement.
Principle 1: Hazard Analysis **Principle 6:** verification	**Communication**	Establish internal and external communication channels related to food safety.			X	-	It requires a functional and documented communication matrix.
Principle 7: Documentation	**Documented information**	Maintains documented procedures and records that support the SGIA.			X	-	You need to document procedures and formats in an organized manner and in digital format.

Note: table prepared by the author with information from the ISO 22000 standard (2018).

Table 11
Operation

HACCP Principle Applied	Requirement	Description	Complies	Partially	Does not comply	Evidence	Observation
Principle 1: Hazard Analysis	**Generalities**	Identify and evaluate hazards that may affect food safety.			X	-	It requires a review of the hazard analysis, in addition to a controls matrix.
Principle 2: determination of critical control points	**Operational Prerequisites (oPRP)**	Implements oPRPs to control non-critical hazards.			X	-	Requires documented monitoring and oPRP list .
Principle 3: Establish critical limits	**Critical control points (CCP)**	Identify and establish critical control points for food safety.			X	Flowchart and checkpoints	It requires a review of critical limits, a flow diagram and control points.
Principle 4: Establish a monitoring system	**oPRP monitoring system**	Establishes procedures for the continuous monitoring of PCCs and oPRPs .			X	Daily monitoring records	The implementation of daily monitoring records is missing.
Principle 4: Establish a monitoring system	**Validation of combinations of control measures**	Validates combinations of control measures to ensure their effectiveness.			X	-	Preliminary results, confirmation and validation reports pending.
Principle 4: Establish a monitoring system	**Determination of critical limits**	The organization determines critical limits for PCCs and oPRPs .			X	-	Scientific references and limit tables are missing.

Principle 5: Establish corrective actions	**oPRP monitoring system**	Establishes procedures for the continuous monitoring of PCCs and oPRPs .		X	-	Monitoring records are missing.
Principle 6: Verification	**Planned actions in the event of deviations**	Plans and executes corrective actions when deviations from critical limits are detected.		X	-	There is no record of actions taken consistent with the HACCP plan.
Principle 6: Verification	**Verification of the hazard control plan**	Verify the effectiveness of hazard controls through internal audits or validations.		X	-	Internal audit reports and closure of findings are missing.
Principle 6: Verification	**Documented information**	Maintains appropriate documentation supporting SGIA decisions and actions.	X		Procedures, forms and records	Documents are missing, and existing ones also need to be organized in digital format.

Note: table prepared by the author with information from the ISO 22000 standard (2018).

3.8.2 Context of the company Nuna flavors of the soul: internal analysis

a) Process management and risk control

Nuna's production process, as part of the dairy sector, carries inherent risks related to microbiological contamination, water quality, and cold chain management. Implementing ISO 22000 provides a structured framework to integrate control measures across these critical areas through Hazard Analysis and Critical Control Points (HACCP) and Critical Control Points (CCPs). For Nuna, processes such as pasteurization and fermentation—particularly for probiotic yogurts—are highly susceptible to contamination, making rigorous microbiological risk management essential.

In terms of supply chain management, Nuna stands to benefit significantly from a robust traceability system, which would enable strict monitoring of raw materials and ensure food safety from source to consumer. ISO 22000 mandates the establishment of a fully documented traceability system, allowing the identification and tracking of products at every stage of the production process, from milk reception to yogurt distribution.

b) Organizational culture and commitment to quality

The analysis demonstrates a strong emphasis on quality and innovation; however, there is a notable lack of formalization in the food safety management system. This gap can pose risks to consistent product quality due to the absence of a properly documented process control system and validated procedures. Implementing the standard would reinforce Nuna's quality culture by providing a formalized management structure with clearly defined roles and responsibilities for every member of the production team.

c) Infrastructure and resources

Nuna's infrastructure, tailored for the production of fresh dairy products and probiotics, must maintain optimal temperature, humidity, and hygiene conditions throughout its facilities. Periodic facility audits, in accordance with ISO 22000 requirements, would help identify and remediate potential deficiencies in critical infrastructure, thereby ensuring a safe and hygienic production environment.

3.8.3 Analysis of external factors: competition, risks and opportunities

a) Competition and market regulation

The Ecuadorian dairy market is highly competitive, with increasing demand for healthier and more natural products, such as probiotic yogurts and other functional dairy items. Implementing ISO 22000 provides Nuna with a competitive advantage over companies lacking a recognized certification. It also ensures compliance with both local and international regulations, facilitating access to more demanding export markets.

In addition, consumer expectations have grown regarding transparency in production processes and corporate social responsibility. Nuna is well-positioned to meet these demands, thanks to its best practices and reputation for sustainability-driven strategies. ISO 22000 promotes the integration of sustainable practices into risk management and environmental stewardship, enhancing the company's competitiveness while mitigating its ecological impact.

b) Global trends in food security

Consumers generally have high expectations regarding food safety. By implementing best production practices, companies can significantly enhance customer satisfaction. Adopting ISO 22000 would allow Nuna to position itself as a leader in regulatory compliance and corporate social responsibility, aligning effectively with both local and international market expectations.

3.8.4 Strategic recommendations for the implementation of ISO 22000

a) Development of internal capacities

Nuna must make a strategic investment in the continuous training of its personnel in food safety, applied microbiology, and traceability. In line with ISO 22000's emphasis on competence and awareness, a structured training program will ensure that control procedures are consistently applied across all operational levels and stakeholders, thereby reinforcing a culture of food safety throughout the organization.

b) Supply Chain Optimization

The implementation of a robust digital traceability system is critical for optimizing supply chain management. By adopting automated traceability solutions, Nuna will gain real-time visibility into the origin and handling of each milk batch throughout the production process. This capability enhances operational efficiency, facilitates rapid response to deviations, and mitigates risks associated with potential contamination, strengthening overall food safety assurance.

c) Strengthening Internal Audit Procedures

Periodic internal audits are a cornerstone of ISO 22000 implementation. These audits, conducted by personnel trained in food safety management, provide an objective evaluation of the system's effectiveness, identify areas for improvement, and support the continuous enhancement of operational processes. By institutionalizing these audits, Nuna ensures compliance with the standard while fostering a proactive approach to risk management and quality assurance.

3.8.5 Action plan

General objective: To implement the ISO 22000 standard at Nuna Sabores del Alma, a dairy products company (yogurt and derivatives), ensuring the safety of its food products, as well as their traceability and compliance with regulations applicable to Ecuador. The process must be aligned with the company's specific operational needs and focus on continuous quality improvement.

Phase 1: Initial diagnosis and evaluation of the current situation

Objective: To comprehensively diagnose the company's current situation, placing special emphasis on food quality and safety, and to assess compliance with national standards and ISO 22000.

Responsible: Quality Manager in conjunction with the Production, Logistics and Operations Directors.

Actions:

- **Evaluation of current operational processes:**

Thoroughly analyze Nuna 's production processes, specifically the production of dairy products such as yogurt. Identify critical points within the pasteurization, packaging, and distribution processes.

- **Review of infrastructure and equipment:**

Inspect production, storage, and distribution facilities, focusing on the proper implementation of hygiene and temperature control practices, which are essential for dairy products.

- **Specific risk analysis:**

Implement a Hazard Analysis and Critical Control Point (HACCP) approach specific to dairy products. This should include microbiological hazards (such as Salmonella or Listeria) and physical hazards (such as packaging or machinery fragments).

- **Ecuadorian regulatory review:**

Nuna 's compliance with local regulations such as INEN Standard 1.409 on dairy products and other provisions of the Ministry of Public Health (MSP) and the National Agency for Health Regulation, Control and Surveillance (ARCSA) that are applicable to the food industry.

- **Expected outcome:** Detailed report identifying gaps in food safety, compliance with Ecuadorian regulations, and areas for improvement in operational processes.

Phase 2: Senior management commitment and strategic planning

Objective: To achieve full commitment from senior management for the effective implementation of ISO 22000 and to establish clear strategic planning.

Responsible: CEO of Nuna, Quality Manager and Food Safety Management Committee.

Actions:

- **Definition of roles and responsibilities:**

Appoint a Food Safety Management System (FSMS) Manager who will be directly responsible for coordinating the implementation of the standard. Additionally, establish an Implementation Team composed of key personnel from production, quality, logistics, purchasing, and warehouse management to ensure cross-functional collaboration and effective execution.

- **Setting clear goals:**

Define clear objectives, such as enhancing the quality index of dairy products by reducing returns, quality complaints, and food safety incidents. These objectives should include measurable key performance indicators (KPIs), such as traceability compliance and the effective control of microbiological risks throughout the production process.

- **Planning of necessary resources:**

Ensure that the company possesses adequately trained personnel, appropriate technological tools—such as traceability and temperature monitoring systems—and the necessary budget to support the implementation of the standard.

Expected Outcome: Formal commitment from senior management and a strategic action plan for implementing ISO 22000 with measurable and achievable objectives.

Phase 3: Staff training and awareness

Objective: To ensure that all personnel understand and assume their role within the food safety management system, specifically in dairy production processes.

Responsible: Quality Manager and Human Resources Department.

Actions:

- **Comprehensive training program:**

Train staff in the application of food safety procedures and good manufacturing practices (GMPs) specific to dairy products. Include topics such as temperature control during the pasteurization process, proper handling of dairy products, and hygiene practices.

- **Training on local regulations:**

Ensure that staff are aware of relevant Ecuadorian regulations, such as the Ministry of Public Health (MSP) requirements on dairy products and applicable INEN standards.

- **Training evaluation:**

Implement periodic evaluations to measure the effectiveness of training and make adjustments when necessary.

Expected Outcome: Properly trained and committed workers who meet the standards established by ISO 22000 and national regulations.

Phase 4: Restructuring of processes and specific documentation

Objective: To adapt operational processes to the requirements of ISO 22000, in addition to preparing the relevant documentation to meet both national and international regulatory requirements.

Responsible: quality manager, production manager and logistics manager.

Actions:

- **Restructuring of operating procedures:**

Updating standard operating procedures to align with the principles of ISO 22000, taking into account areas such as quality control, hygiene practices, and dairy traceability. This also includes implementing a quality control plan tailored to the dairy industry to ensure temperature and pasteurization time controls.

- **Specific regulatory documentation:**

The organization of all necessary records (temperature control sheets, batch traceability forms, and microbiological control protocols, among others) must be ensured and documented in accordance with ISO 22000 and ARCSA regulations.

- **Document management:**

Use a properly registered and easily accessible system that provides assurance regarding the control of all procedures and records, including quality manuals, inspection records, and microbiological analysis results.

Expected outcome: Correct documentation that complies with the requirements of the relevant standard and national regulations, with operating procedures capable of ensuring safety in dairy production.

Phase 5: Implementation of controls and food safety management system

Objective: To implement the ISO 22000 food safety management system in dairy production, placing special emphasis on monitoring critical control points.

Responsible: responsible for the SGSA and quality control team.

Actions:

- **Establish critical control points:**

A control system must be implemented at critical points in dairy production, such as pasteurization, storage, and packaging. Each CCP must be monitored and documented to ensure food safety regulations.

- **Continuous monitoring:**

Using real-time monitoring technology, capable of supervising measures such as pasteurization temperature and refrigeration storage conditions.

- **Internal audits:**

Conduct internal audits periodically to assess compliance with procedures and make adjustments as needed,

Expected Outcome: Successful acquisition of the ISO 22000 system equipped with continuous monitoring to ensure the quality and food safety of Nuna 's dairy products.

Gap reduction plan

Table 12

Bridging gaps. Understanding and understanding the organization's context.

Understanding and context of the organization							
Requirement	**Gap**	**Aim**	**Activities**	**Resources**	**Responsible**	**Term**	**Budget**
Understanding the context	Partially compliant – SWOT not articulated to the SGIA	Integrating SWOT analysis with SGIA	- Review current SWOT - Relate key factors to food safety hazards - Prepare technical integration report	-Technical team -External consultant (if necessary)	SGIA Coordinator	2 weeks	100 USD
Scope of the SGIA	Non-compliant – preliminary declaration not updated	Correctly establish and document the scope of the SGIA	- Draft a new scope statement. - Validate with managers. - Publish official version.	-Quality Advisor - Normative documents	Head of Quality	1 week	$50
Food safety management system	Non-compliant – no system manual exists	Prepare and implement SGIA manual	- Write the manual. - Define fundamental processes. - Validate in technical committee.	- Technical staff -Review time	Food Safety Coordinator	1 month	$200

Note: table prepared by the author with information from the ISO 22000 standard (2018).

Table 13

Narrowing gaps. Leadership.

Leadership							
Requirement	**Gap**	**Aim**	**Activities**	**Resources**	**Responsible**	**Term**	**Budget**
Leadership Commitment	Partially compliant – commitment not formally evidenced	Formalize senior management's commitment to the SGIA	- Draft a food safety policy signed by management - Publish it and share it with staff	Internal documents, management signature	General manager	1 week	$0
Food safety policy	Partially compliant – not aligned with strategic objectives	Align food safety policy with organizational strategy	- Review institutional mission and vision - Reformulate policy according to FSSC 22000 - Internal validation	Technical advice, quality committee	Quality Manager	2 weeks	$50
Roles, responsibilities and authorities	Partially compliant – not defined in organizational chart	Establish and communicate SGIA functions	- Design an updated organizational chart - Prepare job descriptions - Socialize between teams	HR, supporting documents	Head of Human Talent	2 weeks	$0
Culture of safety	Non-compliant – not actively promoted	Promote a culture of food safety at all levels	- Develop awareness plan - Conduct monthly talks - Measure perception with surveys	Facilitators, teaching materials	Training Manager	3 months	$150

Note: table prepared by the author with information from the ISO 22000 standard (2018).

Table 14

Narrowing gaps. Planning.

Planning							
Requirement	**Gap**	**Aim**	**Activities**	**Resources**	**Responsible**	**Term**	**Budget**
Actions to address risks and opportunities	Non-compliant – no risk assessment	Identify and address risks and opportunities of the SGIA	- Create a risk matrix - Prioritize with qualitative analysis - Establish action plans	Matrix model, technical meetings	Head of SGIA	2 weeks	$70
Objectives of the SGIA	Partially compliant – not SMART or tracked	Set SMART goals with tracking indicators	- Redefine objectives with clear KPIs - Assign responsibilities and schedules - Establish a quarterly monitoring mechanism	Technical support, KPI templates	Quality Manager	2 weeks	$50
Change in planning	Non-compliant – documented change is not managed	Implement change management procedures	- Draft change management policy - Train management - Implement structural modifications to the SGIA	Manuals, training sessions	Quality Committee	1 month	$80

Note: table prepared by the author with information from the ISO 22000 standard (2018).

Table 15

Narrowing gaps. Support

Support							
Requirement	**Gap**	**Aim**	**Activities**	**Resources**	**Responsible**	**Term**	**Budget**
Resources	Partially compliant – no sufficiency analysis	Evaluate and ensure availability of resources for the SGIA	- Perform a diagnosis of current resources - Establish minimum requirements - Manage missing resources	Technical staff, analysis templates	Head of Quality and Finance	2 weeks	$0
Competence	Partially compliant – no evidence of competency assessment	Evaluate and strengthen staff competencies	- Apply competency matrix - Identify gaps - Annual training plan	HR, technical advisors	Human Talent	1 month	$200
Awareness	Partially compliant – isolated activities	Implement a systematic food safety awareness program	- Monthly talks - Information boards - Semi-annual verification test	Graphic material, classrooms, printing	Training Manager	3 months	$100
Communication	Partially compliant – no channels defined	Establish formal SGIA communication channels	- Create an internal communication plan - Define information flows - Validate effectiveness every 6 months	Internal manuals, institutional email	Quality Committee	3 weeks	$0
Documented information	Partially compliant – document disorganization	Improve control, access and updating of documentation	- Implement a digital document management system - Train key personnel - Maintain controlled versions	Software (Drive, Dropbox or similar), IT technician	Systems Manager	1 month	$100

Note: table prepared by the author with information from the ISO 22000 standard (2018).

Table 16

Gap reduction. Operation.

Operation							
Requirement	**Gap**	**Aim**	**Activities**	**Resources**	**Responsible**	**Term**	**Budget**
Operational planning and control	operational control is not documented	Formalize the planning and control of operational processes	- Develop standardized procedures - Identify critical control points - Train operational personnel	HACCP manual, templates, instructors	Head of Production	1 month	$150
Prerequisite programs	Partially compliant – incomplete documentation	Complete and update PPRs according to FSSC 22000	- Technical review of current PPRs - Prepare missing forms - Validate compliance in the plant	Technical regulations, external advisor	Food Safety Manager	2 weeks	$80
Control of external products and services	Non-compliant – no supplier evaluation	Implement a supplier evaluation and approval system	- Establish evaluation criteria - Conduct internal audits - Generate a database of approved suppliers	Audit formats, technical visits	Purchasing Department	1 month	$120
Emergency preparedness and response	Non-compliant – no documented plan	Develop and implement an emergency response plan	- Risk diagnosis - Drafting of the contingency plan - Semi-annual drills	Coordination with brigades and firefighters	Industrial Safety	1 month	$100

Note: table prepared by the author with information from the ISO 22000 standard (2018).

Table 17
Narrowing gaps. Performance evaluation.

Performance evaluation							
Requirement	**Gap**	**Aim**	**Activities**	**Resources**	**Responsible**	**Term**	**Budget**
Monitoring, measurement, analysis and evaluation	Partially compliant – no systematic analysis	Establish a system of monitoring and periodic analysis	- Define KPIs - Establish monthly registration and evaluation formats - Train in the use of indicators	Excel software, quality advisor	Quality Manager	3 weeks	$50
Internal audit	Partially compliant – no annual planning	Formalize annual internal audit program	- Develop schedule - Train internal auditors - Apply checklists	FSSC 22000 Manual, trained personnel	SGIA Coordinator	2 weeks	$0
Management review	Partially compliant – no minutes or evidence	Systematize SGIA review meetings with senior management	- Define semiannual frequency - Record minutes with follow-up - Include compliance analysis and actions	Minutes format, SGIA data	General Management	Every 6 months	$0

Note: table prepared by the author with information from the ISO 22000 standard (2018).

Table 18

Narrowing gaps. Improvement.

Improvement							
Requirement	**Gap**	**Aim**	**Activities**	**Resources**	**Responsible**	**Term**	**Budget**
Nonconformity and corrective action	Partially compliant – no defined actions	Establish a documented procedure for non-conformities	- Create corrective action instructions - Train staff - Record cases and follow up	Internal manuals, Excel	Quality Manager	3 weeks	$0
Continuous improvement	Partially compliant – no evidence of implementation	Implement continuous improvement plan with monitoring	- Create an improvement committee - Establish progress indicators - Evaluate results quarterly	SGIA Resources, Committee	Improvement Committee	Quarterly	$0

Note: table prepared by the author with information from the ISO 22000 standard (2018).

Table 19
Gap reduction. Food hazard control

Food Hazard Control							
Requirement	**Gap**	**Aim**	**Activities**	**Resources**	**Responsible**	**Term**	**Budget**
Hazard control, critical points and monitoring programs	Partially compliant – lacks documented implementation	Fully implement the HACCP plan	- Validate hazard analysis - Document CCPs and critical limits - Establish monitoring and verification plan	HACCP manual, formats, measuring equipment	Food Safety Officer	1 month	$150
Validation of control measures	Non-compliant – no evidence	Validate preventive, operational and control measures	- Establish validation criteria - Document tests and results - Update procedures	Measuring equipment, external advisor	Head of SGIA	1 month	$200

Note: table prepared by the author with information from the ISO 22000 standard (2018).

CONCLUSIONS

The study enabled the selection of an appropriate certification model for the Nuna brand, Sabores del Alma, in alignment with the general objective established at the beginning of the research. During the progressive development of the specific objectives, a technical diagnosis of Nuna's current management system was conducted based on the requirements for obtaining ISO 22000 certification. This initial diagnosis revealed both the company's potential for improvement and existing limitations, which can be addressed to meet internationally recognized food safety standards.

The first specific objective, focusing on the theoretical foundation of the research, was addressed through a comprehensive literature review of ISO 22000. This allowed an understanding of the principles, requirements, advantages, and limitations of management systems based on this standard. The theoretical framework developed in the first two chapters provided the necessary support to conduct a critical analysis of the company's internal situation in chapter three, evaluating gaps related to the standard's requirements in areas such as leadership, planning, support, and operations.

Regarding the second objective, the diagnosis of the company revealed structural, operational, and documentation-related limitations. Notably, the absence of a routine of rigorous organizational controls focused on food safety, combined with deficiencies in the systematic documentation of key elements—such as communicated policies, formal processes, and records capable of monitoring each step for future reference—impedes proper evaluation, auditing, and continuous improvement. These weaknesses were assessed against the standard's process and outcome requirements, and a verification table was developed to measure compliance.

The third objective was achieved through the selection and justification of an appropriate certification model. ISO 22000 emerged as the most suitable standard for Nuna, given its alignment with the company's mission, vision, and intended scope. The standard emphasizes optimal management of potential risks to food safety and allows for phased implementation compatible with the company's current capabilities, while promoting continuous improvement. The fourth objective was addressed by developing an improvement plan, detailing specific actions to close identified gaps. This includes

strengthening internal controls with regulatory documentation and records, implementing targeted training, conducting internal audits, and monitoring critical control points.

It is important to note that the evaluated elements—context, organization, leadership, planning, support, and operation—do not yet fully comply with ISO 22000 specifications. Several parameters are either incomplete or have not yet been addressed, including FSMS scope, planning of changes, documentation collection, and the evaluation of control measures, monitoring, and policies for ensuring food safety. Key deficiencies are observed in proper documentation, including the absence of a system manual, formalized procedures, and internal communication matrices, which directly affect continuous improvement implementation.

Leadership also falls short in managing responsibilities and providing training on food safety. The organization must adopt a preventive approach with a commitment to continuous improvement. Critical control points and operational prerequisites have not been fully defined, limiting safety performance. However, with improvements in monitoring and system verification, the implementation of ISO 22000 certification is both desirable and achievable for Nuna through targeted reforms.

RECOMMENDATIONS

It was observed that, given the gaps identified during the investigation, a comprehensive gap reduction plan must be implemented, complemented by targeted training for leadership personnel. This will enable continuous compliance assessment through sector-specific monitoring forms and an internal audit system. The gap reduction plan must be rigorously executed, beginning with the development of the necessary documentation to ensure proper food safety management. Required documents include a food safety manual, policies, basic procedures, standardized records, and detailed instructions for each process. The engagement of a technical advisor is recommended to guide this process.

As a second step, a dedicated Food Safety Compliance Team should be established, including representatives from each functional area. This team will be responsible for the implementation, maintenance, and evaluation of the food safety management system, and will require intensive training focused on the ISO 22000 standard. It is also recommended to develop a phased implementation schedule with realistic deadlines for each process, incorporating these into the allocated budget. External resources, such as partnerships with educational institutions, may be leveraged to support training and implementation. Finally, it is essential to foster an organizational culture that prioritizes food safety and actively involves all staff members in maintaining high standards.

REFERENCES

Añorga, A., & Becerra, A. (2024). *Influence of the application of quality control tools and process standardization on the operating costs of companies: a review of the scientific literature between the years 2007–2019 (Research work).* (Research work): Repository of the Private University of the North. https://doi.org/https://hdl.handle.net/11537/26266

Arriaran, J.F. (2023). *Implementation report on process improvement through a BPM-based analysis and the PDCA cycle for handling queries, complaints, and claims at a healthcare provider (IPRESS) in Huancayo.* [Unpublished doctoral thesis]: Continental University. https://hdl.handle.net/20.500.12394/13373

Beltrán, H., Martínez, G., & Dupeyron, L. (2024). Exploring the dynamics of foreign trade: Perspectives, challenges, and opportunities. *Journal of Academic Research Without Borders: Interdisciplinary Faculty of Administrative Economic Sciences - Department of Administrative Economic Sciences - Navojoa Campus* (41). https://doi.org/https://doi.org/10.46589/riasf.vi41.622

Canizales, L. (2020). Key elements of business innovation. A review based on contemporary trends. *Innova ITFIP Journal, 6* (1), 50–69. https://doi.org/https://doi.org/10.54198/innova06.03

Carranza, M., Aragundi, L., Macias, K., Paredes, E., & Villegas, A. (2024). Soil Conservation and Sustainable Management in Agriculture: A Systematic Review of Traditional and Modern Practices. *Scientific Code Research Journal, 5* (E3), 1- 28. https://doi.org/ https://doi.org/10.55813/gaea/ccri/v5/nE3/303

Carrasquilla, A.D., & Villarreal, K.Y. (2022). Initial Evaluation of the Occupational Health and Safety Management System for Educational Institutions: A Literature Review. *Latin American Focus, 5* (1). https://doi.org/https://revistas.ul.edu.co/index.php/rel/article/view/2

Castro, K., Luna, K., & Erazo, J. (2020). Human talent management for workforce improvement in a solidarity bank. *Telos, 22* (1), 184–203. https://doi.org/10.36390/telos221.13

European Postgraduate Centre. (January 22, 2022). *ISO/IEC 20000: structure, certification, Annex SL, PDCA, SMS scope and requirements, and management responsibility*. CEUPE: https://www.ceupe.com/blog/iso-iec-20000.html

European Postgraduate Centre. (July 30, 2024). *ISO/IEC 20000: structure, certification, Annex SL, PDCA, SMS scope and requirements, and management responsibility (January 22, 2022).* CEUPE: https://www.ceupe.com/blog/iso

Chacón, J., & Rugel, S. (2018). Review Article. Theories, Models and Quality Management Systems. *Espacios Journal, 39* (50), 14. https://doi.org/ISSN 0798 1015

Cordero Carmiol, M. (2016). *Management systems in the gastronomy industry: A comparative study.* [Master's Thesis]. https://doi.org/https://hdl.handle.net/20.500.14230/8855

Correa, A., & Socasi, O. (2021). *Evaluation of a food safety management system under the guidelines of ISO 22000:2018 in a sauce production industry [Master's thesis, University of the Americas].* http://dspace.udla.edu.ec/handle/33000/13727

Dilas, J., Zapata, D., Arce, M., Ascurra, D., & Mugruza, C. (2020). Comparative analysis of production costs and profitability of organically certified and non-certified specialty coffees. *South Sustainability, 1* (2), 1- 10. https://doi.org/https://doi.org/10.21142/SS-0102-2020-017

Enríquez, AM, Nogueira, YM, León, AM, & Nogueira, D. (2020). Theoretical and Conceptual Background of Process Audit. *Management Challenges, 14* (1), 1- 19. http: //scielo.sld.cu/scielo.php?script=sci arttext&pid=S2306-91552020000010000

Escobar, N., Beas, S., Gras, N., & Ronco, A.M. (2023). Food fraud: Past, present and future. *Chilean Journal of Nutrition, 50* (1), 106–116. https://doi.org/https://dx.doi.org/10.4067/S0717-75182023000100106

Espinosa Ugarte, V. (2025). *Development of a sustainability protocol for collective catering services.* https://doi.org/https://repositorio.uchile.cl/handle/2250/203747

Figueredo, C. A., Rincón, N. S., & Salazar, N. S. (2018). Characterization of initial compliance with the GLOBALG.AP standard, applied to small farmers in Duitama. *Entre Ciencia e Ingeniería, 12* (23), 32–39. https://doi.org/https://doi.org/10.31908/19098367.3700

Giraldo, J., Vargas, F., Mena, M., & Delgado, I. (2023). Methods for Managing the Security of Information Assets. *Iberian Journal of Information Systems and Technologies, 1* (62), 252-266. https://www.proquest.com/openview/c9bf3f3b2192c011fc8cb1e

Grados, R.A., & Obregón, A.J. (2018). Implementation of the Deming continuous improvement cycle to improve productivity in the logistics area of the clothing company KUYU SAC LIMA-2016. *ENGINEERING: SCIENCE, TECHNOLOGY AND INNOVATION, 5* (2), 1-12. https://doi.org/https://doi.org/10.26495/icti.v5i2.969

Inquilla, J., Calsina, W., & Velazco, B. (2017). Educational and administrative quality seen from within: The case of the National University of the Altiplano - Puno - Peru 2017. *@ción@ción, 8* (1), 5- 15. https://doi.org/http://www.scielo.org.pe/scielo.php?script=sci_arttext&pid=

Institute for Quality, Pontifical Catholic University of Peru. (August 2, 2023). *Quality Management and Food Safety. Pontifical Catholic University of Peru* . Institute for Quality, Pontifical Catholic University of Peru: https://calidad.pucp.edu.pe/educacion-ejecutiv

Melendez, JR, & Salous, AE (2021). Critical success factors and their impact on business project management: a comprehensive review. *Journal of Social Sciences, 27* (4), 228–242. https://doi.org/ISSN-e 1315-9518

Moreno, & Rubel. (2023). Survey on food quality and safety management systems in Latin America and the European Union. *Revista de Alimentos, 30* (2), 23-35. https://doi.org/https://doi.org/10.31243/aci.v30i2.1967

Navarro, P., Melgarejo, Z., & Vera, M. (2024). Business management and performance in SMEs from the perspective of behavioral finance. A systematic review of the literature. *Innovar Journal, 34* (94). https://doi.org/10.15446/innovar.v34n94.116809

Nuna Flavors of the Soul. (March 8, 2022). We are Nuna Flavors of the Soul [Status Post]. (Facebook, Ed.)

https://www.facebook.com/nunasabores.ec/photos/pb.100063850041584.-2207520000/481723310340364/?type=3

Food and Agriculture Organization of the United Nations FAO. (2021). *Fruits and vegetables – essential in your diet. International Year of Fruits and Vegetables 2021.* Food and Agriculture Organization of the United Nations: https://openknowledge.fao.org/server/api/core/bitstreams/a7fbf654-32d4-4f88-bfde-6ec900deb5dc/content

International Organization for Standardization. (2018). *ISO 22000:2018. Food safety management systems — Requirements for any organization in the food chain (2nd ed., revised 2018-11).* International Organization.

Ortiz, Y. (2018). The impact of Integrated HSEQ Management Systems on Latin American organizations: A systematic review. *Chilean Journal of Economy and Society, 12* (2), 76–93. https://rches.utem.cl/wp-content/uploads/sites/8/2019/01/

Palacios, M. (2021). *Proposal of a new procedure based on the ISO 9001 standard for the joint management of the ISO 31000 standard, the kaizen philosophy, and the lean manufacturing tool in industrial SMEs in the Valencian Community.* [Doctoral Thesis].: Polytechnic University of Valencia. https://doi.org/https://dialnet.unirioja.es/servlet/tesis?codigo=305910

Pons, B., Gisbert, V., & Pérez, A. (2018). Six Sigma methodology. Comparison between PDCA and DMAIC cycles. *Applied Research Notebooks, 9* (37), 27-34. https://doi.org/http://dx.doi.org/10.17993/EcoOrgyCso.2018.47

Riquelme, M. (2020). Michael Porter's Value Chain: What is it and why is it important? *Web and Business, 5* (1), 1-8. https://gc.scalahed.com/recursos/files/r161r/w24520w/Cadena_de_valor_de_michael_porter.pdf

Sánchez, R. (2020). *Systematic review of the literature on process management in the food industry (Research paper).* (R. d. Norte, Ed.) https://hdl.handle.net/11537/26302

Torres, P., Rodríguez, A., & Ochoa, K. (2021). Integrating the Internet of Things into Food Supply Chain Management: A Systematic Literature Review. *Prisma Tecnológico, 12* (1), 38–46. https://doi.org/10.33412/pri.v12.1.244

Villafuerte, F., Sancho, D., Enríquez, M., & Basantes, E. (2024). Unit operations for the production of dark, milk and white chocolate. A systematic review. Colombian Journal of Agroindustrial Research. *Colombian Journal of Agroindustrial Research, 11* (2), 64- 86. https://dialnet.unirioja.es/servlet/articulo?codigo=9807007