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Incidencia de Buenas Prácticas de Manufactura (BPM) en la Producción de Queso Fresco en la Sierra de la Provincia de El Oro, Ecuador

Incidence of Good Manufacturing Practices (GMP) in Fresh Cheese Production in the Highlands of El Oro Province, Ecuador

Incidência de Boas Práticas de Fabricação (BPF) na Produção de Queijo Fresco na Serra da Província de El Oro, Equador

Wilson Emmanuel Carrión-Espinosa [I]
wcarrion@utmachala.edu.ec
https://orcid.org/0000-0002-2069-5634

Verónica Patricia Bravo-Bravo [II]
vbravo@utmachala.edu.ec
https://orcid.org/0000-0002-6175-0484

Sandra Elizabeth Córdova-Márquez [III]
sandracordova_2013@hotmail.com
https://orcid.org/0009-0004-6891-2708

Fabián Patricio Cuenca-Mayorga [IV]
fcuenca@utmachala.edu.ec
https://orcid.org/0000-0002-4760-1458

Correspondencia: wcarrion@utmachala.edu.ec

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I. Faculty of Chemical and Health Sci., Machala University of Technology (UTMACH), Km. 51/2, Vía, Machala, Pasaje, Ecuador.
II. Faculty of Chemical and Health Sci., Machala University of Technology (UTMACH), Km. 51/2, Vía, Machala, Pasaje, Ecuador.
III. Faculty of Chemical and Health Sci., Machala University of Technology (UTMACH), Km. 51/2, Vía, Machala, Pasaje, Ecuador.
IV. Faculty of Chemical and Health Sci., Machala University of Technology (UTMACH), Km. 51/2, Vía, Machala, Pasaje, Ecuador.

Resumen

El queso fresco ocupa un lugar especial en los hogares ecuatorianos, caracterizado por atributos sensoriales únicos influenciados por la cultura y la geografía locales. Debido a su naturaleza perecedera y al proceso de producción artesanal tradicional, la adherencia a las Buenas Prácticas de Manufactura (GMP) es crucial para garantizar la calidad y seguridad del producto final. Este estudio tuvo como objetivo evaluar el cumplimiento de los requisitos mínimos de higiene en los establecimientos de producción de queso fresco. La evaluación tuvo lugar al principio y al final de un proyecto de participación comunitaria de dos años. A través de una lista de cotejo personalizada basada en aspectos regulatorios relevantes, se evaluaron establecimientos en los cantones de Zaruma y Piñas, importantes polos de productos lácteos en la provincia de El Oro. La mayoría de los establecimientos mejoraron su infraestructura física y agilizaron los procesos productivos, abordando las debilidades identificadas. Se espera que estas mejoras eleven la calidad y la seguridad del queso, garantizando la seguridad alimentaria del consumidor. La investigación estableció que el reforzamiento de las prácticas de fabricación y el mantenimiento de las normas GMP tienen un impacto directo y positivo en la calidad y la seguridad del queso fresco sin añejar, una delicia culinaria emblemática en Ecuador. Esta investigación enfatiza la necesidad de mantener un enfoque proactivo y apoyar a los productores en la elaboración de este preciado producto lácteo tradicional, preservando la confianza de las familias ecuatorianas para saborear este delicioso queso en sus mesas. El queso fresco en Ecuador cuenta con distintas características sensoriales formadas por influencias locales y la adherencia a GMP es vital debido a su naturaleza perecedera y producción artesanal. El estudio evaluó el cumplimiento de la higiene en los establecimientos de producción de queso, lo que llevó a mejoras significativas. La investigación destaca el vínculo directo entre GMP y la calidad y seguridad del queso, y destaca la importancia del apoyo continuo para mantener la excelencia en la producción de este preciado producto lácteo.

Palabras clave: Cumplimiento; Calidad; Seguridad; Lácteos; Comunidad.

Abstract

Fresh cheese holds a special place in Ecuadorian households, characterized by unique sensory attributes influenced by local culture and geography. Due to its perishable nature and traditional artisanal production process, adherence to Good Manufacturing Practices (GMP) is crucial for

ensuring the quality and safety of the final product. This study aimed to assess the compliance with minimum hygiene requirements in fresh cheese production establishments. The evaluation took place at the beginning and end of a two-year community engagement project. Using a tailored checklist based on relevant regulatory aspects, establishments in the cantons of Zaruma and Piñas, major dairy product hubs in El Oro province, were evaluated. The majority of the establishments improved their physical infrastructure and streamlined production processes, addressing identified weaknesses. These enhancements are expected to elevate the quality and safety of the cheese, ensuring consumer food safety. The research established that reinforcing manufacturing practices and upholding GMP standards directly and positively impact the quality and safety of the fresh unaged cheese, an emblematic culinary delight in Ecuador. This research emphasizes the need to maintain a proactive approach and support producers in crafting this cherished traditional dairy product, preserving the trust of Ecuadorian families in savoring this delectable cheese at their tables. Fresh cheese in Ecuador boasts distinct sensory characteristics shaped by local influences and the adherence to GMP is vital due to its perishable nature and artisanal production. The study assessed hygiene compliance in cheese production establishments, leading to significant improvements. The research highlights the direct link between GMP and cheese quality and safety, stressing the importance of continued support to maintain excellence in producing this treasured dairy product.

Keywords: Compliance; Quality; Safety; Dairy; Community.

Resumo

O queijo fresco ocupa um lugar especial nos lares equatorianos, caracterizado por atributos sensoriais únicos influenciados pela cultura e geografia locais. Devido ao seu caráter perecível e processo de produção artesanal tradicional, a adesão às Boas Práticas de Fabricação (BPF) é fundamental para garantir a qualidade e segurança do produto final. Este estudo teve como objetivo avaliar o cumprimento dos requisitos mínimos de higiene em estabelecimentos de produção de queijo fresco. A avaliação ocorreu no início e no final de um projeto de engajamento comunitário de dois anos. Usando uma lista de verificação personalizada com base em aspectos regulatórios relevantes, foram avaliados estabelecimentos nos cantões de Zaruma e Piñas, principais centros de produtos lácteos da província de El Oro. A maioria dos estabelecimentos melhorou sua infraestrutura física e simplificou os processos produtivos, suprindo as deficiências

identificadas. Espera-se que essas melhorias elevem a qualidade e a segurança do queijo, garantindo a segurança alimentar do consumidor. A pesquisa estabeleceu que o reforço das práticas de fabricação e o cumprimento dos padrões GMP impactam direta e positivamente a qualidade e a segurança do queijo fresco não maturado, uma delícia culinária emblemática no Equador. Esta pesquisa enfatiza a necessidade de manter uma abordagem proativa e apoiar os produtores na elaboração deste apreciado produto lácteo tradicional, preservando a confiança das famílias equatorianas em saborear este delicioso queijo em suas mesas. O queijo fresco no Equador possui características sensoriais distintas moldadas por influências locais e a adesão ao GMP é vital devido à sua natureza perecível e produção artesanal. O estudo avaliou o cumprimento da higiene nos estabelecimentos de produção de queijo, levando a melhorias significativas. A pesquisa destaca a ligação direta entre GMP e qualidade e segurança do queijo, enfatizando a importância do apoio contínuo para manter a excelência na produção deste precioso produto lácteo.

Palavras-chave: Conformidade; Qualidade; Segurança; Laticínio; Comunidade.

Introduction

El Oro, a province in Southern Ecuador, is endowed with abundant natural resources, particularly in the field of agriculture [1]. Of notable importance is the significant production of fresh milk, concentrated primarily in the highlands of the province, encompassing the cantons of Zaruma, Piñas, Atahualpa, and Portovelo [2]. A canton is a territorial division or administrative subdivision used in certain countries; it is a local government unit that falls between the national level and the municipal or city level [3]. The term “canton” is commonly used in some Latin American countries, including Ecuador, where the provinces are divided into smaller territorial units called as indicated [4]. Fresh milk is the raw material utilized to a substantial extent, accounting for 70% of its application in the production of fresh cheese [5]. The high demand for this product is attributed to its distinct sensory characteristics and cost-effectiveness when compared to processed cheeses sourced from other provinces [6]. For several decades, the production of fresh cheese has followed a traditional artisanal approach, relying on empirical knowledge that has been passed down from one generation to the next [7, 8]. Each producer imparts their unique touch, resulting in distinct characteristics [9]. Nevertheless, the ultimate objective remains consistent - to create a fresh cheese that perfectly aligns with the sensory

preferences of the renowned “queso zarumeño” (Zaruma cheese) [10]. This esteemed variety has garnered substantial consumer recognition and holds a prominent position in the local market, capturing an impressive 53% preference rate among individuals seeking delectable fresh cheese options [11]. The adherence To Good Manufacturing Practices within the food industry for human consumption is a crucial requirement, subject to verification by governmental entities, e.g., the Ecuadorian Agency for Sanitary Regulation and Control (Agencia Nacional para el Control y la Regulación Sanitaria - ARCSA) [12]. This stringent oversight guarantees the quality and safety of the final food products [13]. In this context, a comprehensive evaluation of the application of such practices was conducted in establishments specializing in the production of fresh cheese [14]. This assessment occurred at the inception of the project and conclusion, spanning a duration of two years. Following various training sessions and on- site visits, a substantial transformation may be observed in the establishments, as well as in the entire production process, ensuring utmost care from production to the hands of the consumers. Noteworthy improvements encompass enhanced physical infrastructure, water quality, upgraded utensils, meticulous handling and control of raw materials, integration of key production variables, advancements in packaging, labeling, storage, and meticulous handling until the products reached the retail points. Significant attention is given to comprehending the highly perishable nature of the product and the potential repercussions of inadequate handling throughout the production process, including the transmission of foodborne diseases [15,16]. These insights prompted a comprehensive implementation of better production practices, mitigating potential risks, and safeguarding quality and safety of the product at every stage [17].

Material and methods

This study employed an experimental and field-based approach to conduct an evaluation of producers, both associated and non-associated, from the parishes of Salvias, Arcapamba, and Güizhagüiña in the canton of Zaruma, as well as the parish of Saracay in the canton of Piñas, all these jurisdictions pertaining to El Oro province. The main objective of this evaluation was to assess the level of compliance with the Good Manufacturing Practices (GMP) outlined in resolution ARCSA-DE-067-2015-GGG from the Ecuadorian Agency for Sanitary Regulation and Control [18]. A custom-designed questionnaire was developed for data collection during both the diagnostic and final evaluation stages. The questionnaire was meticulously crafted to encompass

all the essential aspects specified in the resolution ARCSA-DE-067-2015-GGG, ensuring comprehensive coverage of the GMP requirements.

Population and sample

The target population consisted of producers involved in the production of dairy derivatives in the aforementioned regions. A combination of associated and non-associated producers was chosen to represent the diversity of the dairy industry in the study area. From this population, a sample of 19 dairy derivative- producing units was carefully selected to participate in the study, ensuring a representative representation of the sector.

Data collection and analysis

To obtain accurate and relevant data, the questionnaire was administered directly to the producers. This approach allowed us to gain insights into their actual practices and operational environment. Additionally, conducting field visits and on-site observations provided valuable contextual information regarding the implementation of GMP in their daily operations. In this study, a rigorous procedure was implemented to ensure the highest level of objectivity and eliminate any potential bias or conflict of interest that could influence the research outcomes. To achieve this, a unique random number of four digits was assigned to each participating producer prior to their inclusion in the study [19]. The random assignment of numbers was conducted with utmost impartiality, ensuring that it was completely unrelated to the producers' characteristics, affiliations, or positions in the dairy industry. This approach guaranteed a fair and equitable selection process, free from any undue influence or favoritism and minimized the risk of sample selection bias and enhance the validity of the research findings. The results were then compared against the GMP requirements specified in resolution ARCSA-DE-067-2015-GGG. This analysis enabled a comprehensive assessment of the level of compliance among the participating dairy derivative producers.

Ethical considerations and limitations

Prior to data collection, ethical considerations were strictly adhered to. Informed consent was obtained from all participants, ensuring their voluntary participation in the study [20]. Confidentiality and anonymity of the respondents' information were maintained throughout

the research process. It is essential to acknowledge certain limitations of this study. The sample size, while carefully selected to be representative, may not encompass all the nuances and variations present in the wider dairy industry. However, the findings provide valuable insights into GMP compliance in the studied regions and serve as a basis for further research and improvements in the dairy production sector.

Results

Primary assessment

The list includes the essential general requirements for adhering to Good Manufacturing Practices. The compliance assessment is categorized into “Partial Compliance (PC)” for instances where some criteria are met, “Non-Compliance (NC)” for cases where none of the criteria are met, and “Full Compliance (FC)” for complete adherence to all requirements. Out of a total of 19 establishments dedicated to the production of fresh cheese, it was found that only 6 of them, corresponding to 31.57%, partially meet the requirements for implementing Good Manufacturing Practices (GMP) in their physical spaces. These establishments lack important elements, such as a reliable source of potable water and proper equipment distribution to prevent contamination. On the other hand, a concerning number of 13 establishments, representing 68.42%, do not comply with any GMP requirements in this category, posing potential risks to product safety. Moving on to the use of equipment and utensils, 15 establishments, accounting for 78.94%, are found to partially comply with GMP. While they possess materials and equipment in decent condition, they fall short in using appropriate materials to ensure non-interaction with the food. In contrast, only 4 establishments (21.05%) meet all the necessary requirements, demonstrating their commitment to ensuring high standards in this aspect. Regarding the handling of production raw materials, it is observed that 6 establishments, corresponding to 31.57%, partially comply with GMP. Although they conduct rapid tests to check the materials' quality, they lack proper documentation to validate these tests. Moreover, a concerning majority of 15 establishments (78.94%) do not comply with any GMP requirements in this category. They fail to implement quality controls and lack physical evidence of their material inspections. Similarly, in the area of manufacturing operations, 4 establishments (21.05%) are found to partially comply with GMP, applying process control parameters. However, the absence of proper record-keeping to validate

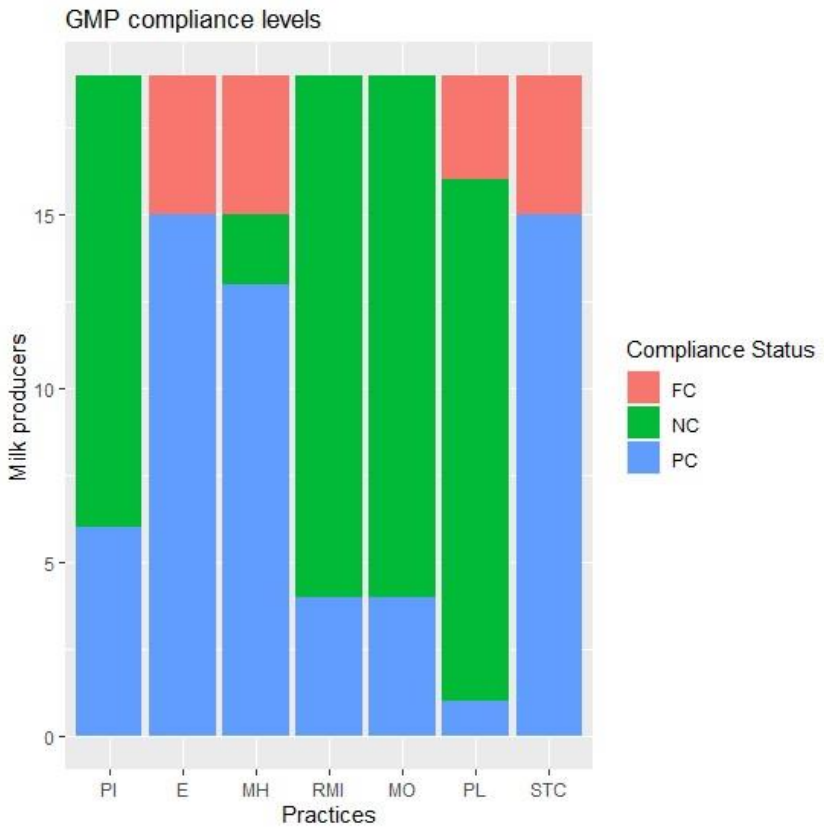
these controls is evident. Alarmingly, 15 establishments (78.94%) neglect any GMP requirements in this area and have yet to implement process variables and control measures within their production processes. When it comes to packaging and labeling practices, only 3 establishments (15.78%) are fully compliant with GMP standards, while 1 establishment (5.26%) partially meets the requirements with minor deficiencies in their labeling practices according to INEN standards. The majority of 15 establishments (78.94%) do not meet any GMP requirements in this category, and issues related to inadequate packaging, packaging materials, and labeling are prevalent. Lastly, focusing on storage and transportation practices, 4 establishments (21.05%) demonstrate proper adherence to GMP standards, ensuring suitable storage conditions and appropriate transportation to commercialization sites. However, a significant number of 13 establishments (78.94%) do not comply with any GMP requirements in this area. They lack proper storage facilities, exhibit careless product transportation practices, and have no established traceability records. Overall, this assessment highlights the need for considerable improvement in adhering to Good Manufacturing Practices within the fresh cheese production industry. Addressing these shortcomings is crucial to ensure the safety and quality of the final products, protecting consumers and maintaining industry standards. Table 1 contains a summary of the results from the first survey. Fig. 1 contains the description of the compliance levels overall for all the producers involved and Fig. 2. Shows the distribution of compliance for GMP at the initial stage.

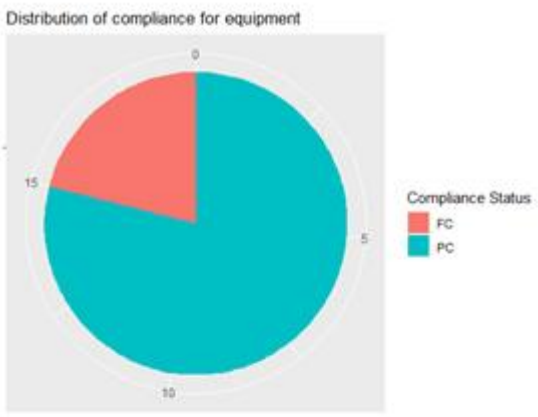
Table 1. Compliance of the general requirements for GMP (initial assessment)

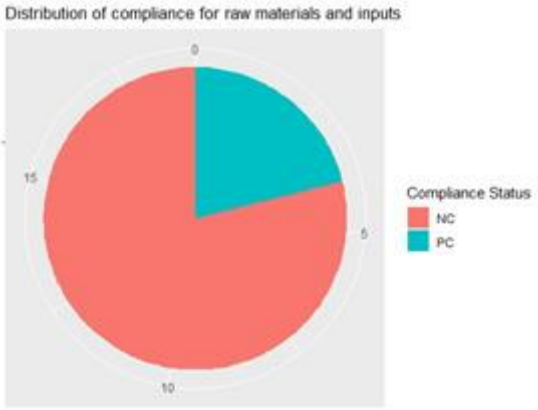
Milk producer	Physical infrastructure	Equipment	Manufacturing hygiene	Raw materials and inputs	Manufacturing operations	Packaging and labeling	Storage, transportation, and commercialization
5901	PC	FC	FC	PC	PC	FC	FC
8967	PC	FC	FC	PC	PC	PC	FC
5684	NC	PC	PC	NC	NC	NC	PC
3443	NC	PC	PC	NC	NC	NC	PC
6089	NC	PC	NC	NC	NC	NC	PC
4812	NC	PC	PC	NC	NC	NC	PC
6534	NC	PC	PC	NC	NC	NC	PC
2763	NC	PC	PC	NC	NC	NC	PC

2354	PC	FC	FC	PC	PC	FC	FC
4631	NC	PC	PC	NC	NC	NC	PC
8345	NC	PC	PC	NC	NC	NC	PC
6721	NC	PC	PC	NC	NC	NC	PC
8351	NC	PC	PC	NC	NC	NC	PC
4453	PC	FC	FC	PC	PC	FC	FC
8789	NC	PC	PC	NC	NC	NC	PC
1344	NC	PC	PC	NC	NC	NC	PC
6723	PC	PC	NC	NC	NC	NC	PC
7932	NC	PC	PC	NC	NC	NC	PC
9851	PC	PC	PC	NC	NC	NC	PC

Fig 1. GMP compliance levels for all the producers of milk in the studied area




Distribution of compliance for equipment
0
5
10
15
Compliance Status
FC
PC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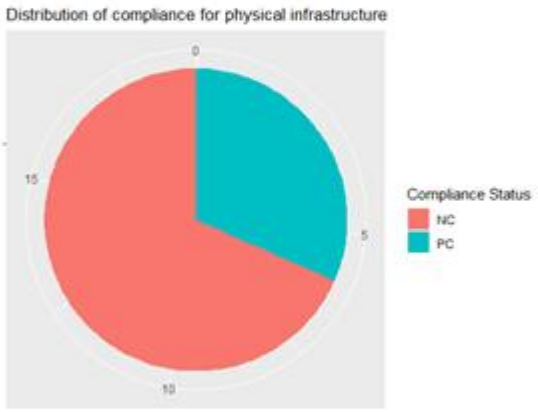
10
15
Compliance Status
NC
PC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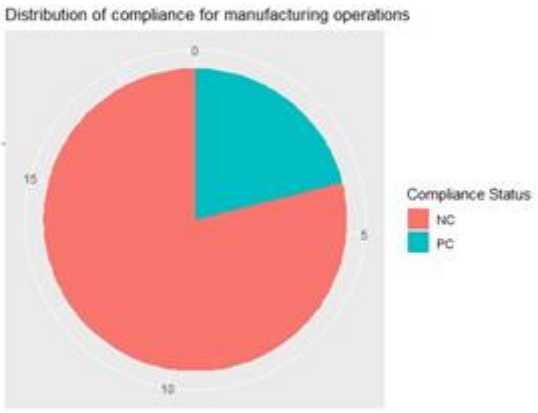
10
15
Compliance Status
NC
PC


Distribution of compliance for manufacturing operations
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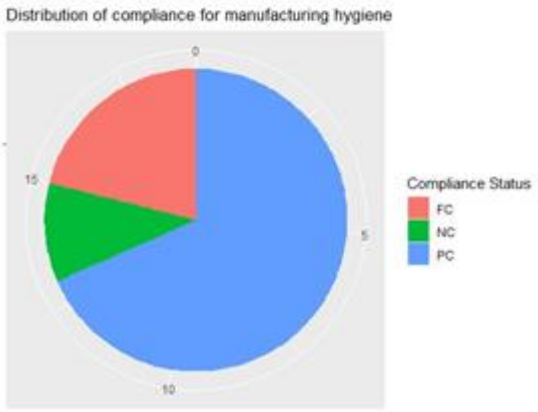
5
10
15
Compliance Status
NC
PC


Distribution of compliance for manufacturing hygiene
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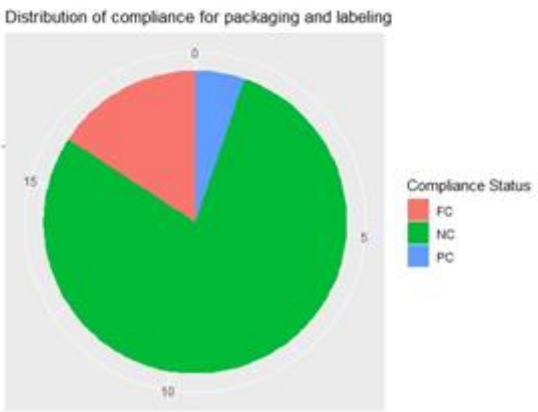
5
10
15
Compliance Status
FC
NC
PC


Distribution of compliance for packaging and labeling
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5
10
15
Compliance Status
FC
NC
PC

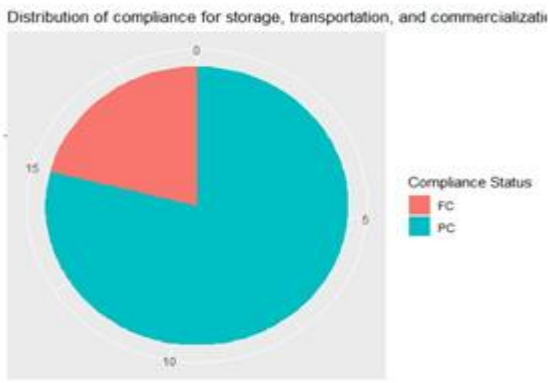


Fig. 2. Distribution of compliance for each GMP at the initial stage

Final assessment

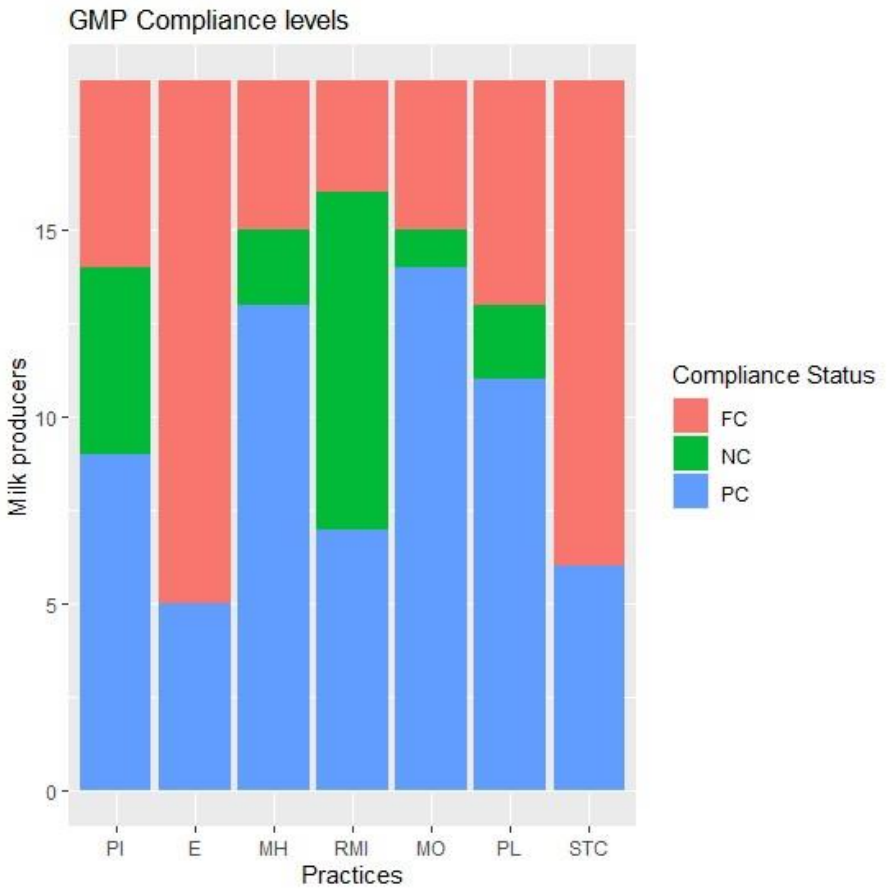
With the aim of ensuring the safety and quality of dairy products, an exhaustive final evaluation was conducted on establishments dedicated to their production. Following the initial assessment, the new review specifically focused on verifying compliance with GMP requirements. This initiative arose as a proactive measure to ensure that the standards and protocols established in the first evaluation were maintained and improved over time. The final evaluation aimed to identify any areas for improvement that may have emerged since the first review and validated whether establishments had implemented the previous recommendations. Additionally, it assessed whether GMP requirements were fully met and if corrective measures had been adopted to address previously identified deficiencies. The achievements of those establishments that demonstrated outstanding commitment to the application of Good Manufacturing Practices were highlighted. Likewise, personalized recommendations were provided to those needing improvement in specific areas to ensure compliance with the standards set by competent authorities. The final evaluation represented a significant step towards continuous improvement and excellence in the dairy industry. Through this initiative, we sought to reaffirm our commitment to food safety and consumer welfare, promoting the implementation of best practices at every stage of the dairy product production chain. Table 2 contains a summary of the results from the first survey. Fig. 3 contains the description of the compliance levels overall

for all the producers involved and Fig. 4. Shows the distribution of compliance for GMP at the initial stage.

Table 2. Compliance of the general requirements for GMP (final assessment)

				Raw materials and		Packaging	Storage, transportation, and
5901	FC	FC	FC	FC	FC	FC	FC
8967	PC	FC	FC	FC	FC	FC	FC
5684	FC	FC	FC	PC	FC	FC	FC
3443	NC	PC	FC	PC	PC	FC	FC
6089	NC	PC	FC	PC	PC	PC	FC
4812	PC	FC	PC	NC	PC	PC	PC
6534	NC	FC	PC	NC	PC	PC	FC
2763	PC	FC	FC	NC	PC	PC	PC
2354	PC	FC	FC	FC	FC	FC	FC
4631	FC	PC	FC	PC	PC	PC	FC
8345	NC	FC	PC	PC	PC	PC	FC
6721	PC	FC	PC	NC	PC	PC	PC
8351	PC	FC	PC	NC	PC	PC	PC
4453	FC	FC	FC	FC	FC	FC	FC
8789	FC	FC	PC	PC	PC	FC	FC
1344	NC	PC	PC	PC	PC	PC	FC
6723	PC	FC	NC	NC	PC	PC	PC
7932	PC	FC	PC	NC	PC	PC	FC
9851	PC	PC	PC	NC	NC	PC	PC

Fig 3. GMP compliance levels for all the producers of milk in the studied area (final assessment)



Out of the 19 establishments, 5 (26.31%) have successfully met the requirements for physical infrastructure. Encouragingly, 9 establishments (47.36%) have made considerable progress in implementing GMP practices in their physical spaces, rectifying important deficiencies to prevent contamination. However, there are still 5 establishments (26.31%) that require significant improvements in this category.

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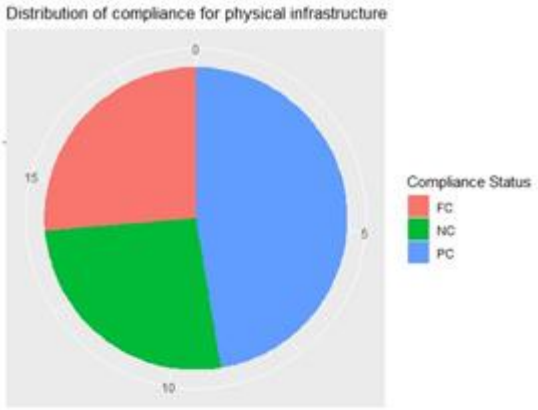
Distribution of compliance for physical infrastructure
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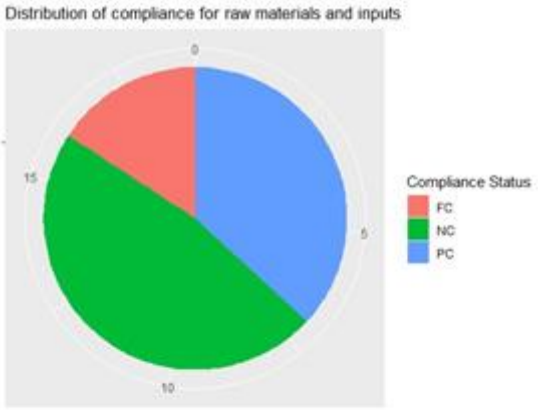
5
10
15
Compliance Status
FC
NC
PC


Distribution of compliance for raw materials and inputs
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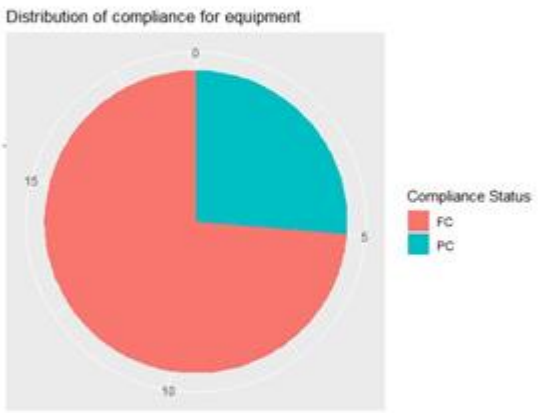
10
15
Compliance Status
FC
NC
PC


Distribution of compliance for equipment
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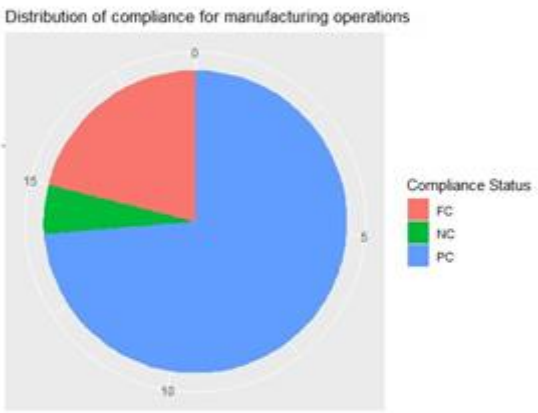
5
10
15
Compliance Status
FC
PC


Distribution of compliance for manufacturing operations
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10
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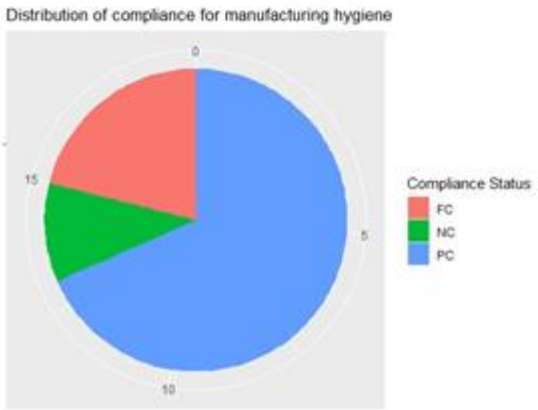
Compliance Status
FC
NC
PC


Distribution of compliance for manufacturing hygiene
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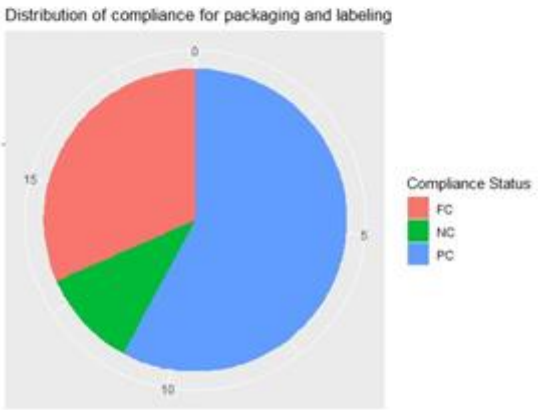
Compliance Status
FC
NC
PC


Distribution of compliance for packaging and labeling
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10
15
Compliance Status
FC
NC
PC

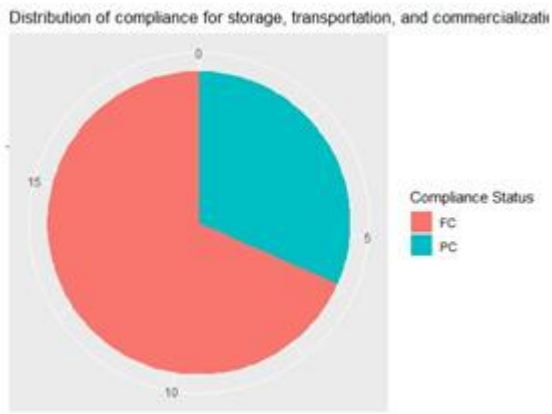

Fig. 4. Distribution of compliance for each GMP at the initial stage

As we delve into the use of equipment and utensils, 14 establishments (73.68%) have showcased commendable compliance with GMP. These establishments possess materials and equipment in excellent condition, ensuring minimal interaction with the food products. Furthermore, 5 establishments (26.31%) have demonstrated exemplary dedication by meeting all the requirements in this category, exemplifying a marked improvement in adherence to the norms. Our evaluation also reveals encouraging developments in GMP compliance across different areas. For instance, 9 establishments (47.36%) have successfully met all the requirements, while another 9 establishments (47.36%) have made notable progress in adopting the proper protective attire during production, significantly improving their overall compliance. However, there remains one establishment (5.26%) that has yet to meet any requirements, underscoring the urgency for them to prioritize product safety. In assessing the handling of production raw materials, we find that 4 establishments comply with the requirements, while 7 establishments (36.84%) partially meet GMP standards. These establishments conduct rapid tests for material assessment but lack necessary documentation. Furthermore, 8 establishments (42.10%) have not met any requirements in this category, indicating a need for them to institute quality controls and maintain physical evidence for enhanced compliance. Moving on to manufacturing operations, 5 establishments (26.31%) now meet the regulatory requirements, reflecting considerable improvement over the course of this evaluation. Meanwhile, 13 establishments (68.42%) exhibit

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commendable partial compliance by implementing process control parameters, albeit without proper record-keeping. Conversely, one establishment (5.26%) remains non- compliant and must address the lack of process variables and control within their production processes. In terms of packaging and labeling practices, 7 establishments (36.85%) have successfully embraced GMP standards, showing significant improvement during the evaluation period. However, 12 establishments (68.15%) still require improvement in their labeling practices to fully meet INEN standards. Lastly, in storage and transportation practices, 13 establishments (68.42%) demonstrate commendable adherence to GMP requirements, while 6 establishments (31.57%) exhibit partial compliance. Although there has been an overall improvement in this area, some establishments still need to focus on appropriate storage and transportation procedures.

Conclusions

After a rigorous two-year project, remarkable progress has been achieved in meeting the minimum hygiene requirements outlined in Good Manufacturing Practices (GMP) for dairy product manufacturing. Notably, significant advancements have been made in ensuring compliance with the requirements for physical infrastructure, handling of raw materials, production, and transportation of dairy derivatives. These improvements are crucial as they directly impact the overall quality and safety of the final products. The fulfillment of the majority of relevant requirements from the GMP regulations places the participating establishments in a favorable position for facing technical inspections carried out by government authorities, including the ARCSA. Furthermore, it sets them on a positive trajectory towards potential GMP certification, a prestigious mark of excellence for their small or micro-enterprises. During the initial phase of the project, diagnostic evaluations revealed shortcomings in the condition of physical facilities and manufacturing operations. However, through targeted technical strengthening sessions and hands-on support in GMP implementation and process management, significant improvements have been achieved by the project's conclusion. These achievements represent significant strides towards ensuring ongoing improvement and elevating industry standards within the dairy sector. The dedication displayed by these establishments in adhering to GMP standards underscores their commitment to food safety and the well- being of consumers. Consequently, continuous training and vigilant oversight are crucial to sustaining and further advancing these accomplishments in the future. In essence, this scientific endeavor has played a

pivotal role in fortifying the local dairy industry, motivating establishments to embrace high levels of GMP compliance, and positioning them competitively within the market. Collaborative efforts between governmental institutions and the private sector are essential to preserve these gains and enhance the safety and quality of dairy products for the benefit of society as a whole. As the project concludes, the seeds of progress have been sown, paving the way for a more resilient and thriving dairy industry in the years to come.

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