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RESEARCH ARTICLE

Application of Failure Mode and Effect Analysis as a verification tool of the Hazard Analysis Critical Control Points System in dairy Factories

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ABSTRACT

A major challenge in food safety worldwide is the food safety outbreak. Despite the implementation of Hazard Analysis Critical Control Points System (HACCP), there have been many foodborne outbreaks linked to food processes reported in many countries. Hence to minimize or eliminate failures in the manufacturing process systematic risk control at each stage of the process is required. Kingdom of Saudi Arabia (KSA), one of the highest economies in the world faces many issues related to food safety including foodborne illness, quality and safety control issues, and weaknesses in the application of risk analysis. The Saudi Food and Drug Administration (SFDA) has mandated the implementation of (HACCP) in food manufacturing in 2022. The study aims to design a precise method to assess and verify the (HACCP) system in practice using the Failure Mode and effect Analysis (FMEA) tool. Audits were conducted in three medium-sized dairy factories in Riyadh, and Qassim, provinces of Saudi between April and June 2023. In the processes, possible failure modes and potential risks for each failure mode were identified and analysed. The risk level of each potential failure was identified using Risk Priority Numbers (RPN). The result showed factory (A) had the lowest risk of potential errors or dangers with the lowest overall FMEA score of 742. With a total FMEA score of 1,364, Factory (B) had a moderate level of risk. Factory (C) had the highest risk of potential errors or dangers with an overall FMEA score of 1,392. Non-conformities found in implemented HACCP systems raise questions on the guaranteeing of complete food safety by the (HACCP) system. A comparison of the FMEA findings to the HACCP ratings showed that Factory B had the highest number of high-risk areas and the lowest HACCP rating.

INTRODUCTION

Scientific understanding of food-borne illnesses and public health awareness have increased in the last three decades. Food manufacturing firms have been increasingly demanded by consumers, inspectors, and regulators to minimize the risks of food safety hazards (Arpanutud et al., 2009). Developing countries are paying increased attention to food safety, because of the growing recognition of its potential impact on public health, food security, and trade competitiveness (Umali-Dieninger & Sur, 2007). Worldwide the food industries as well as government regulatory agencies have accepted the HACCP system as the most cost-effective means to reduce identifiable food-borne hazards. However, the HACCP certification does not guarantee absolute food safety and quality of the end product (Fotopoulos et al., 2009). There is a need to diagnose the Food Safety Management System (FSMS) implemented to assess weaknesses and identify potential points to improve the current system's performance. A risk-based approach identifies the highest risk areas and prioritizes the most effective food safety interventions and mitigation measures. Risk assessment is the most prominent and central approach to risk-based preventative approaches to food safety. The continuous pressure to improve the effectiveness of FSMSs and the need to verify the performance of implemented systems initiated the development of verification tools like Failure Mode and Effect Analysis (FMEA).

The Kingdom of Saudi Arabia (KSA) with about 2,250,000 km2 land area, is the largest Arab state in Western Asia. Kingdom of Saudi Arabia is the 20th strongest economy in the world and the 20th importer and 19th exporter at the global level (CIA, 2019). The food sector has a greater impact on the country's economy through importing, exporting, manufacturing, and distributing food products, and hence is considered as one of the most important sectors in the Kingdom of Saudi Arabia (SFDA, 2006; Al-Kandari and Jukes, 2012). In the Middle East particularly in the Kingdom of Saudi Arabia the dairy industry is considered as one of the most developing food industries. Milk and dairy products are very important sources of food in the Middle East due to their high nutritional value (Saleena et al., 2023). There is an increased consumption of dairy products contributed by the fast-growing population and an increase in per capita income (MEP, 2006).

In the past four decades, the Gulf countries including Kingdom of Saudi Arabia have undergone rapid changes in their socio-economic situation, food consumption patterns, lifestyle, and health status. Foodborne outbreaks, particularly food poisoning due to biological hazards such as Salmonella, B. cereus, S. aureus, and E. coli have become an important problem. To resolve this, the Saudi Food and Drug Authority (SFDA) established by the Kingdom of Saudi Arabia has mandated the implementation of HACCP in all food manufacturing companies. The initial implementation which started in 2020 with only high-risk factories such as meat and dairy was extended to medium and low-risk food factories in 2022. Despite various food safety measures like awareness and knowledge transparency, mandated HACCP framework, verification, and inspections, food poisoning is still reported as the major cause of numerous diseases. Minimization or elimination of failures in the manufacturing process requires systematic risk control at each stage of the process. However, there is a lack of data on the effectiveness and efficiency of the HACCP implementation in the companies that have already implemented the HACCP system in Kingdom of Saudi Arabia. Risk analysis is an internationally accepted framework that provides national food safety authorities with a systematic and disciplined approach to making evidence-based food safety decisions (WHO, 2006). Here in this research article, we used a site of producers consist of date collection, (HACCP) verification, risk calculation and statistical analysis. Hence the quantitative risk analysis method, Failure Mode and Effect Analysis (FMEA) was applied to the risk analysis of various dairy products in Kingdom of Saudi Arabia. The FMEA is a modern tool used to identify the potential failure modes, and the causes and effects of each nonconformity on the system, subsystem, or component, to keep the technological process under control and to improve the quality of finished products. The method is based on a specific and elaborate verification questionnaire on the HACCP process and documentation, including its prerequisites, steps, and principles.

Materials and Methods

1. Data Collection

Both primary and secondary data sources were used for the study. Primary data was collected by surveying the dairy companies located in the Central region of Saudi Arabia namely Riyadh, and Qasim provinces. The direct personal interview method was used to obtain primary data for the verification of HACCP in these industries. The secondary data were obtained from the review of the literature. Three dairy companies were chosen from these two provinces. The dairy companies were involved in the production of pasteurized milk and milk products such as yogurt, Laban, Labneh, cheese, and cream. All three plants had implemented the HACCP system in their factory which operated differently however the three factories were chosen as their profiles were comparable. This allowed a comparison of the HACCP system functioning in similar enterprises alongside determining the risk areas in the production of an important food product (Trafialek & Kolanowski, 2014).

2. Audit Questionnaire

A structured questionnaire was prepared to contain a list of verification questions related to the implementation and functioning of the HACCP system. This was divided into two parts. The first part of the verification questionnaire consisted of 110 questions related to the implementation of the

HACCP system. Part 2 consisted of 35 questions corresponding to principles of the HACCP system functioning in practice related to employees and management. A ranking system with four ratings of 2, 3, 4, and 5 was used to assess the verification criteria. The adopted scale lacked a precisely identified centre, which prompted the inspector to reconsider the evaluation. The maximum score (5) showed compliance or meeting all criteria, while the lowest score (2) indicated nonconformity (Table 2.1). Only a rank of 5 assured that food quality was guaranteed and that the finished product was suitable for customers.

Table 2.1 Verification Rating Scale of Criteria (Source: Trafialek & Kolanowski, 2014)

Score	Description	Approximate % Conformity
5	In each detail requirements for all evaluated criteria were fulfilled. i.e., complete ensuring of food safety	100
4	A slight deviation in the fulfilment of the requirements but non-significant nonconformities for food safety at the time of verification	80
3	Inadequacy in the requirements fulfilled i.e., food safety was not assured	60
2	None of the requirements were fulfilled i.e., food safety was not assured	≤40

A statistical calculation was used to calculate the measurement data of each parameter according to the approved scale, and the lists of verification questions were prepared. The final scores for each block of questions were determined after all conditions had been analyzed. The first section of the questionnaire encompasses the HACCP system's documentation. In certain cases, paperwork was meticulously organized. Negligence in the use of the HACCP device could cause a substantial increase in food safety hazards (Luning et al., 2002).

3. Risk Calculation

Table 2.2 Severity of nonconformities for each level of implementation and functioning of HACCP system - S coefficient (Source: Trafialek & Kolanowski, 2014)

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The final score for each block was calculated, and the scores were assessed to determine the risk to food safety. (FMEA) analysis was used to quantify the risk for each block (Luning, et al., 2002). (FMEA) is a standardized method for assessing reliability. It raises the operational productivity of the manufacturing cycle while decreasing the risk level (Scipioni et al., 2002). The possibility was determined using FMEA as a ratio of three coefficients: the importance of verification criteria for food safety (S), the likelihood of nonconformity incidence based on verification proof (O), and the detectability of the nonconformity (D). Each coefficient was assigned a value between 1 and 10, and the relative risk index (R) was calculated, as in the basic equation.

Risk Calculation, $R = S \times O \times D$; Where (R) = Risk, (S) = Severity, (O) = Occurrence, (D) = Detectability (Source: Trafialek & Kolanowski, 2014).

The severity of the effect reflects the risk impact, and the ability to detect a factor's predictive power before it occurs (Sharifi et al., 2022). In the second part of the audit questionnaire, on the (HACCP) system implementation, for the five preliminary steps values 1 to 5, and from steps 6 to 12 on HACCP system principles, values 6 to 9 were assigned (Table 2.2). The O parameter values were calculated as the mean of scores obtained during the audit for a particular block of questions (Table 3.4). A higher score was presumed to be correlated with the lower incidence of nonconformity. The D value, was the possibility of nonconformity detection in the system without the need for an audit (Trafialek & Kolanowski, 2014) (Table 2.3). Each of the risk assessment criteria is scored on a scale of 0–10. More adverse effect of factors on the system was indicated by higher values (Sharifi et al., 2022). The axis of food safety risk was divided into four risk categories: minor (1-250), moderate (250-500), high (500-750), and critical (750-1000).

Table 2.3 Detectability of non-conformities without the need for audit – D Coefficient (Source: Trafialek & Kolanowski, 2014)

D value	D value Detectability of the nonconformity
1	Very easy - Every employee who worked in each area could notice the non-conformity where it occurred.
2	Easy - The employee responsible for the monitoring of CCP, production manager, and HACCP system supervisor could notice the non-conformity
3	Average - The production manager and HACCP system supervisor could notice the non-conformity
4	Hard - The internal verification of the HACCP system could detect the non-conformity
5	
6	
7	Very hard – By chance detection of nonconformity
8	
9	Unlikely - Only by the use of advanced audit techniques nonconformity could be detected
10	

4. Statistical Analysis

The final score is calculated using the mean of the individual audit score percentage of conformity of each factory.

Mean, $\bar{X} = \frac{\sum x}{n}$

Where Σ X is the Mean Score, X̄ is the sum of the audit scores of each question (based on parameters) in the HACCP questionnaire, and n is the sum of questions in each step of the questionnaire.

4.1. laboratory analysis

This method involves testing for three primary contaminations (Microbial, Chemical, and Drug Residues) all of which according to the GSO Standards could be grounds for diseases associated with dairy factories: low-level contamination of the product or contamination of the product during processing, packaging, and further handling. The principles of the (Microbial, Chemical, and Drug Residues) assessment scheme protocol was developed to determine the actual containment output of an implemented HACCP. All analyses were conducted at an accredited lab.

RESULTS & DISCUSSION

The FTIR spectra of ACDS, ACDS@Tu, and Pb(II)-loaded ACDS@Tu (Fig. 2) reveal significant differences in surface functional groups.

Hazard Analysis and Critical Control Points (HACCP) is a widely accepted system for ensuring food safety. However, practical implementation of HACCP can be difficult, and identifying risk areas within the system is essential for minimizing potential hazards. The performance of a HACCP-based program is the measure of consistency, and reliability, in achieving safety and quality objectives successively from batch to batch or lot to lot during a production cycle or a season of operation while its effectiveness of the HACCP-based programs is considered as the capacity to achieve safety and quality objectives (Cormier et al., 2007). In this study, we aim to evaluate the HACCP compliance of three milk processing plants and identify potential food safety hazards.

The results of audit criteria for three different factories, A, B, and C are given in Table 3.1. The audit criteria were divided into three parts: Part I, which measured the prerequisite program for the

HACCP, Part II, which measured the implementation of the HACCP, and Part III, which measured the functioning of the HACCP in practice.

For part I of the audit criteria, Factory C had the highest score of 4.80, indicating 95% conformity to the prerequisite program for HACCP. Factories A and B also had a good score, 4.60 (90%) and 4.70 (85%), respectively. For Part II, Factory C had the highest score of 4.68, with 92.12% conformity to the implementation of the HACCP. Factories A and B scored 4.43 (85.86%) and 4.13 (77.61%), respectively. For Part III, Factory C again had the highest score of 4.60, with 90.03% conformity to the functioning of HACCP in practice while Factories A and B scored 4.33 and 3.94, with 83.37% and 72.07% conformity respectively.

Table 3.1 Overall Mean Scores of the HACCP System Conformity

Audit Criteria	**Factory A**		**Factory B**		Factory C	
	Score	% Conformity	Score	% Conformity	Score	% Conformity
Part I – Prerequisite program for the HACCP	4.60	90.00	4.70	85.00	4.80	95.00
Part II – Implementation of the HACCP	4.43	85.86	4.13	77.61	4.68	92.12
Part III – Functioning of the HACCP in Practice	4.33	83.37	3.94	72.07	4.60	90.03

Overall, Factory C scored the highest of all three Factories in all three parts of the audit, indicating a high level of conformity to the HACCP. Factories A and B too performed reasonably well with slightly lower scores than Factory C.

3.2 Prerequisite Program for the HACCP in the Dairy Factories A, B, and C

The Prerequisite Program for HACCP has five steps involved in it. The five steps are Management Commitment, Pest Control, Preventive Maintenance PRPs/Foreign Material Control, Storage/Returned Product, and Employee Training. Figure 3.1 shows the scores of Factory A, B, and C for each of the five steps. Factory C has the highest scores for all five steps, indicating a high level of conformity to the prerequisite program.

However, Factory A and B scored lower in Steps 3 and 4 compared to C. Steps 3 and 4 are about Preventive Maintenance PRPs/Foreign Material Control, and Storage/Returned Products. This indicates that there are areas for improvement in Preventive Maintenance PRPs/Foreign Material Control and Storage/Returned Product in Factories A and B.

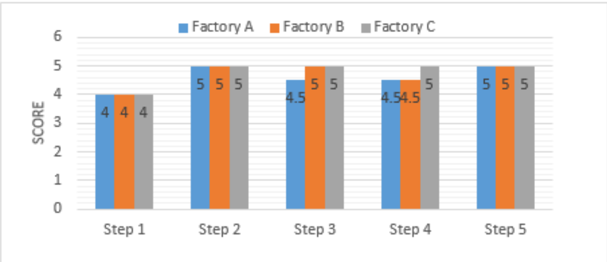

Figure 3.1 Prerequisite Program for HACCP of Factory A, B, and C.

3.3 Implementation of the HACCP System in the Dairy Factories A, B, and C

The provided Figure 3.2 displays the scores of Factory A, B, and C for the 12 implementation steps for the Hazard Analysis and Critical Control Points (HACCP) system. HACCP is a systematic approach to identify and control potential foodborne illness-causing hazards. Throughout the food production process, it involves identifying and controlling potential hazards.

Each step in the HACCP system implementation represents a distinct task that must be completed to ensure the system's effectiveness. The scores provided in the table indicate how well each factory adheres to each of these requirements. Factory C has the highest overall score, indicating a high level of compliance with the HACCP system requirements. Although both Factory A and Factory B scored well, their scores are slightly lower than Factory C. Specifically, Factory C has higher scores for most of the steps excluding steps 1, 2, 11, and 12. However, excluding steps 5, 8, and 9 Factory B had the lowest scores than the other two factories, indicating that there is scope for improvement in identifying hazards, establishment of corrective actions, verifying procedures, documentation, and record-keeping in the implementation of the HACCP system.

Overall, the table's scores indicate how effectively each factory is implementing the HACCP system. Even though all three factories scored relatively well, there may be scope for improvement, and the scores can be used to identify specific areas where each factory needs to focus on HACCP implementation.

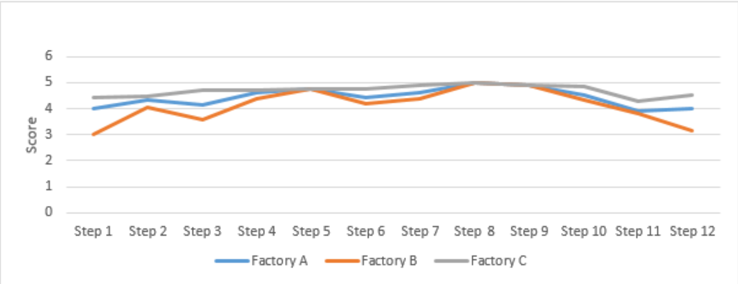

Figure 3.2 Implementation of the HACCP system for Factory A, B, and C

3.4 Functioning of the HACCP system in the Dairy Factories A, B, and C

The given results demonstrate the effectiveness of operating the HACCP system in the three factories A, B, and C in accordance with the seven principles of HACCP. The summary of the outcomes is showed in figurer 3.3 and stated below:

Principle I addressed the identification of potential hazards in the food production process and the establishment of critical control points (CCPs) to prevent or eliminate those hazards. Factory C received the highest score of 4.5, while Factory B received the lowest score of 3.5. Principle III establishes critical limits for each CCP identified in Principle I. Factory C received the highest score of 4.75, while Factory B received the lowest score of 3.75. Principle IV required the implementation of monitoring procedures to ensure the critical limits are met for each CCP. The highest score for Factory C was 4.57, while both Factories A and B scored 4.43. Principle IV was related to the establishment of corrective actions if critical limits are not met. Factory C received the highest score of 4.5, whereas Factory B received the lowest score of 3.83. For principle VI which involved the verification of procedures for the effective operation of the HACCP system, Factory C received the highest score of 4.71 and Factory B received the lowest score of 3.86. In the final principle which comprised of establishing record keeping and documentation procedures to demonstrate the HACCP system's effective operation Factories C received a score of 4.57, while Factories A, and B received a score of 4.43, and 4.29 respectively.

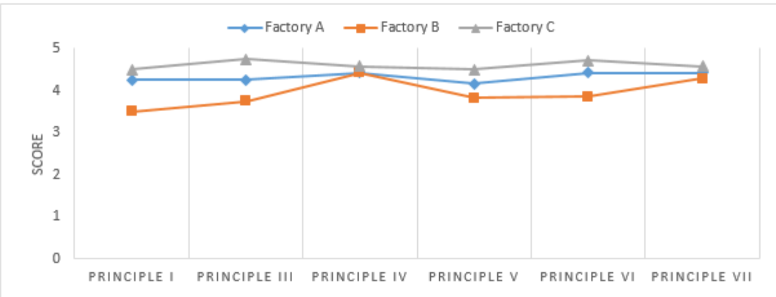

Figure 3.3 Functioning of HACCP systems in Factory A, B, and C

3.5 Failure Mode and Effect Analysis (FMEA) in the Dairy Factories A, B, and C

Risk analysis is a procedure that provides the information and conditions for the appeared risks, in order to decide which are important for food safety and which should be examined in the HACCP applied by each firm. Table 3.2 displays the FMEA (Failure Mode and Effects Analysis) results for three milk factories (A, B, and C) on the implementation and operation of the HACCP system. The table was divided into two parts: Part I consists of 12 blocks to evaluate how well the HACCP is being implemented and Part II consists of six blocks on how well the HACCP works in practice. This analysis aims to identify and prioritize the potential risks for prevention and control. The numbers in the table represent the evaluation scores for each FMEA criterion, which are divided into four categories: Severity (S), Occurrence (O), Detection (D), and Risk (R). Using the axis of food safety risk, calculated risk values were assigned to the corresponding risk levels. Further risk assessment was carried out in two parts: the implementation of HACCP and HACCP functioning in practice. Higher risk levels correspond to higher scores.

Table 3.2 FMEA Table, Shaded areas indicate areas of increased risk.

Blocks of Evaluated Criteria	**Audit Results**			**FMEA**			
	Dairy Factory	**Mean Score**	**% Conformity**	**S**	**O**	**D**	**R**
Part I: Implementation of HACCP (12 blocks)							
Step 1. Establishment of a HACCP Team	A	4	75	1	3	6	18
	B	3	50	1	7	6	42
	C	4.43	85.71	1	3	6	18
Step 2. Description of Products	A	4.33	85.33	2	3	6	36
	B	4.07	76.67	2	3	6	36
	C	4.47	86.67	2	3	6	36
Step 3. Identification of Intended Use	A	4.14	78.57	3	3	6	54
	B	3.57	64.29	3	5	6	90
	C	4.71	92.86	3	2	6	36
Step 4. Construction of Flow Diagram	A	4.62	90.38	4	2	6	48
	B	4.38	84.38	4	3	6	72
	C	4.69	92.31	4	2	6	48
Step 5. On-site Confirmation of Flow Diagram	A	4.75	93.75	5	2	6	60
	B	4.75	87.5	5	2	6	60
	C	4.75	93.75	5	2	6	60
Step 6. Principle I. Conducting a Hazard Analysis	A	4.44	85.94	7	3	10	210
	B	4.19	79.69	7	3	10	210
	C	4.75	93.75	7	2	10	140
Step 7. Principle II. Identification of Critical Control Points (CCP)	A	4.63	90.63	7	2	10	140
	B	4.38	84.38	7	3	10	210
	C	4.88	96.88	7	2	10	140
Step 8. Principle III. Establishment of Critical Limits	A	5.00	100.00	7	1	4	28
	B	5.00	100.00	7	1	4	28
	C	5.00	100.00	7	1	4	28
Step 9. Principle IV. Establishment of Monitoring Systems for each CCP	A	4.91	97.73	8	2	6	96
	B	4.91	97.73	8	2	6	96
	C	4.91	97.73	8	2	6	96
Step 10. Principle V. Establishment of Corrective Action	A	4.50	87.50	8	3	6	144
	B	4.33	83.33	8	3	6	144

	C	4.83	95.83	8	2	6	96
Step 11. Principle VI. Establishment of Verification Procedures	A	3.90	72.50	9	4	10	360
	B	3.80	70.00	9	4	10	360
	C	4.30	82.50	9	3	10	270
Step12. Principle VII. Establishment of Documentation and Recordkeeping	A	4	75.00	6	3	10	180
	B	3.13	53.13	6	7	10	420
	C	4.50	87.50	6	3	10	180
Part II: The functioning of HACCP in Practice (6 blocks)							
Principle I. Identification of Critical Control Point (CCP)	A	4.25	81.25	10	3	6	180
	B	3.50	62.50	10	5	6	300
	C	4.50	87.50	10	2	6	120
Principle III. Establishment of Critical Limits	A	4.25	81.25	10	3	3	90
	B	3.75	68.75	10	4	3	120
	C	4.75	93.75	10	.2	3	60
Principle IV. Monitoring of CCPs	A	4.43	87.14	10	3	6	180
	B	4.43	86.43	10	3	6	180
	C	4.57	89.29	10	2	6	120
Principle V. Establishment of Corrective Action	A	4.17	79.17	10	3	8	240
	B	3.83	63.33	10	4	8	320
	C	4.50	87.50	10	2	8	160
Principle VI. Verification of Procedures	A	4.43	85.71	10	3	10	300
	B	3.86	67.14	10	4	10	400
	C	4.71	92.86	10	2	10	200
Principle VII. Recordkeeping and Documentation	A	4.43	58.71	10	3	10	300
	B	4.29	84.29	10	3	10	300
	C	4.57	89.29	10	2	10	200

3.6 Failure Mode and Effect Analysis of Factory A

The FMEA results for factory A showed the areas of moderate risk were in step 11 (Principle VI. Establishment of Verification Procedures) and minor risk in step 6 (Principle I. Conducting a Hazard Analysis) of the HACCP implementation. In the case of HACCP functioning in factory A, moderate risk areas were found in principle VII (Recordkeeping and Documentation), and minor risk areas were found in principle V (Establishment of Corrective Action). In terms of R values, Step 11 (Principle VI. Establishment of verification procedures) of the HACCP implementation had the highest value of 360 which indicated moderate risk at this step for factory A. Verification which demonstrates the application of measures and methods, is the most effective and reliable method to detect whether the HACCP system operates in accordance with the established plan (Notermans & Teunis, 1996; Sperber, 1998). Similar results were obtained in the studies of Czarniecka-Skubina & Trafialek (2011) and Trafialek and Kolanowski (2014), where the nonconformities related to the verification of the system were observed. In the functioning of the HACCP in factory A, moderate risk areas were found in both Principle VI (Verification of Procedures) and VII (Recordkeeping and Documentation), which had an R-value of 300, indicating the risk of failure in these areas. According to the Codex Alimentarius (2003), effective and accurate records are important elements in the application of the HACCP system and EC guidelines stipulate the documentation of the implemented HACCP procedures. The records and documentation are also used by the company for the purpose of due diligence. Without proper documentation, in the case of client conflicts during a food poisoning or foodborne illness, there are no documents to prove due diligence in food handling and production (McSwane et al., 2003). Identification of risks associated with documentation can be detrimental to factories A and B where a moderate level of risk was identified in the functioning of the HACCP. Consideration of documentation as a burden and lack of supervision and awareness of food safety by the management are some of the reasons for improper record keeping and documentation (Lucke & Trafialek, 2010; Trafialek and Kolanowski, 2014). Principle V (Establishment of Corrective Action) had areas of minor risks. On the whole, the results imply that Factory A should strengthen its establishment of corrective action verification, and recordkeeping procedures, to lower the risk of food safety hazards in its operations.

3.7 Failure Mode and Effect Analysis of Factory B

Establishing a HACCP team (Step 1), describing a product (Step 2), and creating a flow diagram (Step 4) for Factory B had relatively low-risk values in Part I, indicating that the risks involved in these steps were manageable. The identification of intended use (Step 3), however, has a higher risk value of 90, indicating that, if handled improperly, this step could significantly impact food safety. The low-risk value of 210 in Part I, was found in the hazard analysis (Step 6), and the identification of critical control points (Step 7) which both had a significant impact on food safety and hence demanded careful considerations. In the implementation of the HACCP in factory B, both steps 11 (Principle VI. Establishment of Verification Procedures) and 12 (Principle VII. Establishment of Documentation and Recordkeeping) had areas of moderate risks, however in terms of R-value Step 12 had the highest value of 420 compared to the step 11 which was 360, indicating critical risk of failure. Factory B had four areas of moderate risks in the case of the HACCP functioning. A moderate risk value indicated that the Identification of Critical Control Point (Principle I), Establishment of Corrective Action (Principle V), establishment of verification procedures (Principle VI), and record-keeping and documentation (Principle VII) may have a significant impact on food safety if not managed properly. Many studies have reported that employees play a key role in the prevention of food safety risks during food production and distribution (Walker et al., 2003). Often the lack of knowledge of the procedures of corrective actions and the lack of awareness of their responsibility towards the safety and quality of the product are the reasons for inconsistencies in the corrective actions implemented. Principle VI had the highest value of 400 followed by principle V with an R-value of 320 indicating a critical risk of failure at these steps. Both principles 1 and 7 had an R-value of 300. Overall, Factory B's FMEA table shows several areas of increased risk in implementing and operating the HACCP system that calls for attention and management to ensure food safety.

3.8 Failure Mode and Effect Analysis of Factory C

In the implementation of the HACCP in the factory, only step 11 (Principle VI. Establishment of Verification Procedures) had areas of moderate risks, with an R-value of 270 indicating an increased risk of failure at this step. However, in the functioning of the HACCP only minor risk areas were identified in Factory C in principles VI ((Verification of Procedures),) and VII (Recordkeeping and Documentation). Overall, the FMEA results for Factory C indicated the least areas of risks in comparison to comparison to Factory A and B.

3.9 Comparison of FMEA Results of Factory A, B, and C

The overall FMEA score for each factory, which is the sum of the R-values for all assessed criteria, was used to compare the outcomes of factories A, B, and C. In comparison to factories A and B, Factory C had the lowest overall FMEA score. In the implementation of the HACCP, the FMEA overall score was 1148 and in the functioning of the HACCP, it was 860. This suggests that Factory C's milk production process had a comparatively lower risk of potential errors or dangers than Factories A, and B. However, the overall FMEA scores of Factory A and B in the implementation of HACCP were found to be 1374 and 1558 respectively, while their FMEA scores for the functioning of the HACCP were 1290 and 1620 respectively. Factory B with its highest overall FMEA score and six moderate-level risks had the highest chance of experiencing potential problems or dangers in the production of milk. The areas in which food safety risks were identified in factories A, B, and C are given in Figure 3.4.

It was found that in the implementation of the HACCP, only in step 11 (i.e., establishment of verification procedures) food safety risk was moderate in all three factories. In the factory A and B, the value of estimated risk was higher than in factory C, which was only slightly higher than the upper level of the assumed minimal risk limit. In the factory A and B, several aspects subjected to question were inadequate frequency and adequacy of planned verifications and disregard for the verification of the calibration of the instrumentation used for CCP monitoring. In factory B the concern was in the case of the last two criteria. Other aspects of HACCP implementation in all three factories were characterized by only minor risks. However, both factories' evaluations of HACCP functioning in practice showed a higher risk of food safety loss.

The result of the study revealed that the greatest risks were connected to the functioning of the HACCP system in areas of verification, documentation and recordkeeping, and corrective actions although the risk levels were different.

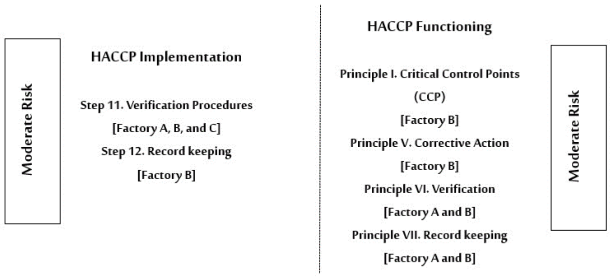

Figure 3.4 Areas of identified food safety risks in the HACCP system of Factory A, B, and C

The HACCP score evaluates how well the HACCP system is implemented in each factory, while the FMEA results give information on potential risks related to the implementation of the HACCP system in the milk factories. All three factories have areas of increased risks, which were marked by the shaded cells in the FMEA table. Factory B has the most shaded cells (6), which showed that it had the highest number of moderate risk areas when compared to Factory C which had only a few shaded areas (1) than Factory A (3). However, both factories A and C had comparable levels of risks. The HACCP score offers a general assessment of how well the HACCP system is applied in every factory. Factory C had the best HACCP system as evidenced by its score of 4.80 with a conformity of 95%, which was the highest of all the three factories. Factory B had the lowest HACCP score of 4.70 with a conformity of 85% while Factory A had a score of 4.60 with 90% conformity, emphasizing that the HACCP system still needs work. When comparing the FMEA findings to the HACCP ratings, it becomes clear that Factory C which had the lowest number of high-risk areas, also has the highest HACCP rating, and Factory B, which had the highest number of high-risk areas, also has the lowest HACCP rating. Accordingly, addressing the FMEA-identified areas of higher risk may aid in enhancing the efficiency of the HACCP system in this factory. Factory A, on the other hand, had a good HACCP score and the fewest areas with increased risks. This suggests that improving the overall effectiveness of the HACCP system may depend on addressing areas of increased risk. The high HACCP score in Factory A may, however, be the result of other factors that have not been considered by the FMEA.

3.10 Microbiological Criteria of Dairy Products in Dairy Factories A, B, and C

The results of the evaluation of dairy products in Factories A, B, and C were based on the GSO Technical Regulations for the Microbiological Criteria for Foodstuff (GSO 1016/2015), and the Maximum Residues Limits (MRLs) Of Veterinary Drugs in Food (GSO 2481/2019). The GCC Standard Organization (GSO) technical regulation is concerned with the microbiological criteria for foodstuffs and for some food ingredients used as raw materials in food processing whose limits are based on those proposed by the International Commission of Microbiological Specifications for Foods (ICMSF) and the international standards in the field of food safety and quality (GSO, 2015; GSO, 2019). In case of failure, there is a need to investigate its cause and its impact on the finished product. The sampling and microbiological analysis for microorganisms, toxins, or metabolites of milk and yogurt in factories A, B, and C (Table 3.3 and 3.4) revealed results within the normal ranges. This method was deemed necessary due to the suspicion of unsafe food products in the context of hazard and FMEA analysis which revealed the presence of moderate risk levels predominantly in the implementation and functioning of the HACCP in factories A and B.

Table 3.3. Assessment of Microbiological Parameters in the Milk and Yogurt Production in Dairy Factories A, B, and C

NO	Microbiological Parameters	Factory A	Factory B	Factory C
DAIRY PRODUCT – MILK				
1	Aerobic Count	<1.00e+01 cfu/g	<1.00e+01 cfu/g	<1.00e+01 cfu/g
2	Listeria monocytogenes	Not Detected In 25 (g)	Not Detected In 25 (g)	Not Detected In 25 (g)
3	Salmonella spp.	Not Detected In 25 (g)	Not Detected In 25 (g)	Not Detected In 25 (g)
4	Staphylococcus Aureus Count	<1.00e+01 cfu/g	<1.00e+01 cfu/g	<1.00e+01 cfu/g
5	Enterobacteriaceae Count	<1.00e+01 cfu/g	<1.00e+01 cfu/g	<1.00e+01 cfu/g
6	Coliform Count	<1.00e+01 cfu/g	<1.00e+01 cfu/g	<1.00e+01 cfu/g
7	Yeasts and Molds Count	<1.00e+01 cfu/g	<1.00e+01 cfu/g	<1.00e+01 cfu/g
DAIRY PRODUCT – YOGURT				
1	Aerobic Count	<1.00e+01 cfu/g	<1.00e+01 cfu/g	<1.00e+01 cfu/g
2	Listeria monocytogenes	Not Detected In 25 (g)	Not Detected In 25 (g)	Not Detected In 25 (g)
3	Salmonella spp.	Not Detected In 25 (g)	Not Detected In 25 (g)	Not Detected In 25 (g)
4	Staphylococcus Aureus Count	<1.00e+01 cfu/g	<1.00e+01 cfu/g	<1.00e+01 cfu/g
5	Enterobacteriaceae Count	<1.00e+01 cfu/g	<1.00e+01 cfu/g	<1.00e+01 cfu/g
6	Coliform Count	<1.00e+01 cfu/g	<1.00e+01 cfu/g	<1.00e+01 cfu/g
7	Yeasts and Molds Count	<1.00e+01 cfu/g	<1.00e+01 cfu/g	<1.00e+01 cfu/g

Table 3.4. Assessment of Chemical Parameters in the Milk and Yogurt Production in Dairy Factories A, B, and C

Chemical Parameters	Factory A	Factory B	Factory C
DAIRY PRODUCT – MILK			
24 Antibiotics including: Gentamicin Neomycin Streptomycin Beta-Lactam Penicillins Chloramphenicol	Not Detected	Not Detected	Not Detected
DAIRY PRODUCT – YOGURT			
24 Antibiotics including: Gentamicin Neomycin Streptomycin Beta-Lactam	Not Detected	Not Detected	Not Detected

Penicillins Chloramphenicol			

The FMEA method could be recommendable for both internal and external audit purposes due to its high accuracy. With the help of scientific methods like FMEA, managers and supervisors of the HACCP system especially in small and medium-sized food enterprises can address the risks by continuously recognizing and assessing the company's risks. FMEA can help managers make more effective decisions by focusing their attention on critical risks that need improvement and suggesting risk mitigation strategies to improve their HACCP.

CONCLUSIONS

There are multiple issues in the food industry that Saudi Arabia needs to address to guarantee the invariable safety of the food supply chain and ensure compliance with the food safety standards of the country. With the mandatory implementation of the HACCP in the Saudi Arabian food industry, the increasing cases of food poisoning, and the failure of food safety by the implemented HACCP system, there is a demand for the verification of the implemented HACCP system. Hence, the FMEA analysis can be a quintessential tool within the verification procedure of the HACCP system for the assurance of food safety. The FMEA technique can calculate the risk of product production and prevent it from happening or take the necessary measures to eliminate the risks. The food safety managers of the food factories can structure the risks appropriately to analyze the extent of their effect and suggest mitigation strategies to improve their HACCP model and make more effective decisions. Any decisions made without the use of appropriate scientific methods could be costly for the food companies. Hence the FMEA-based risk assessment could be applied to other food products and processes to identify the risks involved in the implemented HACCP processes and eliminate them to strengthen the HACCP model of the companies. This method helps in the identification of frail components of the HACCP system and can be a convenient tool for HACCP system verification both for food producers and auditors. Multicriteria approaches using FMEA and other methods could also be used to determine, assess, and render risk reduction programs in the food industry.

Following the risk assessment and application of mitigation measures, further improvements in the implementation and functioning of the HACCP can also be analyzed using FMEA to compare the results before and after the implementation of this technique. Multicriteria approaches using FMEA and other methods could also be used to determine, assess, and render risk reduction programs in the food industry. In addition, the possibility of setting up a verification mechanism through a phone application that allows factories to self-verify the effectiveness of their HACCP system can be examined.

Authors' Contributions

HSA: the researcher who performed all tests and wrote the research draft and data analysis; MAA wrote the study's design. AAN: The manuscript's correspondent author made edits to the paper. RFH: made edits to the paper. MHM: made edits to the paper. All writers read and approved the final manuscript.

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Declaration of competing interest

There are no conflicts to declare.

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FIGURES

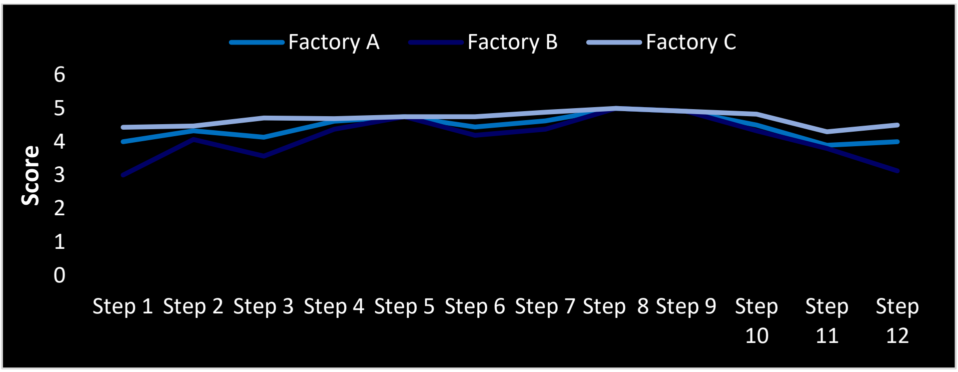

Fig.1. Implementation of the HACCP system for Factory A, B, and C

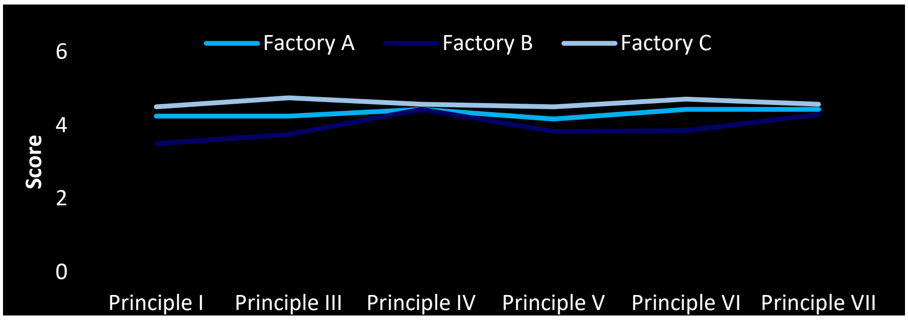

Fig. 2. Functioning of HACCP systems in Factory A, B, and C

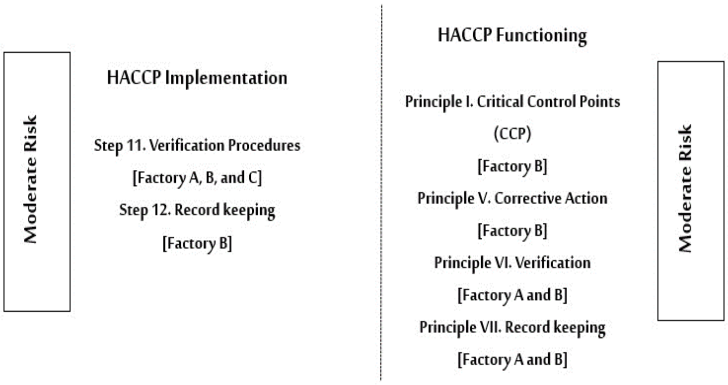

Fig. 3. Areas of identified food safety risks in the HACCP system of Factory A, B, and C