Original Article

A Practical Hazard Analysis and Critical Control Points Implementation Model in Biscuit Production

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ABSTRACT

Background and Objectives: Ensuring food safety is critical for consumer confidence and regulatory compliance in the food industry. This study explores implementing the Hazard Analysis and Critical Control Points (HACCP) system in biscuit production to mitigate risks and enhance safety standards.

Materials and Methods: A structured approach to HACCP implementation was adopted at the Shirin Eram Sepanta biscuit manufacturing plant. The process included evaluating prerequisite programs (PRPs), forming a multidisciplinary team, developing a detailed product description, preparing a validated production flow diagram, and conducting a detailed hazard analysis using a risk assessment matrix. Critical control points (CCPs) were identified, including sieving, metal detection, and baking. Control measures, critical limits, and monitoring procedures were developed to manage these CCPs effectively.

Results: Applying the HACCP system improved food safety practices, enhanced documentation processes, and strengthened the verification of safety measures. Key CCPs were effectively managed, leading to zero reported safety or quality issues during the study period. The study highlights the model's adaptability to other food manufacturing operations.

Conclusions: This study provides a practical and replicable HACCP implementation framework, emphasizing its role in identifying and controlling hazards in biscuit production. The model enhances product quality and consumer trust by ensuring compliance with food safety standards, offering valuable insights for broader applications in the food industry.

Keywords: HACCP, Biscuit Production, Food Safety, Prerequisite Programs (PRPs), Risk Assessment

Highlights

- Eram Biscuit Plant consistently exceeded inspection standards, enabling HACCP and ISO 22000 certification.
- A multidisciplinary HACCP team strengthened risk management, cross-department coordination, and accountability.
- Comprehensive hazard analysis and a validated production flow diagram identified critical control points (CCPs), including sieving, metal detection, and baking.
- Tailored control measures, proper PRP implementation, and continuous verification ensured food safety compliance and high-quality production.
- This adaptable HACCP model provides a practical guideline for other food industries to enhance safety, documentation, and operational effectiveness.

Introduction

Emerging pathogens, growing consumer awareness, and reduced oversight in food production underscore the importance of robust food safety regulations across public and private sectors (1). By 2050, food production will need to increase by 70% due to global population growth, posing challenges for sustainable systems. Food safety is

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crucial for ensuring safe products and global food security (2).

Organizations must implement food safety management systems (FSMS) to reduce risks like foodborne illnesses and contamination. FSMS should be applied across the food supply chain, from production to consumer, ensuring effective operation and harm prevention. A shared understanding of food safety principles is essential for effective management (3). FSMS ensures effective processes, boosting customer and stakeholder confidence (4) .

The hazard analysis and critical control points (HACCP) system is essential to any FSMS (5). HACCP uses preventive measures to protect food and consumers from chemical, physical, and biological hazards (6). It has been widely studied in food industries, including biscuit production, to improve safety and minimize risks.

Biscuits, as widely consumed snacks, are vulnerable to contamination from physical, chemical, and microbial sources, requiring stringent quality control (7). This emphasizes the need for HACCP to ensure biscuit safety and quality.

Several studies have examined HACCP implementation in biscuit manufacturing. For instance, Figueiredo and Costa Neto (2001) applied HACCP and good manufacturing practices (GMP), reducing customer complaints about foreign bodies by 25% and highlighting the need for employee training (8). Suliman et al. (2013) developed a HACCP plan for a biscuit plant, identifying critical control points (CCPs) in raw material receipt, mixing, baking, and packaging (9). Shuvo et al. (2019) used a decision tree method to identify CCPs, ensuring safe production through limits, monitoring, and corrective actions(10). Dzyundzya and Fokin (2021) showed HACCP's flexibility in producing gluten-free shortbread cookies with pumpkin powder (11).

Previous studies on HACCP implementation in biscuit manufacturing have primarily focused on developing generic plans or identifying critical control points within specific production facilities, often employing descriptive, case-based approaches. However, many of these studies lack structured risk prioritization using quantitative assessment tools, comprehensive integration of biological, chemical, physical, allergenic, and emerging hazards (e.g., GMOs and radiological risks), as well as clear industrial-scale validation of system performance.

Therefore, the present study aims to develop and validate an integrated, practical HACCP implementation model tailored to biscuit production. By incorporating a structured 5 × 5 risk assessment matrix, a systematic CCP determination based on the Codex decision tree, integration of national and international standards, and defined monitoring, corrective, and verification procedures, the proposed framework provides a reproducible, industry-oriented approach. The model was further validated using inspection performance records and compliance data, demonstrating its practical effectiveness in strengthening food safety management and process control in biscuit manufacturing.

Materials and Methods

Company description

This study was conducted at the Shirin Eram Sepanta biscuit plant in Isfahan, Iran, established in September 2020. The plant is equipped with industrial-scale processing machinery and procures raw materials from approved suppliers in accordance with internal quality specifications and regulatory requirements. The facility first obtained HACCP certification in 2021 and has successfully maintained annual certification renewal since then

Implementation of prerequisite programs (PRPs) for the HACCP system

Before implementing the HACCP system in any food plant, the establishment and execution of PRPs are essential .The evaluation of PRPs at the Eram Biscuit Plant was based on ISO/TS 22002 standards, using a 200-question checklist by the Iranian Food and Drug Administration (12). This checklist covered building and facility design, site layout, utilities, waste management, equipment accessibility, cross-contamination prevention, cleaning, pest control, employee hygiene, and training programs (4). The assessment involved self-evaluation and periodic regulatory inspections to ensure compliance with food safety standards.

HACCP implementation methodology

In this study, the HACCP system implementation for flavored biscuit production was based on the Codex Alimentarius - Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (13). Additionally, the process adhered to Standard No. 4557, titled Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System (14), which aligns with Codex guidelines. This study's HACCP implementation process was carried out in 12 steps outlined below (15).

Form the HACCP team and define the scope (step 1)

The food safety team at the Eram Biscuit Plant, led by a team leader from the quality control department, included key representatives from various departments such as the CEO, maintenance, production, raw material procurement, storage, R&D, and health, safety, and environment. This diverse team ensured a comprehensive approach to food safety across all stages of production. The team leader oversaw the HACCP system's development, implementation, and validation, conducted training and audits, and led team meetings. The Vice Chairman supported the team leader and contributed to training and goal achievement. The Secretary managed HACCP documentation and record-keeping. Other members participated in documentation and oversight within their departments (16).

Characterize the product in detail/determine the product's intended use and potential consumers (steps 2 and 3)

The flavored biscuit product was described, covering its composition, processing, packaging, storage, distribution, intended use, and potential consumers.

Develop a flow diagram outlining the production process /confirm the accuracy of the flow diagram (steps 4 and 5)

A flow diagram was created to outline the production process, from raw material receipt to the finished product. It was verified through on-site observations to ensure accuracy.

Full implementation of the seven HACCP principles (steps 6 to 12)

Following the seven key principles, this study applied the HACCP system to assess and control hazards in flavored biscuit production.

Principle 1: The production process was thoroughly analyzed, and potential hazards were identified. A 5x5 risk matrix was used to assess risks by combining the likelihood and consequences to determine the risk score (Figure 1) (17,18). Low-risk hazards (P × S ≤ 6) were controlled through PRPs, while high risks (P × S ≥ 8) were managed with OPRPs or CCPs (19). Unlike previous HACCP case studies in biscuit production that relied primarily on qualitative hazard identification, this study applied a structured 5 × 5 risk matrix to quantitatively prioritize hazards and support CCP selection.

				Likelihood				
			Historical	It may happen, but only under rare conditions	Occurs due to uncertainty	This could happen at some point in the future	Likely to happen	Expected to happen in most situations
			Probability	1 in 10000-100000	1 in 1000-10000	1 in 100-1000	1 in 10-100	<1 in 10
				Rare	Unlikely	Possible	Likely	Almost certain
	The amount of public damage			1	2	3	4	5
Severity	Injuries or illnesses not requiring medical intervention	Insignificant	1	1	2	3	4	5
	Minor injuries that need only first-aid	Minor	2	2	4	6	8	10
	Serious injuries needing hospitalization or extensive treatment	Moderate	3	3	6	9	12	15
	Life-threatening or multiple injuries needing hospitalization	Major	4	4	8	12	16	20
	Fatalities or multiple life-threatening injuries	Catastrophic	5	5	10	15	20	25

Response measures		
Risk Score	Risk Level	Required Action
25	Not Tolerable	Stop the process until the risk is reduced. If it cannot be prevented, cancel activities.
15, 16, 20	Critical	Immediate action is needed. If there is no danger, continue under supervision.
8, 9, 10, 12	Moderate	Take protective actions to reduce risk.
2, 3, 4, 5, 6	Minor	No emergency actions, but maintain control measures.
1	Negligible	No precautions are needed.

Figure 1. 5x5 Risk Assessment Matrix: Likelihood, Severity, and Response Actions. Adapted from (17) and (18)

Principle 2: CCPs were identified using the Codex decision tree (20), which helps pinpoint critical stages requiring control. The decision tree involves four key questions:

1- Are control measures in place for the identified hazard? If yes, proceed to Question 2; if no, assess if control is necessary for safety.
2- Is the step designed to eliminate or reduce the hazard to an acceptable level? If yes, it is a CCP; if no, proceed to Question 3.
3- Could contamination increase to unacceptable levels? If yes, proceed to Question 4; if no, move to the next step.
4- Will a subsequent step reduce the hazard? If yes, this step is not a CCP; if no, it is.

This process ensures that critical stages are accurately identified and adequately controlled.

Principle 3: For each CCP, critical limits were defined.

Principle 4: Suitable monitoring procedures were implemented to ensure control over CCPs.

Principle 5: Corrective actions, such as adjusting control parameters or modifying production processes, were established to restore safety if a CCP exceeded its critical limit.

Principle 6: Periodic verification procedures were implemented to assess and reassess the system and its processes at specified intervals.

Principle 7: All stages of hazard analysis, decisions, and actions were documented to ensure traceability and practical evaluation of monitoring and corrective actions (21).

This approach ensured the identification and control of all potential hazards while maintaining the product's quality and safety. In addition, the HACCP implementation model was aligned with national regulatory standards and incorporated multidisciplinary evaluation of emerging hazards such as allergens and GMOs within an industrial operational framework. The effectiveness of the HACCP system was subsequently validated using defined verification and monitoring indicators, as reported in the “Results and Discussion” section

For clarity and quick reference, the HACCP implementation process and the CCP management framework used in this study are illustrated in Figure 2.

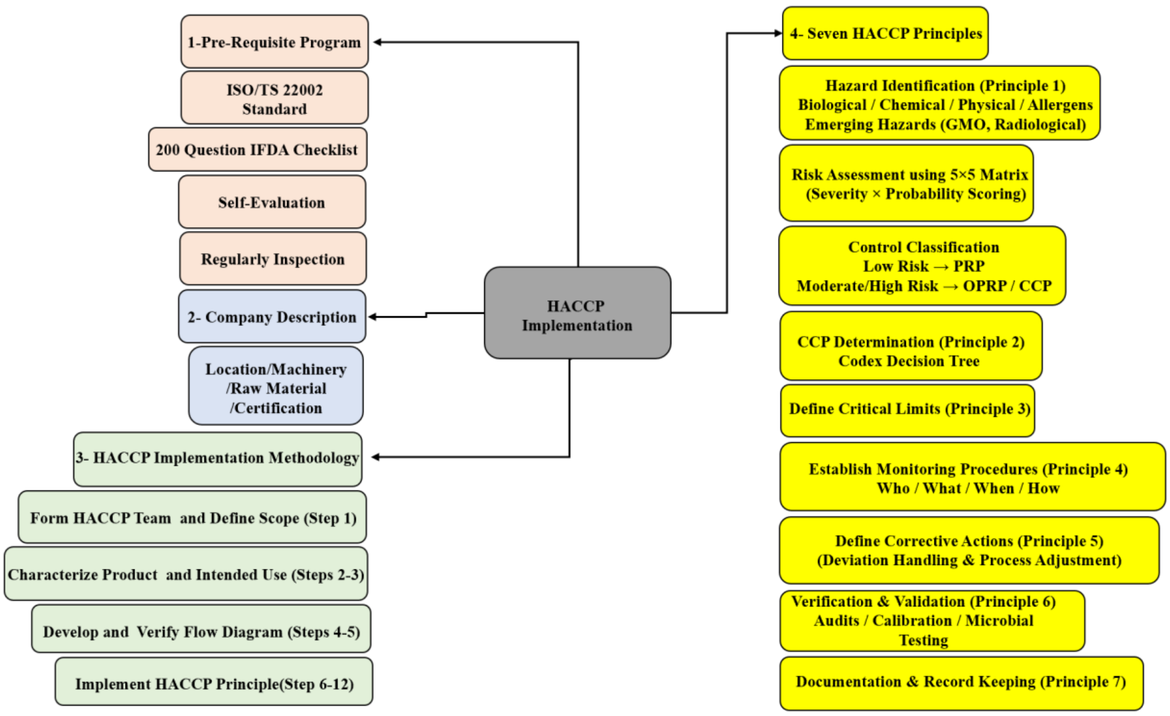

Figure 2. Overview of the HACCP implementation methodology and CCP management framework applied in biscuit production.

Results and Discussion

Essential prerequisite programs (PRPs) for HACCP implementation

Since its establishment, the Eram Biscuit Production Plant has consistently scored above 180 in all periodic inspections by the Iranian Food and Drug Administration, reflecting its strict adherence to PRPs and food safety standards. This performance is also reflected in internal self-assessments, which have enabled the plant to qualify for a five-year manufacturing license and pursue HACCP and ISO 22000 certifications. A score of 180-200 is required for these certifications and for utilizing unutilized capacity (22).

HACCP team impact

Establishing the HACCP team at the Eram biscuit plant significantly enhanced the implementation of the food safety system. The team effectively managed food safety risks by integrating engineering, production, quality control, and laboratory experts. Their collaborative efforts improved interdepartmental communication and accountability, enabling thorough hazard analysis and effective implementation of the system (21).

Product characterization and consumer identification

The fruit-flavored biscuits at the Eram plant were characterized by their raw materials, production steps, packaging, and storage conditions. Special emphasis was placed on identifying raw materials with potential allergenic properties, which were highlighted. Packaging details, shelf life, and storage requirements were defined to ensure consumer safety and compliance with standards. The study also detailed the type of packaging, ideal storage conditions (e.g., temperature), and distribution methods. The product's shelf life and target consumers, including individuals with specific sensitivities, were carefully considered. Additionally, labeling provided essential information, including composition, nutritional facts, and health certifications, ensuring transparency and alignment with consumer expectations. These findings, summarized in Table 1, assisted the HACCP team in managing potential hazards effectively.

Table 1. Key Specifications of Fruit-Flavored Biscuits at the Eram plant

Specification		Description
Raw materials and ingredients used in the product		**Wheat flour**, Sugar, Hydrogenated vegetable oil, Invert syrup, **Skim milk powder**, **Whole egg powder**, Ammonium bicarbonate (E503), Fruit flavor, Sodium pyrophosphate (E450), Sodium bicarbonate (E500), **Lecithin (E322)**, Water.
Product production steps		Preparation and weighing of raw materials according to the formulation, Mixing, Forming with Molding Roller, Baking, Cooling, and Packaging.
Type of product packaging		Plastic inside the box (Polyethylene-PE), Cardboard box (single carton), Cellophane box cover (Polyolefin-POF), Small cellophane (PE)
Conditions maintenance		Keep in a dry, Cool place away from direct sunlight (The temperature range is 10 - 30 °C)
Shelf life		For a year
Consumer		The general public, except for contraindications
Contraindications		People with Celiac disease, Lactose intolerance, Allergic reactions to soy, milk, and egg protein, and Gluten intolerance
Weight/Volume		Boxes containing 3000 grams of biscuits. Shrinking two boxes Boxes containing 800 grams of biscuits. Shrinking six boxes Packages containing three biscuits. Small cartons containing 24 packages. Large carton containing six small cartons.
Instructions for preparation and consumption (product use)		Ready-to-eat
How to store (storage method)		Boxes should be stored in clean, dry, and cool storage on pallets with a certain height from the boxes and a certain distance from the wall.
How to distribute (distribute method)		With suitable vehicle
The places of sale of the product		No limit
Risks	Biologically	Departure from the specified in the biological characteristics section
	Chemical	Departure from the specified in the chemical characteristics section
	physical	Departure from the specified in the physical characteristics section
	Allergen	Gluten, egg yolk, and egg white allergens, Whey protein, Caseins, and soy allergens
	Radiological	Does not exist
	GMO	Does not exist
Reference	Biological characteristics	Standard No. 2395 (23)
	Physicochemical character	Standard No. 37 (24)
	labeling	Product logo, product type, nutritional facts table, traffic light table[1], health apple (License of Food and Drug Administration in Iran), ingredient composition table, national bar code, production/ expiration date, prices, manufacturing series, SMS system, plant address, contact details, social media, Isiri symbol (related Institute of Standards and Industrial Research of Iran)

[1] The traffic light labeling system highlights food products' fat, sugar, salt, and calorie levels.

Development and verification of the production flow diagram

The biscuit production flow diagram at the Eram biscuit plant was developed based on observations of the process, as shown in the operation process chart (OPC) in Figure 3. The HACCP team verified the diagram against real-world conditions to ensure accuracy. Any discrepancies were identified and revised. The flow diagram is essential for identifying contamination sources and developing mitigation strategies. After creation, the HACCP team authenticated the flow diagram in the production environment (25).

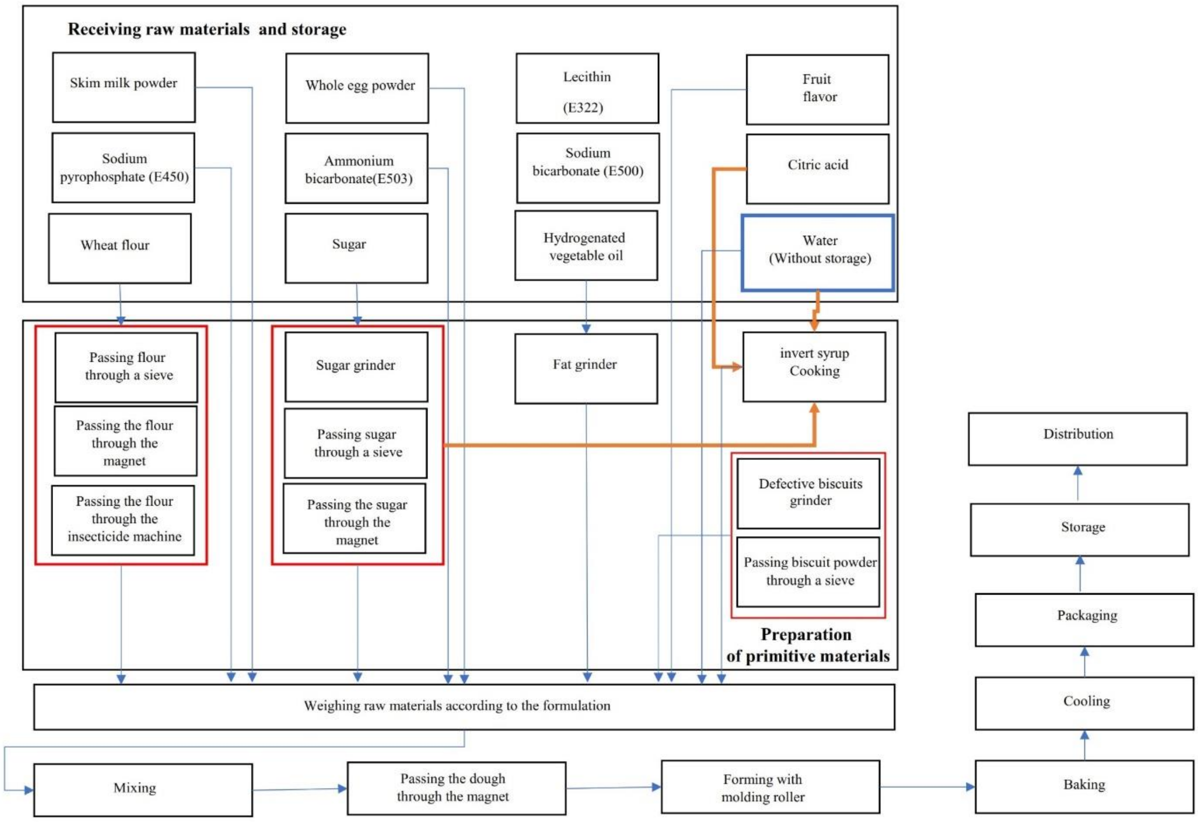

Figure 3. Flow diagram of biscuit production at the Eram plant.

Comprehensive hazard analysis and risk assessment in primitive material receipt, storage, and biscuit production processes

Foods become contaminated when they contain harmful substances. Contamination can occur at any stage, from production to consumption, and is caused by chemical, physical, or biological agents (6,26).

Given the critical importance of food safety and the need for precise hazard control, Tables 2 and 3 provide frameworks for hazard analysis in the flavored biscuit production process. These tables support identifying, assessing, and mitigating risks to ensure product safety. Table 2 presents the detailed hazard analysis results, focusing on key risks during raw material receipt and storage. Identified hazards include physical, chemical, and microbiological contaminants, allergens, GMOs, and radioactive materials. Each hazard was evaluated using a risk assessment framework based on severity and probability of occurrence. Significant risks were highlighted, and specific control measures were defined to mitigate them. Table 2 also identifies CCPs requiring stringent controls and hygiene programs (PRPs) to manage these hazards effectively.

Foreign bodies can contaminate raw materials during improper storage or transportation, posing significant physical hazards. These contaminants, classified as hard or sharp, may include metallic (e.g., nails, hooks, coins) and non-metallic objects (e.g., glass, wood fragments, stones). While some, like glass, are categorized as food safety hazards, others, such as dirt, fall under non-food safety hazards. Contaminants measuring 7–25 millimeters are particularly concerning and have led to regulatory actions by the FDA due to their potential to cause tooth injuries, impact trauma, or chemical hazards depending on their composition (27). Sources of such hazards include raw materials, personal items, and storage processes. This study assessed the hazard as having low severity (score: 2) and low probability (score: 2), with higher severity ratings of 3 for wheat flour, sugar, and biscuit powder, classifying it as a minor risk.

To mitigate this issue, the following preventive measures are recommended:

- Sourcing raw materials from reputable suppliers with necessary certifications to ensure compliance with standards.
- Conducting physical inspections of raw materials upon receipt.
- Adhering to proper storage practices (28)

As this hazard is considered manageable through PRPs, it does not require control at a CCP.

Chemical characteristics significantly influence product safety and quality. Contamination may arise from naturally occurring chemicals (e.g., allergens, mycotoxins, marine toxins, fungi) or additives (e.g., pesticides, hormones, toxic elements like lead and arsenic, food additives, packaging contaminants, and prohibited substances). Familiar sources of chemical contamination include herbicides, veterinary drugs, environmental pollution, migration from packaging materials, natural toxins, food adulteration, and illegal additives (6). This study assessed the hazard as having low severity (score: 2) and low probability (score: 2), classifying it as a minimal risk. Management involves sourcing raw materials from reputable suppliers, obtaining certifications, performing chemical testing, and ensuring proper storage (28). Identified as a PRP, it does not require CCP control.

Gluten intolerance (non-celiac sensitivity) (29) and lactose intolerance (30) are critical hazards for sensitive individuals due to wheat flour gluten and milk powder lactose. Although these do not fall under allergen-related risks, they are managed by highlighting allergenic ingredients (e.g., wheat flour and milk powder) on product labels and controlling them as part of PRPs.

Microbiological hazards involve contamination by microorganisms, which can occur due to improper storage or failure to follow hygiene practices during material receipt and transport. Foodborne illnesses are caused by bacteria, viruses, parasites, protozoa, and fungi, with symptoms like nausea, vomiting, and diarrhea. While often mild, they can be dangerous for vulnerable groups. Prevention involves hygiene, cleaning, sanitizing, and temperature control (30). Mycotoxins, chemical residues from fungal contamination, pose significant risks in plant-based raw materials, especially flours used in biscuit production, making mycotoxin management crucial for food safety (7). This hazard is assessed as a minor risk with low severity (score: 2) and probability (score:2). Raw materials should come from reputable suppliers with microbiological compliance certifications to prevent it. Microbiological testing upon receipt, proper storage, and hygiene programs for personnel and equipment are essential to controlling microorganism growth (28). Identified as a PRP, this hazard does not require CCP control.

Managing food allergens is critical to global food safety, as allergies are becoming increasingly prevalent (31). This study identified raw materials such as wheat flour, non-fat dry milk powder, whole egg powder, and lecithin as allergenic risks due to gluten, milk, egg, and soy proteins. These allergens pose serious health risks for individuals with conditions such as celiac disease or soy and egg allergies (32). Although these risks were considered intolerable, they were managed through clear and prominent allergen labeling, ensuring compliance with international food safety standards. This approach mitigates allergenic risks, shifting management to PRPs without CCP interventions. Proper labeling enables consumers to make informed decisions, enhancing transparency and regulatory compliance.

Potential hazards associated with GMOs were identified in improperly sourced oils and lecithin lacking non-GMO labels. Risk assessment determined this as a minor hazard with a low-risk score (S=1, P=1), controlled under PRPs. Preventive measures include sourcing non-GMO-labeled products in compliance with the Food and Drug Organization of Iran's standards. While GMOs are associated with concerns such as toxicity, allergenicity, and herbicide-related issues like cancer and neurological disorders (33).

The use of herbicides in GMOs has been linked to cancer and neurological disorders (34). Animal studies report mortality, tumors, and reproductive issues, highlighting the need for further research on long-term effects (35). Despite concerns, regulatory bodies consider GMOs safe if they meet testing standards. Transparent labeling and ongoing research are crucial for public trust. Contaminants in drinking water include radionuclides from nuclear discharges and chemicals. Preventive measures include regular monitoring, ion exchange filtration, reverse osmosis, and managing polluted sources to maintain water quality (36) . Radioactive contamination in water refers to the presence of radioactive compounds, potentially resulting from disruptions in municipal water supply. The risk assessment indicates low severity and likelihood, classifying it as a low-priority hazard. Control measures include sending water to facilities for radiological testing to ensure safety. This hazard is a PRP and not a CCP.

This study comprehensively assessed the biscuit production process for hazards and risks (Table 3). Hazards were identified at each production stage, and their probability of occurrence and severity were evaluated using a risk assessment system. Hazards with a risk product (severity × probability) of 8 or higher were classified as critical and analyzed using a decision tree to identify critical control points (CCPs).

Key CCPs included:

- Sieving: Passing wheat flour, sugar, and biscuit powder through sieves to remove foreign bodies.
- Metal Detection: Detecting and separating metal contaminants in the biscuit dough.
- Baking: Eliminating microorganisms and preventing their growth in the final product.

In Table 3, certain stages, such as using magnetic separators to remove iron particles, were classified as operational prerequisite programs (OPRPs) requiring specific control measures. Stages with a risk product of less than 8 were managed as PRPs, necessitating fundamental measures like operator training, hygiene protocols, and equipment maintenance (28). Modern methods for reducing and detecting physical hazards include washing, filtering, metal detection, X-ray imaging, and advanced technologies like hyperspectral imaging, thermal imaging, and continuous wave terahertz imaging (37).

Defining critical limits, monitoring, corrective actions, documentation, and verification of the HACCP system in biscuit production

The CCPs identified in biscuit production, along with their control measures, critical limits, monitoring procedures, corrective actions, and verification steps, are detailed in Table 4. Key elements for managing CCPs include:

- Critical Limits: Defined thresholds to determine when production should be halted or products rejected.
- Monitoring: Regular checks to ensure processes stay within acceptable parameters.
- Corrective Actions: Actions taken to address deviations, such as repairing faulty equipment, re-examining ingredients, or removing defective products.

For example, monitoring contamination by foreign bodies often leads to product rejection and investigation of contamination sources. The focus remains on preventing contamination through consistent monitoring and timely corrective measures.

To ensure effective HACCP implementation:

- Documentation: Comprehensive record-keeping of all CCP-related activities is mandatory.
- Verification: Regular reviews, calibration tests, and microbiological assessments confirm the system's effectiveness and compliance with food safety standards (38).
- The HACCP plan, customized to the Eram biscuit plant, helped control significant hazards and support the production of products that meet defined safety and quality requirements (9) . All control measures and procedures outlined in the table were implemented in accordance with the plant's established operational guidelines.

Validation of HACCP System Effectiveness

The effectiveness of the implemented HACCP system was validated through continuous batch-wise chemical and microbiological analyses conducted in the factory laboratory in accordance with the Iranian National Standard requirements for biscuits. Throughout the monitoring period, all analytical results remained within the permissible limits defined by the relevant national standards. Compliance with national regulatory requirements was further confirmed through periodic external inspections, during which product testing reports consistently met the acceptance criteria. In addition, routine evaluations performed by the Iranian Food and Drug Administration (IFDA) demonstrated sustained high levels of compliance with prerequisite programs (PRPs), with inspection checklist scores consistently remaining within the acceptable certification range (e.g., above 180 out of 200). The facility has also successfully maintained HACCP certification through annual renewal audits. Importantly, no major safety deviations, product recalls, or customer complaints related to food safety or product quality were reported during the study period, further supporting the operational effectiveness and stability of the implemented food safety management system.

Although the present HACCP implementation model was developed and validated in a biscuit manufacturing facility, its structured framework—including prerequisite program evaluation, multidisciplinary team organization, hazard analysis, CCP identification, monitoring procedures, corrective actions, and verification activities—can be adapted to other food-processing industries with similar production characteristics. In particular, this model may serve as a practical reference for bakery and cereal-based product manufacturers seeking an operational and reproducible approach to HACCP implementation under industrial conditions. Therefore, the proposed framework provides a transferable guideline for improving food safety management performance beyond the studied plant.

Conclusion

The implementation of the HACCP system at the Shirin Eram Sepanta biscuit manufacturing plant demonstrated its practical effectiveness in supporting food safety management and process control.

By systematically identifying and controlling potential hazards across all production stages, the study emphasizes the importance of adhering to PRPs as the foundation for HACCP success.

The multidisciplinary HACCP team played a crucial role in conducting thorough hazard analysis and fostering interdepartmental coordination. Key CCPs—such as sieving, metal detection, and baking—were rigorously monitored to minimize contamination risks. A risk assessment matrix and the Codex CCP decision tree effectively prioritized hazards and guided the development of targeted control measures.

Meticulous documentation and regular verification confirmed the system’s efficacy and compliance with safety standards. The absence of safety defects during inspections validated the robustness of the HACCP system.

This study presents a practical and adaptable HACCP implementation model for biscuit manufacturing and similar industries, enhancing food safety, consumer trust, and compliance with industry standards.

Author Contributions

Mahour Bagheri designed and collected the study; Mohammad-Taghi Golmakani contributed to data interpretation, critically revised the manuscript, and approved the final version. Both authors read and approved the final manuscript.

Table 2. Hazard analysis, risk assessment, the control mechanism for primitive material-receiving and storage

Hazards	Causes	Risk assessment		Outcome	Significant risk	Control / Preventive measures	Decision tree				Conclusion (CCP or NOT?)
		s	p				Q 1	Q 2	Q 3	Q 4	
(P): foreign bodies[1](wheat flour, sugar and biscuit powder)	Failure to supply raw materials from a reliable supplier Keeping the raw material in improper storage conditions and improper handling	2	3	6	Minor	Supply raw materials from reliable suppliers. Obtaining a certificate related to the analysis of the raw material and its compliance with the standard requirements Performing Physical tests upon arrival compliance with good storage practices (GSP)	-	-	-	-	PRP
(P): foreign bodies (other primitive materials)	Failure to supply raw materials from a reliable supplier Keeping the raw material in improper storage conditions and improper handling	2	2	4	Minor	Supply raw materials from reliable suppliers. Obtaining a certificate related to the analysis of the raw material and its compliance with the standard requirements Performing Physical tests upon arrival compliance with good storage practices (GSP)	-	-	-	-	PRP
(C): Departure from the items mentioned in the standards related to the chemical properties of the material	Failure to supply raw materials from a reliable supplier Keeping the raw material in improper storage conditions.	2	2	4	Minor	Supply raw materials from reliable suppliers. Obtaining a certificate related to the analysis of the raw material and its compliance with the standard requirements Performing chemical tests upon arrival Storing raw materials in appropriate and defined environmental conditions compliance with good storage practices (GSP)	-	-	-	-	PRP
(C): gluten intolerance/ Lactose intoleran ce	The inevitable presence of gluten in wheat flour and Lactose in Skim milk powder	3	5	15	Critical	Bolding the words wheat flour and Skim milk powder on the label of the box to inform the consumer about the presence of gluten and Lactose	-	-	-	-	PRP
(M): Departure from the items mentioned in the standard related to the microbial properties of the material	Failure to supply raw materials from a reliable supplier Keeping the raw material in improper storage conditions and improper handling Failure to comply with the cleaning and disinfection program of personnel and containers Failure to comply with the Pest and insect control program	2	2	4	Minor	Supply raw materials from reliable suppliers. Obtaining a certificate related to the analysis of the raw material and its compliance with the standard requirements Performing microbial tests upon arrival Storing raw materials in appropriate and defined environmental conditions compliance with good storage practices (GSP) Compliance with the cleaning and disinfection program of personnel and containers Compliance with the Pest and insect control program	-	-	-	-	PRP

(A) :celiac disease	The inevitable presence of gluten in wheat flour	5	5	25	Not Tolerable	Bolding the word wheat flour on the box label to inform the consumer about the presence of gluten.	-	-	-	-	PRP
(A): proteins of milk	The inevitable presence of casein (αs1- CN) and β-lactoglobulin in Skim milk powder	5	5	25	Not Tolerable	Bolding the word Skim milk powder on the label of the box to inform the consumer about the presence of casein (αs1- CN) and β-lactoglobulin	-	-	-	-	PRP
(A) : proteins of eggs	The inevitable presence of Different proteins in Whole egg powder	5	5	25	Not Tolerable	Bolding the word Whole egg powder on the label of the box to inform the consumer about the presence of Egg Allergens	-	-	-	-	PRP
(A): proteins of soybean-based products	The inevitable presence of Different proteins in Lecithin	5	5	25	Not Tolerable	Bolding the word Lecithin (E322) on the label of the box to inform the consumer about the presence of Allergens	-	-	-	-	PRP
GMO: Genetically modified organism (Produced from canola, corn, soy, etc.)	Failure to pay attention to the implementation method and evaluation training of suppliers in the purchase unit about the purchase of oil and lecithin with a non-GMO label	1	1	1	Minor	Uncertain use of the organization due to the commitment to the Food and Drug Organization of Iran and control of the incoming oils Purchase control of all types of oil with non-transgenic labels by the purchasing unit	-	-	-	-	PRP
Radiological materials: Departure from the items mentioned in the standards related to the radioactive components of water	Disturbance in the urban drinking water supply process	1	1	1	Minor	Sending water to equipped centers to perform radiological tests	-	-	-	-	PRP

Physical (P)/ Chemical (C)/ Microbial (M)/ Allergen (A)/ Genetically modified organism (GMO)/ Severity (S)/probability of occurrence(P)
foreign bodies: Hard and sharp objects such as metal parts, glass, and wood
The hazards for each type of material used are defined separately with the help of national (Institute of Standards and Industrial Research of IRAN) and international standards. Therefore, a hazard may be defined for one material but not another.
Primitive Material: Wheat Flour, Sugar, Hydrogenated vegetable oil, Skim milk powder, Whole egg powder, Leavening Agent, Fruit flavor, Lecithin (E322), Invert syrup, Water, Packaging materials, biscuit powder.

Table 3. Hazard analysis identification in biscuit processing steps

Step	Description	Hazards	Causes	Risk assessment		Outcome	Significant Risk	Control / Preventive measures	Decision tree				Conclusion (CCP OR NOT)?
				S	P				Q 1	Q 2	Q 3	Q 4	
Passing wheat flour through a sieve	The wheat flour is passed through a sieve to separate larger particles of flour from it	(P): foreign bodies	Possible impurities in wheat flour	3	3	9	Moderate	Passing through a sieve to remove particles other than wheat flour	Y	Y	-	-	CCP
Passing wheat flour through a magnet	The wheat flour passes through a magnet to separate Iron Particles	(P): foreign bodies	Possible Iron Particles in wheat flour	3	3	9	Moderate	Passing a magnet to remove Iron Particles	Y	N	Y	Y	OPRP
Passing the wheat flour insecticide machine	Insects and insect eggs are disintegrated by centrifugal force.	(M): pathogenic microorganisms	Insects and eggs of possible insects in wheat flour	2	3	6	Minor	Passing through insecticide machines to destroy insects and their eggs	-	-	-	-	PRP
Passing sugar through a sieve	sugar is passed through a sieve to separate larger particles of flour from it	(P): foreign bodies	Possible impurities in sugar	3	3	9	Moderate	Passing through a sieve to remove particles other than sugar	Y	Y	-	-	CCP
Passing sugar through a magnet	sugar passes through a magnet to separate Iron Particles	(P): foreign bodies	Possible Iron Particles in Sugar	3	3	9	Moderate	Passing through a magnet to remove Iron Particles	Y	N	Y	Y	OPRP
Passing biscuit powder through a sieve	Biscuit powder is passed through a sieve to separate larger particles of flour from it	(P): foreign bodies	Possible impurities in biscuit powder	3	3	9	Moderate	Passing through a sieve to remove particles other than biscuit powder	Y	Y	-	-	CCP
Invert syrup cooking	Heating sugar and water with citric acid to produce inverted syrup	(C): Residual acid or pH imbalance	Improper acid usage or incorrect sugar-to-water ratio	2	2	4	Minor	Monitoring ingredient ratio, controlling cooking time and temperature, testing the pH of the final syrup	-	-	-	-	PRP

		(M) pathogenic microorganisms	Cross-contamination from equipment, containers, and Personnel.	3	1	3	Minor	Compliance with the cleaning and disinfection program of equipment and containers. Personnel cleaning and disinfection Program.	-	-	-	-	PRP
Fat Grinding	Grinding solid fat to achieve smoother texture and uniform blending	(P): foreign bodies	Cross-contamination from equipment and Personnel Improper building and facilities	3	2	6	Minor	Operator training Compliance with prerequisite programs Compliance with the maintenance programs	-	-	-	-	PRP
		(M) pathogenic microorganisms	Cross-contamination from equipment, containers, and Personnel.	3	1	3	Minor	Compliance with the cleaning and disinfection program of equipment and containers. Personnel cleaning and disinfection Program. Compliance with the pest control program.	-	-	-	-	PRP
Weighing raw materials	Raw materials are weighed according to the weights included in the formulation.	(P): foreign bodies	Cross-contamination from equipment and Personnel Improper building and facilities	3	2	6	Minor	Operator training Compliance with prerequisite programs Compliance with the maintenance programs	-	-	-	-	PRP
		(C): excessive leavening agents/ residue of detergents	Weighing operator error Not having a standard formulation. measuring equipment is not calibrated Non-compliance with the cleaning and disinfection program	1	3	3	Minor	Operator training. Designate formulas under the requirements of the Standards for Specification, Scope, Application, and Limit of Food Additives. Calibration of measuring equipment. Compliance with the cleaning and disinfection program of equipment and containers.	-	-	-	-	PRP
		(M): pathogenic microorganisms	Cross-contamination from equipment, containers, and Personnel. The presence of pests in the place of production.	3	1	3	Minor	Compliance with the cleaning and disinfection program of equipment and containers. Personnel cleaning and disinfection Program. Compliance with the pest control program	-	-	-	-	PRP
Mixing	Mixing is a process where all ingredients are put together in the right proportion for dough formation.	(M) pathogenic microorganisms	Cross-contamination from equipment,	3	1	3	Minor	Compliance with the cleaning and disinfection program of equipment	-	-	-	-	PRP

Metal detection	The biscuit dough is passed through the metal detector to check all kinds of metal	(P): foreign bodies	Cross-contamination from equipment and Personnel Improper building and facilities Metals in raw materials	5	3	15	Critical	Operator training Compliance with prerequisite programs Compliance with the maintenance programs Passing dough through the metal detector to check all kinds of metal	Y	Y	-	-	CCP
Forming with Molding Roller	The dough is passed through several rolls to form sheets in forming sections. These sheets are then converted into One uniform sheet of the desired thickness Molders and cutters are used to cut sheets or convert dough into desired shapes and sizes	(M) pathogenic microorganisms	Cross-contamination from equipment, The presence of pests in the place of production	3	1	3	Minor	Compliance with the cleaning and disinfection program of equipment Compliance with the pest control program	-	-	-	-	PRP
Baking	Wet dough pieces are passed on to the oven. Heat is transferred to the biscuit on the band through one-way convection, And the biscuits are baked	(C): Increase product acidity and product peroxide	Improper temperature setting, time, and conveyor speed for cooking are also important. Improper operation of burner suction fans. Failure to properly train the oven operator	2	3	6	Minor	Controlling the temperature, time, and speed of the conveyor belt. Compliance with the maintenance Oven operator training	-	-	-	-	PRP
		(M): Remaining and not disappearing pathogenic microorganisms	Improper temperature setting, time, and conveyor speed for cooking are also important. Improper operation of burner suction fans. Failure to properly train the oven operator	5	3	15	Critical	Controlling the temperature, time, and speed of the conveyor belt. Compliance with the maintenance Oven operator training	Y	Y	-	-	CCP
Cooling	Biscuits are placed on a long conveyor belt to reach room temperature, and biscuits are handled for packing.	(P): foreign bodies	Cross-contamination from equipment and Personnel Improper building and facilities	3	1	3	Minor	Compliance with the maintenance programs Compliance with prerequisite programs	-	-	-	-	PRP
		(M): pathogenic microorganisms	Cross-contamination from equipment. The presence of pests in the place of production.	3	1	3	Minor	Compliance with the cleaning and disinfection program of equipment. Compliance with the pest control program	-	-	-	-	PRP

Packaging	Biscuits are placed in a box. The boxes have plastic.	(P): foreign bodies	Cross-contamination from equipment and Personnel Improper building and facilities	3	1	3	Minor	Compliance with the maintenance programs. Personnel training Compliance with prerequisite programs	-	-	-	-	PRP
		(M): pathogenic microorganisms	Cross-contamination from equipment, Boxes and plastics, and Personnel. The presence of pests in the place of production.	3	1	3	Minor	Compliance with the cleaning and disinfection program of equipment. Compliance with the requirements of good storage conditions and packaging requirements. Personnel cleaning and disinfection Program. Compliance with the pest control program	-	-	-	-	PRP
Storage	The finished product is stored in the warehouse.	(C): Increase product acidity and product peroxide	Failure to comply with the principles of storage and storage conditions Lack of thermometer calibration Failure to control the temperature and humidity of the warehouse	2	2	4	Minor	Correct implementation of storage principles Timely calibration of temperature and humidity control instruments Application of the First In First Out (FIFO) system	-	-	-	-	PRP
		(M): Increase pathogenic microorganisms load during storage	Failure to comply with the principles of storage and storage conditions Failure to observe the correct implementation of cleaning and disinfection Lack of thermometer calibration Failure to control the temperature and humidity of the warehouse	2	2	4	Minor	Correct implementation of storage principles Timely calibration of temperature and humidity control instruments Compliance with the cleaning and disinfection program Application of the First In First Out (FIFO) system	-	-	-	-	PRP
Distribution	This product is loaded and distributed in clean and suitable vehicles	(P)	-										
		(C)	-										
		(M)	-										

Physical (P)/ Chemical (C)/ Microbial (M)/ Allergen (A)/ Genetically modified organism (GMO)/ Severity (S)/probability of occurrence(P)
foreign bodies: Hard and sharp objects such as metal parts, glass, and wood.

Table 4. HACCP Critical Control Points (CCPs) and Their Critical Limits, Monitoring, Corrective Actions, and Verification Procedures

CCP (Process steps)	Control measure	Critical limits	Monitoring procedures				Recording	Corrective action		Recording	Verification			Recording
			Who	What	When	How		Procedure	Responsibility		Who	What	When	
Passing wheat flour/sugar/biscuit powder through a sieve	Sieve Inspection	No foreign particles more significant than the defined size in the manual	Operator responsible for sieving powder / QC expert on the production line	Condition of sieves used	Before starting sieving powdered materials – once per shift	Visual inspection	Recorded in relevant forms by the operator responsible for sieving powdered materials - Recorded in QC forms	Remove, replace, or repair defective sieves / Re-sieve all non-compliant powdered material for re-sieving - Ensure proper operation after corrective action.	Operator responsible for sieving powder / QC expert on the production line	Recorded in QC forms (for non-compliance issues and corrective actions)	Laboratory expert	Check sieve performance in the lab (sampling of sieved powdered material)	Monthly	Record the test report and periodic inspections
Metal detection	Metal Detector sensitivity check	There is no warning signal and no metal particles more significant than the defined size in the manual.	Dough forming section operator / QC expert on the production line	Check metal detector performance	Before starting the biscuit production process – once per shift	Check performance by passing sheets with metal parts through it and evaluate the sensitivity and accuracy of the metal detector	Recorded in relevant forms by the dough forming section operator - Recorded in QC forms	Troubleshoot metal detector settings - Adjust metal detector settings - If necessary, repair or replace metal detector - Remove products produced during metal detector malfunction - Ensure proper operation after corrective action	Dough forming section operator / QC expert on the production line / Maintenance personnel	Recorded in QC forms (for non-compliance issues and corrective actions)	QC expert / Maintenance personnel	Calibration of the metal detector with its related equipment	Monthly	Record calibration and its results
Baking	Baking Temperature and Time Control	Temperature and baking time within the defined limits in the manual	Oven operator / QC expert on the production line	Check oven performance	Before starting production – each time there are changes in baking	Use a thermometer and clock	Recorded in relevant forms by the operator - Recorded in QC forms	Adjust temperature and time according to the manual - Ensure proper operation after corrective action	Oven operator / QC expert on the production line	Recorded in QC forms (for non-compliance issues and corrective actions)	QC expert / Microbiology laboratory expert	Check using a calibrated thermometer / Perform microbiological tests	Monthly/Daily	Record thermometer calibration and results / Record microbiological test results

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The authors declare no conflicts of interest.

Ethical Consideration

No experiments involving human subjects were conducted in this study.

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