

Safety Design Framework for Short Shelf-Life Food Products in SMEs Using HACCP and FMEA Methods

Danar Agus Susanto

Department of Industrial and Systems Engineering,
Institut Teknologi Sepuluh Nopember, Surabaya, Indonesia
Email: danar.agus.susanto@brin.go.id (*Corresponding Author*)

Mokh Suef

Department of Industrial and Systems Engineering,
Institut Teknologi Sepuluh Nopember, Surabaya, Indonesia
Email: danar.agus.susanto@brin.go.id.

Putu Dana Karningsih

Department of Industrial and Systems Engineering,
Institut Teknologi Sepuluh Nopember, Surabaya, Indonesia
Email: danar.agus.susanto@brin.go.id.

Bambang Prasetya

Research Centre for Testing Technology and Standard,
National Research and Innovation Agency, South Tangerang City, Indonesia
Email: danar.agus.susanto@brin.go.id.

ABSTRACT

This study aimed to develop a safety design framework for short shelf-life food products using HACCP and FMEA methods. This framework is divided into four main stages. The first stage involves identifying the condition of the business premises to obtain an overview and gather information about the production process. The second stage focuses on collecting primary data regarding potential hazards in the production process and determining critical control points (CCP) based on HACCP principles 1-3. In the third stage, the identified potential hazards are controlled at the critical control points. The final stage involves prioritizing the CCPs using the FMEA method through the calculation of the Risk Priority Number (RPN) score. A trial of the proposed framework has been conducted on an SME that produces wet noodles. The results showed that the potential hazard of wet noodle production process comes from biological, chemical, and physical contaminants. Potential food safety hazards that are significant and become CCP based on the prioritized Risk Priority Number (RPN) are the packaging process (RPN: 144), steaming process (RPN: 60), and storage process (RPN: 36). Under conditions in which the control of hazards cannot be carried out at once, then priority controls may be carried out using this sequence. This research focuses on determining CCPs and prioritizing strategies to control these hazards through FMEA. This is especially important for SMEs with limited resources to control all CCPs. The balance between available resources, processes, and results from managing risks is important and ideal for SMEs.

Keywords: *critical control points, FMEA, food safety, HACCP, SMEs.*

1. INTRODUCTION

Efforts to manage and realize food conditions that are not polluted by contaminants are the basis for food safety to reduce potential losses and hazards to consumer health. Food safety must be ensured by personnel who are responsible for the food chain which includes the food production, storage, transportation, and distribution process. Ease and ability to obtain safe and healthy food is a basic human need (Fukuda, 2015). One of the criteria for a good food is that it meets good safety aspects and conforms to applicable standards. The food safety factor is one of the factors for potential consumers to choose a product to buy and consume. Food and beverage sector companies have an important duty to maintain food safety in an increasingly complex business competition (Liu *et al.*, 2021). Food products that do not meet the safety aspects will affect the emergence of potential hazards and risks both for consumers and producers will not get sustainability benefits (Benjamin *et al.*, 2023), termasuk dalam persaingan pasar (Pramudika *et al.*, 2024).

The result of food safety hazards is the risk of poisoning and disease for consumers, while for producers there is a decrease in product image, consumer confidence regarding product quality is lost, customers are reduced, sales and profits are also reduced. Food safety hazards and risks should be identified as soon as possible, then get controlled, so that the impacts of these hazards and risks can be prevented and do not spread and result in a greater impact. Over the last decade, it was found that the number of contaminants and

toxins in food has increased, affecting the safety of raw materials and food (Omarov *et al.*, 2017). Every year, WHO estimates 23 million cases of food-related illness in Europe (Flynn *et al.*, 2019). Detection, elimination, and control of hazards and risks from hazardous substance contamination, from harvesting to consumption will always be necessary (Wang *et al.*, 2019), and maintaining food supply security is an activity that must always be carried out (Flynn *et al.*, 2019).

The shelf life of food products is the period during which a food product remains in an acceptable condition in terms of quality and safety for consumption, under specific storage conditions. The quality in question encompasses various aspects such as taste, texture, aroma, and appearance, as well as the nutritional content, which must remain stable throughout this period. Additionally, the safety aspect refers to the product not undergoing microbiological, chemical, or physical degradation that could pose a health risk to consumers (Susanto *et al.*, 2022). The shelf life is influenced by several factors, including the type of food ingredients, processing methods, packaging, and storage conditions such as temperature, humidity, and exposure to light (Martelli *et al.*, 2021). Manufacturers usually determine the shelf life based on tests involving simulated storage conditions and periodic product testing to monitor changes in quality and safety. The shelf-life label is often expressed as an "expiration date" or "best before" date on the packaging, helping consumers understand the safe and optimal consumption period.

Food products with a short shelf life are those that experience a relatively rapid decline in quality after production, thus requiring consumption within a short period to maintain safety and quality (Hosseini & Jafari, 2020). Products with a short shelf life generally fall into the category of fresh foods or those that have not undergone intensive preservation processes. Examples include fresh fruits, vegetables, dairy products, raw meat, fish, and bread products that do not contain preservatives (Saxena *et al.*, 2024). The primary characteristic of short-shelf-life food products is their high water content and water activity (aw), which promote the growth of microorganisms and accelerate chemical and enzymatic deterioration (Settier-Ramirez *et al.*, 2022). Another characteristic is the minimal presence of natural or added preservatives. Without preservation methods such as drying, salting, or adding chemical preservatives, these products are susceptible to spoilage or the growth of pathogens, such as bacteria and fungi (Hosseini & Jafari, 2020). These products are also sensitive to environmental conditions. Storage temperature, humidity, and light exposure significantly influence the rate of deterioration. High temperatures or temperature fluctuations can speed up spoilage and shorten shelf life (Settier-Ramirez *et al.*, 2022). Factors influencing the short shelf life of food products include microbiological activity, chemical and enzymatic degradation, and physical instability (Saxena *et al.*, 2024).

Previous studies have indicated that some short shelf-life food products produced by small and medium enterprises (SMEs) exhibit inadequate sanitation and hygiene practices, with nearly all product samples testing positive for *E. coli* bacteria. Additionally, an analysis of short shelf-life food samples from traditional markets in Malang revealed that 14% of the samples contained borax, while 100% tested

positive for formaldehyde and methanil yellow. In Gorontalo, 66% of short shelf-life product samples were found to have bacterial contamination levels exceeding acceptable limits, with some samples posing significant health risks and being linked to illnesses such as acute diarrhea, dysentery, and pneumonia.

This condition creates a research gap regarding the need for safety design for short shelf-life food products. The water content in short shelf-life food products is relatively high, so the shelf life is relatively short. Hazardous materials such as formalin and boric acid are strictly prohibited. High water content in food products has a higher potential for contamination risk. Manufacturers committed fraud by using hazardous chemicals or substances such as formalin as a preservative, which, at high doses or when consumed frequently, may cause cancer in the human digestive tract. Short shelf-life food products have a high and medium risk level, so production, storage, marketing and distribution must be controlled. Control over the food safety of short shelf-life food products is needed so that it is safe and healthy when consumed. So, the question arises regarding safety design research on short shelf-life food products so that they are safe when consumed?

Previous research regarding the application of HACCP in maintaining food safety has been widely applied, including to food in general (Liu *et al.*, 2021), seafood (Al-Busaidi *et al.*, 2017), liquor (Yin *et al.*, 2020), snacks chips and cheese and vegetable (Varzakas & Arvanitoyannis, 2008). In general, this research produces CCP which is used as the core problem of food organization. However, HACCP has disadvantages related to too many critical controls so that it becomes a burden on the organization (especially for SMEs) and loses focus on relevant hazards and does not give priority to managing all the risks from the resulting CCP. This is certainly an obstacle for small organizations (SMEs) trying to implement it. SMEs have limitations in implementing HACCP effectively and efficiently due to lack of resources and knowledge. Once the CCP has been established, obstacles are faced by SMEs in implementing the CCP control strategy. Priority is required by HACCP implementers when the organization or company is unable or constrained when carrying out all CCPs well together. There is potential for the development of knowledge in the future regarding the application of HACCP to SMEs and priority strategies for managing CCP effectively and efficiently due to the limitations of these SMEs. In this regard, the aim of this research is to develop a safety design for short shelf-life food products using HACCP and FMEA methods, especially for SMEs by setting CCPs and prioritizing them to control potential hazards that may occur.

2. LITERATURE REVIEW

2.1 Food Safety Hazards

Since a food safety hazard is a contaminant that includes any condition that may pose an undesired health risk to consumers. Hazards are contaminant that can cause food to become unsafe for consumption. Although risk is a combination of the possibility of an event related to an illness or injury resulting from a food safety hazard or exposure of a person to a hazard. Thus, hazard is the nature of the process that can harm the individual, while risk is the probability that it will occur, as well as the severity of the consequences.

Table 1 Research framework food contaminants

Biological Contaminants	Chemical Contaminants	Physical Contaminants
Virus	Mycotoxin	Glass
Bacteria	Mushroom toxin	Wood
Protozoa	Shellfish toxin	Stone
Parasite	Pesticides	Metal (nail pieces, stapler seeds)
Prion	Herbicides	Insect
	Insecticides	Bone
	Residues of antibiotics and growth hormone	Plastic
	Fertilizer	
	Heavy metal	

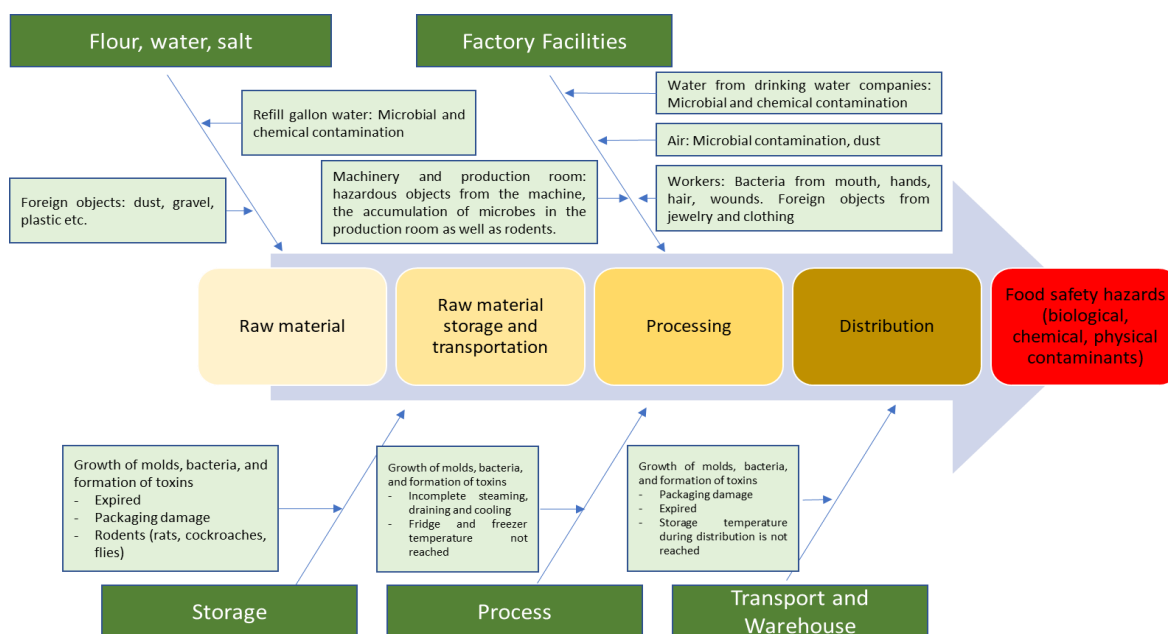


Figure 1 Origin of hazard in the short shelf-life food products production process

Food safety hazards and risks arise, one of which is due to food contamination. The severe consequences that consumers can receive when consuming contaminated food are health risks. Food contaminants presented in **Table 1**. The origin of food safety hazards can occur from transportation and warehouses, factory facilities, processes, warehouses, and the origin of raw materials (fields, rice fields, ponds, sea). Based on **Figure 1**, the origin of the hazard can and is possible from the internal and external as well as the supply of raw materials to distribution to consumers.

2.2 Hazard Analysis and Critical Control Point (HACCP)

HACCP is a method used to determine hazards and control systems with more focus on preventing food contamination, developed by Codex Alimentarius Commission (CAC) (Nwaiwu & Ibekwe, 2017). HACCP systems can adapt to changes, such as changes in production process design and procedures. The application of HACCP should be guided by scientific evidence of the risks that may occur from food contamination, so that it can be applied throughout the food chain.

The implementation of the Hazard Analysis and Critical Control Point (HACCP) system is based on the CAC/RCP 1-1969 Rev. 4 (2003) standards, which are outlined in the Recommended International Code of Practice

General Principles of Food Hygiene. This standard is a quality assurance system model that prioritizes food safety as its main approach. Food safety refers to aspects of the production process that could potentially cause disease or death, commonly associated with biological, chemical, or physical hazards. HACCP is designed to be used by food businesses to implement food safety assurance measures. The application of HACCP is based on seven key principles, as follows:

1. Conducting a hazard analysis
2. Determining critical control points (CCP)
3. Establishing critical limits
4. Setting up a system for monitoring the control of critical control points
5. Establishing corrective actions to be taken when monitoring indicates that a particular CCP is not under control
6. Establishing verification procedures to ensure that the HACCP system is working effectively
7. Establishing documentation concerning all procedures and records in accordance with these principles and their application.

This structured approach ensures that potential hazards in food production are identified, monitored, and controlled, significantly reducing the risk of foodborne illnesses and ensuring consumer safety. HACCP implementation and certification provide benefits in financial aspects, productivity and organizational efficiency (Liu *et al.*, 2021).

The implementation of HACCP can ensure product safety and stability as well as providing a reference for management in making decisions about the result of each production process (Yin *et al.*, 2020). The implementation of HACCP uses seven main principles.

2.3 Failure Mode Effect Analysis (FMEA).

The security and reliability of a system can be analyzed with FMEA. The FMEA method is embodied in systematic steps and processes to identify potential failures prior to their occurrence with the aim of eliminating or minimizing the risks associated with the identified failures also articulating the suggestion that FMEA should serve as a basis for risk reduction activities to an acceptable level (Dedimas & Gebeyehu, 2019). FMEA consists of four stages, which are identification, confirmation, ranking determination and

corrective action (Huang *et al.*, 2020). The FMEA output is to rank the recognized failure modes based on the Risk Priority Number (RPN).

2.4 Failure Mode Effect Analysis (FMEA).

Previous research refers to studies that have been conducted previously related to the application of HACCP and FMEA, either separately or in combination, across different types of businesses and the outputs produced. This review helps researchers identify concepts, theories, or findings that have already been established, as well as research gaps that have yet to be addressed. The research gap or novelty represents the unique or innovative aspect that distinguishes a study from previous research. Previous research and research novelty are presented in **Table 2**.

Table 2 Research novelty

Domain Field Problem	Research methods		Research Locus			Output	
	HACCP	FMEA	Multinational industry	National industry	Small and Medium Enterprises (SMEs)	Critical Control Point	Prioritizing Critical Control Points
Food (general)	(Liu <i>et al.</i> , 2021)	(Selim <i>et al.</i> , 2016)	(Liu <i>et al.</i> , 2021) (Wallace <i>et al.</i> , 2014)		(Razak & Daud, 2020) (Dzwolak, 2019) (Ramalho <i>et al.</i> , 2015)	(Razak & Daud, 2020) (Dzwolak, 2019),(Ramalho <i>et al.</i> , 2015)	
Seafood	(Al-Busaidi <i>et al.</i> , 2017)			(Al-Busaidi <i>et al.</i> , 2017)			
Liquor	(Yin <i>et al.</i> , 2020)			(Yin <i>et al.</i> , 2020)		(Yin <i>et al.</i> , 2020)	
Snacks (chips and cheese)	(Carrascosa <i>et al.</i> , 2016)			(Carrascosa <i>et al.</i> , 2016)		(Carrascosa <i>et al.</i> , 2016)	
Medical		(Faiella <i>et al.</i> , 2018)		(Faiella <i>et al.</i> , 2018)			(Faiella <i>et al.</i> , 2018)
Textile		(Dedimas & Gebeyehu, 2019)		(Dedimas & Gebeyehu, 2019)			(Dedimas & Gebeyehu, 2019)
Shelf-life food products	This research				This research		

3. METHODOLOGY

This research is a qualitative and quantitative descriptive study using the HACCP method to identify hazards, determine and control CCP in the Short shelf-life food production process. Meanwhile, prioritize CCP using the FMEA method. HACCP approach such as regulation that is economically efficient (Unnevehr & Jensen, 1999). However, HACCP has the disadvantage of producing too much control and losing focus on relevant hazards and not performing quantification calculations to prioritize risks. Therefore, in this study, it was combined with the FMEA method to prioritize CCPs to control hazards. Priority is required by HACCP implementers when the organization or company is unable or constrained when carrying out all CCPs well together.

4. PROPOSED SAFETY DESIGN FRAMEWORK FOR SHORT SHELF-LIFE FOOD PRODUCTS

The proposed research framework is divided into 4 main stages. The first stage is identifying the condition of the place of business to get an overview and information about the condition of the production process. The second stage is collecting primary data regarding data on potential hazards in the production process and determine critical control points according to HACCP 1-3 principles. Meanwhile, in the third stage is controlling the potential hazards at critical control points, which is carried out using principles 3-7 HACCP, namely setting critical limits, establishing a monitoring system for controlling critical control points, determining corrective actions to be taken if monitoring results indicate that a certain CCP is not in control,

determining verification procedures to ensure that the HACCP system is working effectively, and documenting all procedures and records are in accordance with HACCP principles and practices. In the final stage, the CCP prioritized using the FMEA method through the RPN score.

4.1 Identify the Condition of the Place of Business

At this stage, an analysis of the business premises conditions is carried out using the assessment categories of Good Manufacturing Practices (GMP). GMP serve as a guideline for all food processing industries to ensure they adhere to food safety principles, thereby producing high-quality and safe food products for consumers. The food and beverages consumed by the public must meet health standards; otherwise, they are prohibited from being sold (Rudiyanto, 2016). GMP practices aim to ensure product quality, requiring every food processing industry to control its production processes to achieve the quality standards set. Adhering to GMP guidelines is essential in minimizing the risk of poor product quality (Kumar & Jha, 2015). In general, GMP regulations encompass various aspects, including the hygienic design and construction of food production facilities, proper equipment design and construction, cleaning and disinfection protocols, selection of high-quality raw materials, worker hygiene training, and comprehensive company documentation. Good Manufacturing Practices cover 19 key aspects, which include location, building, sanitation facilities, machinery and equipment, materials, process control, final products, laboratory procedures, employees, packaging, product labeling, storage, maintenance and sanitation programs, transportation, documentation and record-keeping, training, product recall,

and guideline implementation (Rudiyanto, 2016; Wahid, 2021).

4.2 Interviews

In accordance with the seven principles of HACCP, at second stage begins with a hazard analysis at each stage of the short shelf-life food products production process and then analyzes the determination of critical control points to control it. Each process is analyzed for hazards that may occur using an analysis of the possibility of contaminants. The analysis of determining the level of hazard significance uses references in **Table 3**. Meanwhile, the determination of the CCP is carried out if the hazard in a production process is a significant hazard. The analysis used the HACCP decision tree as shown in the CAC/RCP 1: 2011 document as shown in **Figure 2**.

The probability of occurrence is determined by examining records of manufacturing activities or production activities. This is done using the calculation of the mode, mean, and median of statistical calculations and through adequate scientific references. Specifically, for determining the severity level resulting from identified food poisoning events, references, and expert judgment are used.

Table 3 Determination of hazards significance

	Severity		
	L	M	H
Reasonably likely to occur	L	ML	HL
	M	MM	HM)*
	H	MH)*	HH)*

Description: L = low, M = medium, H = High
)* = significant and will be considered in determining the CCP
 Source: (Rosak-Szyrocka & Abbase, 2020)

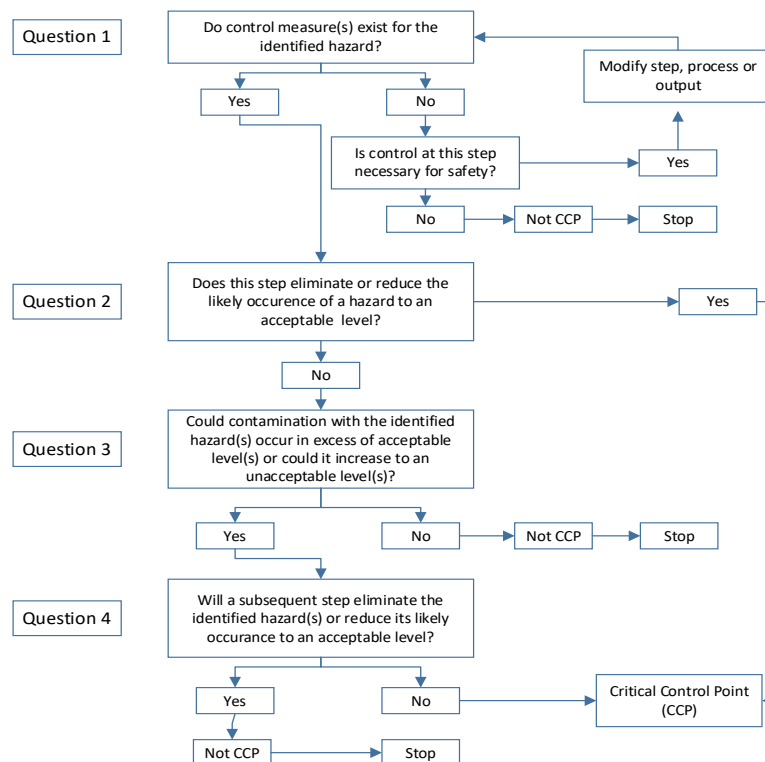


Figure 2 Decision tree for determining critical control points
 Source: (Rosak-Szyrocka & Abbase, 2020)

4.3 Control the Potential Hazards at Critical Control Points

The control process is carried out using principles 3-7 in the HACCP method, which are setting critical limits, monitoring system for controlling critical control points, corrective actions taken if monitoring results indicate that a certain CCP is not under control, verification procedures to ensure the effectiveness of the HACCP system and the documentation and records of all procedures are in accordance with HACCP principles and practices.

At the initial stage, each CCP is determined by the critical limit that must be achieved. Acceptable tolerance limits to maintain potential hazards are critical limits that must not be violated or exceeded. After determining the critical limit, monitoring is carried out using the 5W+1H method (what, where, why, when, who, and how). Observations of CCP controls are required with appropriate records for use in verification activities. Hazard assessment is the most critical area of implementing HACCP (Dzwolak, 2019).

After the CCP monitoring process has been carried out consistently, it is necessary to take corrective action if the critical limit is not reached or exceeded. Corrective action must be able to reduce or eliminate potential hazards and risks that occur when the critical limit of CCP is exceeded, to ensure that the disposition of products that do not meet does not result in new potential hazards. The verification stage is aimed to verify whether the HACCP program has

been implemented in accordance with the established HACCP design and ensuring that the established HACCP design is still effective and correct. At the final stage, recording is carried out as documentation of all the procedures and records. The purpose of this stage is to archive the HACCP program design by compiling accurate and neat records of the entire system and the application of HACCP and facilitating inspection by managers or authorized agencies if the product produced is known or suspected to be the cause of food poisoning cases.

4.4 CCP Prioritized Using the FMEA

The security and reliability of a system can be analyzed with FMEA. The FMEA method is embodied in systematic steps and processes to identify potential failures prior to their occurrence with the aim of eliminating or minimizing the risks associated with the identified failures also articulating the suggestion that FMEA should serve as a basis for risk reduction activities to an acceptable level (Dedimas & Gebeyehu, 2019). FMEA consists of four stages, which are identification, confirmation, ranking determination and corrective action (Huang *et al.*, 2020). The FMEA output is to rank the recognized failure modes based on the Risk Priority Number (RPN). Measurement of RPN FMEA is carried out based on the ranking of severity, likelihood, and level of detection as presented in **Tables 4 - 6**.

Table 4 Criteria for assessing the severity of consequences “s”

Description of consequences of severity	Rank Value	Rank
Hazardous components are present in the product, exceeding standard values, causing serious health consequences	Fully complies	9-10
Hazardous components are present in the product and slightly exceed the standard values, which do not cause serious health consequences	Partially complies	7-8
The hazardous components in the product are within the specified standard values	Partially complies	5-6
Hazardous components are present in the finished product but do not exceed the value of the established standard (if there is no standard, there is no harm to health in the estimated concentration)	Partially complies	3-4
Hazardous components are not present in the finished product	Fully complies	1-2

Source: (Kazhymurat *et al.*, 2021)

Table 5 Criteria for assessing the probability of occurrence “o”

Description for the probability of occurrence	Rank Value	Rank
Almost inevitable	Very high	9-10
Occurs over and over	High	7-8
Sometimes occurs	Average	5-6
Relatively rare	Low	3-4
Very low	Very low	1-2

Source: (Kazhymurat *et al.*, 2021)

Table 6 Criterion for assessing detectability “d”

Detectability of nonconformity Detection	Rank Value	Rank
Detection method not available	Very difficult	9-10
Detection methods are available, but control is not possible at this stage, or the indicators are not regulated by law	Difficult	7-8
Detection method is available, but control is not carried out at this stage	Moderately	5-6
Hazards can be detected at this stage, methods are available	Low	3-4
There are stages designed to detect hazards; necessary methods are in place	Simple	1-2

5. SAFETY DESIGN FOR WET NOODLE PRODUCT: CASE STUDY

5.1. Identify the Condition of the Place of Business

The raw materials for wet noodle products are wheat flour and other permitted additives, whether through the cooking process or not. In simple terms, wet noodles are the result of processing from the basic ingredients of flour mixed with other additives. As one of the most popular foods, wet noodles are widely consumed as snacks and main dishes, and can substitute rice as a base food for the Indonesians. Wet noodles have short shelf life, ranging from 10 to 12 hours at room temperature due to its relatively high-water content. The water content in wet noodle products is relatively high, so the shelf life is relatively short. Hazardous materials such as formalin and boric acid are strictly prohibited.

Wet noodles are produced through a process of mixing, milling, printing, boiling, and draining to produce good noodles with chewy characteristics, uniform noodle color, not easy to soften when boiled and soft noodle taste. If it goes through the process of steaming or boiling, it is called cooked wet noodles. Meanwhile, they are called raw if they do not go through these stages. Because it is practical and easy to process into other forms of food, wet noodles are widely used. The level of consumption in Indonesia is quite large, with 2.49 portions per month and per capita expenditure for consumption of wet noodles is Rp. 19,466 every month.

This case study research was conducted in SME producing wet noodles in Indonesia. SMEs have 21

employees and a production capacity of 2.800 kg per month, with marketing throughout Indonesia. In general, the product description is presented in **Table 7**.

Table 7 Description of wet noodles products

Description	Information
Final product	Wet noodles
Raw materials	Wheat flour, water, salt
Processing	Weighing and mixing raw materials, grinding, molding, steaming, draining (cooling), packaging, storage and marketing.
Type of packaging	Sealed plastic for net weight of 115 grams and 95 grams
Product characteristics	Biological, chemical and physical characteristics according to SNI 2987:2015
Shelf life	Room temperature (20°C – 25°C): for 3 days Freezer temperature (-18°C): for 1 month
Distribution	Sold directly at outlets, via the web and online social media
Product use	Fried or boiled
Consumers	Children to adults

According to **Table 6**, wet noodle products have biological, chemical and physical characteristics in accordance with the quality parameters in the Indonesian National Standard (SNI) 2987: 2015. This SNI regulates the terms and definitions, composition, quality requirements, sampling and testing methods for raw wet noodles and cooked wet noodles. At this stage, GMP analysis is also carried out as a prerequisite program before implementing HACCP. GMP aspects in wet noodle producing SMEs are presented in **Table 8**.

Table 8 Compliance of SME conditions with GMP aspects

No	GMP Aspect	SME Condition
1.	Location	The production facility is situated in a shop-house, yet it is located away from polluted areas, waste disposal sites, or potential waste sources. Production activities are carried out in a closed and clean environment, with a designated production room that is separated from other areas.
2.	Buildings	The design and layout of the facility have been organized by sub-processes, ensuring a smooth flow of production. However, information labels indicating different sections of the production area have not yet been installed. The production floor is tiled with ceramic, the walls are covered with wallpaper, and wooden production tables are used. The ceiling is supported by a lightweight steel frame, and the lighting fixtures are not shielded, posing a potential contamination risk.
3.	Sanitation facilities	Separate facilities are provided for cleaning raw materials and washing production equipment. Toilet facilities are located outside the production area, adjacent to the production room.
4.	Machinery and equipment	Most machines and equipment are constructed from aluminum, although some components, such as trays for temporarily storing noodles and water containers, are made from plastic. All equipment is cleaned immediately after use.
5.	Materials	The raw materials, including wheat flour, water, and salt, conform to the Indonesian National Standards (SNI).
6.	Process supervision	Process monitoring is not fully implemented, as some production sections lack monitoring forms.
7.	Final product	The final product meets quality standards and has been approved for distribution by the Indonesian Food and Drug Authority (BPOM).
8.	Laboratory	The facility does not yet have an in-house laboratory or quality control tools such as thermometers or moisture analyzers.
9.	Employees	Not all employees are equipped with proper production attire, including special uniforms, aprons, gloves, footwear, and masks during production.
10.	Packaging	The packaging process is conducted using a single vacuum packaging machine with food-grade plastic packaging.

Table 9 Compliance of SME conditions with GMP aspects (Cont'd)

No	GMP Aspect	SME Condition
11.	Location	The production facility is situated in a shop-house, yet it is located away from polluted areas, waste disposal sites, or potential waste sources. Production activities are carried out in a closed and clean environment, with a designated production room that is separated from other areas.
12.	Buildings	The design and layout of the facility have been organized by sub-processes, ensuring a smooth flow of production. However, information labels indicating different sections of the production area have not yet been installed. The production floor is tiled with ceramic, the walls are covered with wallpaper, and wooden production tables are used. The ceiling is supported by a lightweight steel frame, and the lighting fixtures are not shielded, posing a potential contamination risk.
13.	Sanitation facilities	Separate facilities are provided for cleaning raw materials and washing production equipment. Toilet facilities are located outside the production area, adjacent to the production room.
14.	Machinery equipment and	Most machines and equipment are constructed from aluminum, although some components, such as trays for temporarily storing noodles and water containers, are made from plastic. All equipment is cleaned immediately after use.
15.	Materials	The raw materials, including wheat flour, water, and salt, conform to the Indonesian National Standards (SNI).
16.	Process supervision	Process monitoring is not fully implemented, as some production sections lack monitoring forms.
17.	Final product	The final product meets quality standards and has been approved for distribution by the Indonesian Food and Drug Authority (BPOM).
18.	Laboratory	The facility does not yet have an in-house laboratory or quality control tools such as thermometers or moisture analyzers.
19.	Employees	Not all employees are equipped with proper production attire, including special uniforms, aprons, gloves, footwear, and masks during production.
20.	Packaging	The packaging process is conducted using a single vacuum packaging machine with food-grade plastic packaging.
21.	Product labels or descriptions	Product labeling complies with regulatory standards, including the product name, list of ingredients, net weight, company name and address, and expiration date.
22.	Storage	Finished products are stored in designated refrigerators and freezers, while raw materials are stored in an on-site warehouse.
23.	Maintenance and sanitation program	Although a checklist for regular maintenance and sanitation has been developed, it does not yet cover all sections.
24.	Transportation	Transportation of raw materials and finished products is handled using cars and motorcycles.
25.	Container transportation equipment maintenance	No further information is available regarding the specific logistics procedures.
26.	Documentation record keeping	Documentation and record-keeping are incomplete, though a monthly sustainability report has been initiated.
27.	Training	Employees have not yet received training on Good Manufacturing Practices (GMP) or Hazard Analysis and Critical Control Points (HACCP).
28.	Product recalls	Additionally, there are no established procedures or mechanisms for product recalls, and no detailed information on these processes is currently available.
29.	Guideline implementation	No detailed information on these processes is currently available.

5.2. Hazard Identification and Determination of Critical Control Points

The determination of the critical control point (CCP) is carried out in the production process that has a significant level of danger according to **Table 2**. The analysis uses the HACCP decision tree in the CAC/RCP 1: 2011 document as in **Figure 2**. There are 5 production processes that have significant potential hazards, namely making thin sheet dough, making noodle strands, steaming, packaging and storage. These five processes are analyzed using a decision

tree, so that the results obtained are that 3 processes are TKK, namely steaming, packaging and storage.

Based on **Table 10**, there are 3 production processes that have significant potential hazards, which are steaming, packaging, and storage. The steaming process aims to gelatinize starch and protein coagulation so that the noodles become chewy. Steaming is carried out at high temperatures with the right time span. Over-cooking will cause the noodles to be too mushy. The packaging must be done with the right method and time, the temperature of the noodles when packaged must match the room temperature homogeneously.

Meanwhile, storage is CCP because this process is the final process of hazard control, where the final product is stored in the freezer before being distributed to consumers.

5.3. Control of CCP

The process of steaming, packaging, and storage must be controlled to maintain the quality and the safeness of the wet noodle product. The control process is carried out using

principles 3-7 in the HACCP method, which are setting critical limits, monitoring system for controlling critical control points, corrective actions taken if monitoring results indicate that a certain CCP is not under control, verification procedures to ensure the effectiveness of the HACCP system and the documentation and records of all procedures are in accordance with HACCP principles and practices. The CCP control process is presented in **Table 11**.

Table 10 Hazard analysis and determination of CCP

No	Stages of production process	Source of hazard	Severity	Likely to occur	Significance
1.	Noodle Steaming	Contamination from employees and production equipment	M	H	S
2.	Packaging	Contamination from personnel, production equipment and air	M	H	S
3.	Storage	Contamination from employees who do not use production clothing according to procedures	M	H	S

Table 11 Control of CCP of wet noodle production process

No	Stage of production process	Critical Limit	Monitoring	Corrective action	Verification	Recording
1.	Steaming	Temperature 100-105°C for 30 minutes, for 7 kg of dough	The operator measures the temperature in the skillet/pan after about 12 minutes of steaming using a thermometer-gun every production process.	Increase the steaming time and report it to the supervisor on duty.	Perform regular heating condition checks, final product testing, and internal audit	Steaming Logbook and Noodle Steaming CCP Supervision Form
2.	Packaging	The noodle temperature corresponds to a room temperature of 20°C - 25°C homogeneously.	The operator measures the temperature using a thermometer gun when the noodles will be packed.	Set the air conditioner (AC) to condition and normalize the room temperature, go back and forth and increase the draining/cooling time and report it to the supervisor on duty.	Check the condition of the room temperature regularly, final product testing, and internal audit	Packaging Logbook and Packaging CCP Supervision Form
3.	Storage	Freezer temperature of -18°C	The operator ensures that the freezer temperature is reached -8°C every 6-8 hours (3 times a day).	Report it to the supervisor on duty.	Air test in the storage room against yeast, testing of final product, and internal audit	Storage Logbook and Product Storage CCP Supervision Form

Potential hazards in the production process chain can be controlled with HACCP, starting with determination of hazard, critical limits and monitoring activity (Yin *et al.*, 2020). The application of HACCP provides benefits related to financial and non-financial aspects, including growth and market acceptance (Liu *et al.*, 2021). Food safety management can be used as a method for wet noodle marketing strategy. Although the knowledge and awareness of SMEs in implementing HACCP is still low, the benefits will be greater (Razak & Daud, 2020). As a result, the government's active role is needed to encourage SMEs to implement HACCP certification. Implementation of the HACCP standard provides economic benefits for its implementers.

5.4. FMEA Analysis

FMEA analysis was used to prioritize each CCP. This analysis was carried out to complement the shortcomings of the HACCP method, in which the information on the priority of each CCP could not be obtained. This priority order can be used by the organization to take preventive and corrective action if it cannot be done simultaneously. due to a certain situation. Based on this priority, the condition of food safety can be maintained in the best condition because a priority has been set for its implementation. The output of the FMEA is to rank the recognized failure modes based on the risk priority number (RPN), as presented in **Table 12**.

Table 12 Analysis of CCP priorities using the FMEA method

No	Stage of production process	Consequences of possible product defects	Risk from potential product defects	Current control system	S	O	D	RPN
1.	Steaming	Biological (pathogenic microbes and bacteria), chemical and physical contamination	Unmaintained equipment, cross-contamination from operators and transfer of microorganisms from employees Biological hazards can cause product spoilage and food poisoning	<ul style="list-style-type: none"> • Steam logbook • Noodle steaming CCP supervision form. • Control of steaming temperature and time 	5	4	3	60
2.	Packaging	Biological (pathogenic microbes and bacteria), chemical and physical contamination	Pathogenic microorganisms in finished products can cause severe intestinal disease	<ul style="list-style-type: none"> • Packaging logbook • CCP packaging supervision form • Control the temperature of noodles evenly and homogeneously 	6	8	3	144
3.	Storage	Non-compliance with the hygienic characteristics of the product storage area will cause product damage	Damage to the product will cause a high-security risk in terms of health, safety, and consumer safety	<ul style="list-style-type: none"> • Logbook storage • Product storage CCP supervision form • Storage temperature control 	4	3	3	36

Based on **Table 11**, the order of priority for controlling CCP is packaging (RPN: 144), steaming (RPN: 60), and storage (RPN: 36). Packaging is the most important stage to control, because at this stage, it represents the final product that will be consumed by consumers. At this stage, the product has the potential to come into contact and direct contact with the hands of workers. This is because the noodles are inserted manually by their hands into the packaging. Although according to the procedure, workers are required to wear gloves. Prior to packaging, the noodles must be ensured to have a homogeneous room temperature, and this condition is one of the keys to maintain product quality. The condition of noodles that are not suitable for room temperature will cause humidity when packaged, which will cause the increasing of water content in the product, which will cause the growth of microbes and bacteria. If the microbes and bacteria grow beyond the specified limit, then the product is inappropriate to be marketed and consumed.

The application of FMEA provides many benefits, including saving downtime in the production process and improving performance (Dedimas & Gebeyehu, 2019), obtaining information on the main sources of problems in health services (Goodrum & Varkey, 2017), determining the appropriate method of administering medication at home (Faiella *et al.*, 2018), and setting risk priorities for international food companies (Selim *et al.*, 2016). It is important to manage risks to avoid greater losses (Umami *et al.*, 2023). Proper hazard control through the application of standards can increase product competitiveness.

6. DISCUSSION

Food contamination has the potential to occur in the food processing chain. Sources of contamination can come from food processors as well as from equipment used in

processing and the processing environment. Contamination can occur due to direct contact between the limbs of a sick person and food, either intentionally or unintentionally. Microbial contamination, especially pathogenic bacteria, can be found anywhere, in soil, water, air, plants, animals, foodstuffs, processing equipment and even in the human body (Susanto *et al.*, 2022). Food carries various types of microbes, which can come from the natural microflora of plants or animals, both from the environment and those that enter during harvesting or slaughtering, distribution, post-harvest handling, processing, and product storage. Based on this condition, especially for SMEs, controlling food safety in all production process chains is not easy and requires resources. Through CCP control, it provides convenience for SMEs in maintaining food safety.

In previous research, the application of HACCP was carried out in large food sector companies and provided many benefits in maintaining food safety, and even improving quality (Liu *et al.*, 2021). HACCP implementation is widely carried out in the food sector such as seafood (Al-Busaidi *et al.*, 2017), liquor (Yin *et al.*, 2020), chips and cheese (Carrascosa *et al.*, 2016). However, the accuracy and reliability of control and monitoring systems are key to the effectiveness of CCPs in controlling hazards (Doménech *et al.*, 2008; Manning & Baines, 2004). Factors that make HACCP implementation ineffective are due to weaknesses in knowledge of significant hazard identification and errors in the hazard analysis process, including errors in the application of structured risk evaluation methods. HACCP will be effective when control identification and monitoring are well developed, then validated whether the critical limit variables determined are able to maintain food safety hazards (Manning & Baines, 2004). The development of severity assessment procedures is the most important and

often problematic part (Dzwolak, 2019). Therefore, a high level of knowledge and understanding is required in this section so that the HACCP system can be implemented with true benefit. Commitment from business owners to apply consistently is the main key to the success of implementing HACCP in maintaining food safety. An effective and efficient guiding mechanism for monitoring critical limits is a key factor in good HACCP implementation (Trafiałek *et al.*, 2015). In addition, lack of knowledge in hazard identification and analysis is also a basic mistake (Wallace *et al.*, 2014). The attitudes, intentions, and behavior of SMEs have a significant effect on the implementation of HACCP (Ramalho *et al.*, 2015). The effective and efficient implementation of HACCP provides benefits for maintaining and improving quality, increasing competitiveness, and potential for wider market access (Al-Busaidi *et al.*, 2017).

SMEs have limited knowledge and resources in managing food safety hazards through CCP control. Under special conditions, SMEs cannot control CCPs simultaneously, due to limited human resources, lack of equipment, capital and external constraints. Through the prioritisation of hazard control based on RPN-FMEA, SMEs can control CCPs based on the highest priority with all the limitations they have. FMEA is able to determine risk priorities in international food companies (Selim *et al.*, 2016). FMEA results can be used as a basis for further design, analysis or to guide the deployment of resources to manage risk (Oliveira *et al.*, 2020), which has been widely applied in the manufacturing and service industries, profit and non-profit organisations, private, public, or government organisations. FMEA provides benefits in saving downtime in the production process and improving performance (Dedimas & Gebeyehu, 2019), obtaining information on the main source of problems (Goodrum & Varkey, 2017), determining the right method in hazard control strategies (Faiella *et al.*, 2018). The application of HACCP and FMEA to manage food safety in products with a short shelf life can be used as quality assurance in Total Quality Management 4.0 (TQM 4.0) (Van Nguyen *et al.*, 2023).

The limitation of the study is that the combination of HACCP and FMEA was carried out specifically at SMEs producing wet noodles in Indonesia (as a case study). Each SME with different products produced has a different production process and level of potential food safety hazards. Even SMEs have major differences with large companies, in terms of production processes, equipment used, resource levels, marketing, and distribution processes. Future research can be conducted on SMEs in other sectors or on large companies, including different countries. In addition, research can also be conducted to assess the level of effectiveness of HACCP-FMEA implementation associated with improved product quality, market acceptance, economic benefits, including social and environmental sustainability benefits.

7. CONCLUSION

The proposed research framework for designing food safety systems for products with a short shelf life in SMEs employs a combination of HACCP and FMEA approaches. This framework is divided into four main stages. The first stage involves identifying the condition of the business

premises to obtain an overview and gather information about the production process. The second stage focuses on collecting primary data regarding potential hazards in the production process and determining critical control points (CCP) based on HACCP principles 1-3. In the third stage, the identified potential hazards are controlled at the critical control points. The final stage involves prioritizing the CCPs using the FMEA method through the calculation of the Risk Priority Number (RPN) score.

Although HACCP is an effective method, it has limitations such as generating too many control points, potentially losing focus on relevant hazards, and lacking a mechanism for quantifying risk prioritization. SMEs often face challenges in implementing HACCP effectively and efficiently due to limited resources and knowledge. Therefore, this proposed research framework combines HACCP with the FMEA method to prioritize CCPs, enabling more effective hazard control. Prioritization is crucial for HACCP practitioners, especially when an organization or company is unable to manage all CCPs simultaneously.

A trial of the proposed framework has been conducted on an SME that produces fresh noodles. The potential hazard in the wet noodle production process is from biological and physical contaminants, which have a significant value and constitute a CCP in the steaming, packaging, and storage processes. Through these 3 CCPs, SMEs can control potential food safety hazards, so that the resulting products do not pose adverse risks to consumers who consume wet noodles. The control of potential hazards is carried out in accordance with HACCP principles 3-7, namely the identification of critical limits, monitoring, corrective actions, verification, and recording or documentation. The priority order for controlling CCP is packaging (RPN: 144), steaming (RPN: 60), and storage (RPN: 36). Packaging is the most important stage to control, because at this stage, it represents the finished product that will be consumed by consumers. At this stage, the product has the potential to come into contact and direct contact with the hands of workers, because the noodles are inserted manually into the packaging using their hands to the packaging, although the procedure is that workers are required to wear gloves.

The implementation of food safety management through HACCP and FMEA will have a positive impact on SMEs. In addition to maintaining food safety, it also guarantees the consumers of product quality and increases the competitiveness in trade competition for similar products. Disadvantage from HACCP regarding the number of CCPs that must be controlled by SMEs, can be balanced with priority from FMEA. When SMEs have limited resources and it is not possible to control all CCPs, then in this condition the priority becomes a solution. SMEs can carry out food safety hazard control in stages, starting with the highest priority and the next priority. The balance between available resources, processes, and results from managing risks to produce food products that are safe for consumption is the goal of the organization to increase product competitiveness in trade.

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Danar Agus Susanto is a researcher at the National Research and Innovation Agency (BRIN) and a doctoral candidate at the Department of Industrial and Systems Engineering, Institut Teknologi Sepuluh Nopember (ITS). He works in the Research Center for Testing Technology and Standards, a unit within BRIN that focuses on research related to testing technologies and standards in energy and manufacturing. He earned his Bachelor's degree in Industrial Engineering from Universitas Sebelas Maret in 2008, followed by a Master's in Industrial Engineering from Institut Teknologi Sepuluh Nopember in 2022. Before joining BRIN, Danar Agus Susanto worked at the National Standardization Agency (BSN) from 2011 to 2021, gaining extensive standardization experience. As a researcher, Danar Agus Susanto specializes in standardization, conformity assessment, and quality management, focusing on energy and manufacturing sectors. His work aims to improve the development and implementation of standards ensuring the quality, safety, and performance of products and systems in Indonesia and globally.

Mokh Suef is a Professor in Department of Industrial & System Engineering at ITS Surabaya, where he has been teaching since 1990. From 1997 to 2007 he served as the Department Secretary and from 2016 to 2018 he served as Director of Magister of Technology Management of ITS Surabaya. He received an Engineer degree from ITS Surabaya in 1989, and an M.Sc. (Eng.) from the Birmingham University, United Kingdom in 1997. He received his Doctor in Quality & Manufacturing Management from ITS Surabaya in 2016. His research interests span both in Quality and Manufacturing Engineering. Some of his work has been on improving the understanding, design, and performance of manufacturing systems. In the quality management area, he has been working on characterizing product design with respect to customer satisfaction level. In addition, he has made numerous papers both in conference proceeding and journal publication.

Putu Dana Karningsih is an Associate Professor of Lean & Smart Manufacturing Systems at the Department of Industrial Engineering, Institut Teknologi Sepuluh Nopember (ITS), Surabaya, Indonesia. She is currently the Head of Manufacturing System Laboratory in ITS. She received a Master degree and PhD in Mechanical and Manufacturing Engineering from the University of New South Wales (UNSW), Australia. Her research interests are in Lean, Manufacturing Systems, Supply Chain Risk Management and Collaborative Product and Process Development.

Bambang Prasetya is a researcher, scientist, and leader in biotechnology, standards, and conformity assessment, with over 35 years of experience in research and policy. He has been a Research Professor at the Research Center for Testing Technology and Standards, the National Research and Innovation Agency (BRIN) since 2022. He has also been the chairman of the Indonesia Biosafety Committee (Komite Keamanan Hayati, KKH) since 2018. Previously, he was the Chairman of the National Standardization Agency (BSN) and the National Accreditation Committee (KAN) from 2012 to 2020. He began his career as a researcher at the Indonesian Institute of Sciences (LIPI) in 1985. He later became the Assistant Deputy for Research, Science, and Technology at Indonesia's Ministry of Research and Technology from 2002 to 2004. In 2005, he became the Head of the Research Center for Biotechnology at LIPI and subsequently served as the Deputy for Life Sciences at LIPI from 2010 to 2012.