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Food Hygiene, Sanitation, and Safety Hazards in Frozen Pempek: GMP, SSOP, and HACCP Evaluation

Running title: Food Hygiene and Safety of Frozen Pempek

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Abstract

Background: Food hygiene and sanitation are essential environmental health safeguards in small-scale food production because deficiencies in the production environment, sanitation facilities, food-contact equipment, and food-handler hygiene can create contamination pathways. **Objective:** To evaluate hygiene-sanitation conditions and potential food safety hazards in a small-scale frozen pempek enterprise using Good Manufacturing Practices (GMP), Sanitation Standard Operating Procedures (SSOP), and Hazard Analysis and Critical Control Point (HACCP) frameworks. **Methods:** A descriptive qualitative study was conducted at small-scale enterprise X in Maros Regency, Indonesia, during March-April 2025. Data were collected through in-depth interviews, direct observation, and documentation. GMP conformity was assessed against 28 requirements, SSOP implementation was reviewed across key sanitation components, and hazards were identified across 11 production stages. **Results:** Overall GMP conformity was 71% (20/28), with the lowest conformity in maintenance and sanitation programs (33%). SSOP gaps involved food-contact equipment, shared washing facilities, inconsistent food-handler hygiene, and the absence of structured worker-health records. Four critical control points were identified: starter-paste cooling, pempek boiling, frozen storage, and distribution. **Conclusion:** Strengthening sanitation infrastructure, equipment maintenance, food-handler hygiene, sanitation documentation, and cold-chain management is necessary to reduce contamination potential and improve food safety in small-scale frozen food production.

Keywords: food hygiene; sanitation; GMP; SSOP; HACCP

Research Highlights

- Overall GMP conformity reached 71%, while maintenance and sanitation programs showed the lowest conformity (33%).
- Integrated GMP-SSOP-HACCP evaluation identified environmental contamination pathways and four critical control points across production and cold-chain stages.
- Priority actions include improving sanitation facilities, cleanable equipment, food-handler hygiene, documented sanitation routines, and cold-chain continuity.

1 Introduction

Food safety is an integral component of environmental health because food quality and safety are determined not only by raw materials but also by production-environment conditions, sanitation facilities, equipment cleanliness, food-handler hygiene, storage, and distribution. In small-scale food enterprises, limited infrastructure and process controls may create pathways through which environmental contaminants reach food. Hygiene and sanitation control should therefore be positioned as a fundamental measure for preventing foodborne disease and protecting consumer health.

Good Manufacturing Practices (GMP), Sanitation Standard Operating Procedures (SSOP), and Hazard Analysis and Critical Control Point (HACCP) provide complementary frameworks for food safety control. GMP evaluates basic production conditions, including location, building design, sanitation facilities, equipment, worker hygiene, storage, and sanitation programs. SSOP focuses on sanitation procedures covering water safety, cleanliness of food-contact surfaces, prevention of cross-contamination, handwashing and toilet facilities, worker health, labeling and storage, pest control, and protection from chemicals. HACCP is then used to identify hazards at each stage of production and to determine critical control points requiring stricter control [1,2].

From an environmental health perspective, the physical condition of the production area and the adequacy of sanitation facilities are important determinants of contaminant transfer to food. Difficult-to-clean surfaces, inadequate handwashing facilities, rough-surfaced equipment, and inconsistent environmental maintenance may increase the opportunity for cross-contamination. Studies of food-handling premises have similarly shown that non-compliance with hygiene and sanitation requirements is often associated with wastewater systems, handwashing facilities, equipment cleanliness, and food-handler practices [3-5].

Small-scale frozen-food enterprises face additional challenges because food safety control does not end with processing. Cooling, frozen storage, and distribution require appropriate time-temperature control and continuity of the cold chain. Temperature instability during storage or distribution may weaken control over microbial growth and compromise product safety; therefore, sanitation of the production environment should be integrated with process control and cold-chain management [6-8].

Small-scale enterprise X in Maros Regency produces frozen pempek dos, a fish-free variety of pempek, in a household/small-enterprise production setting. The initial evaluation indicated that the enterprise had implemented several basic food safety practices; however, non-conformities remained in sanitation facilities, equipment, food-handler hygiene, environmental maintenance, and temperature control at several processing stages. These conditions make an environmental-health-oriented evaluation relevant for assessing not only implementation of food safety systems but also potential contamination pathways arising from the production environment and food-handling processes.

This study aimed to evaluate hygiene-sanitation conditions and potential food safety hazards in small-scale frozen pempek enterprise X through GMP and SSOP assessment and the identification of hazards and critical control points using a HACCP approach.

2 Materials and Methods

2.1 Study design and setting

This descriptive qualitative study used an evaluative approach and was conducted in a single small-scale frozen pempek enterprise (enterprise X) in Maros Regency, South Sulawesi, Indonesia. Data were collected during March-April 2025 on production days, approximately between 08:00 and 17:00 Central Indonesia Time (WITA). The evaluation positioned hygiene and sanitation as the foundation of food safety: basic production conditions were assessed using GMP, sanitation implementation was evaluated using SSOP, and potential hazards along the production flow were analyzed using a HACCP approach.

2.2 Population, sampling, and sample size

Informants were selected purposively on the basis of their understanding of the study context and their involvement in production or business operations. Inclusion criteria were being an owner, active employee, or other person directly or indirectly involved in production activities; having at least one year of experience related to the enterprise; understanding the production process, operational activities, or food safety policies; and being willing to provide information openly. Exclusion criteria were having no relevant involvement or knowledge of food production, declining to participate in the interview, or having communication limitations that interfered with the interview process.

2.3 Variables and measurements

The study instruments consisted of an interview guide and an observation checklist. Primary data were collected through in-depth interviews and direct observation, while documentation was used to complement information on environmental conditions and the production process. The GMP assessment referred to Regulation of the Minister of Industry of the Republic of Indonesia No. 75/M-IND/PER/7/2010 on Guidelines for Good Manufacturing Practices for Processed Food [9]. GMP observation covered 28 requirements across 10 components: location, building, sanitation facilities, processing equipment, raw materials, process control, employee hygiene, packaging, storage, and maintenance and sanitation programs.

The SSOP evaluation covered water safety, cleanliness of food-contact surfaces, prevention of cross-contamination, handwashing and toilet facilities, worker-health control, labeling and storage of materials, pest control, and protection from chemicals and other hazardous objects. The HACCP analysis included product description, identification of hazards at each process stage, available control measures, and determination of critical control points based on the decision tree used in the study instrument. Hazard identification was conducted across 11 production stages, from material preparation to distribution.

2.4 Statistical analysis

Interview and observation data were organized through data collection, data reduction, data display, and conclusion drawing. GMP observations were summarized as the number and percentage of conforming requirements for each component. SSOP findings were presented descriptively according to the sanitation conditions observed. In the HACCP analysis, potential biological and physical hazards were identified according to process stage, hazard source, and available control measures, after which stages requiring critical control were determined. No inferential statistical analysis was performed.

2.5 Ethical consideration

The research protocol was reviewed by the Health Research Ethics Committee of Universitas Islam Negeri Alauddin Makassar and was granted ethical exemption under approval No. B.186/KEPK/FKIK/III/2025, issued on March 11, 2025. The ethical approval was valid from March 11, 2025, to March 11, 2026. The protocol was assessed in accordance with the applicable ethical standards covering social value, scientific validity, equitable distribution of risks and benefits, risk assessment, confidentiality and privacy, and informed consent principles.

3 Results

3.1 Hygiene and sanitation conditions based on GMP

The GMP assessment showed that 20 of 28 requirements conformed to the assessment criteria, giving an overall conformity of 71%, categorized as minor according to the study instrument (Table 1). Four components met all assessed requirements: raw materials, process control, packaging, and storage. Two components were categorized as minor: location (75% conformity) and building (80%). Sanitation facilities, processing equipment, and employee hygiene each showed 50% conformity and were categorized as major. Maintenance and sanitation programs had the lowest conformity (33%) and were categorized as critical.

Table 1. Conformity with Good Manufacturing Practices (GMP) in small-scale enterprise X

No.	GMP component	Req. (n)	Met (n)	Not met (n)	Met (%)	Not met (%)	Category
1	Location	4	3	1	75	25	Minor
2	Building	5	4	1	80	20	Minor
3	Sanitation facilities	2	1	1	50	50	Major
4	Processing equipment	2	1	1	50	50	Major
5	Raw materials	2	2	0	100	0	Conforming
6	Process control	3	3	0	100	0	Conforming
7	Employee hygiene	4	2	2	50	50	Major
8	Packaging	1	1	0	100	0	Conforming
9	Storage	2	2	0	100	0	Conforming
10	Maintenance and sanitation programs	3	1	2	33	67	Critical
	Overall assessment	28	20	8	71	29	Minor

Note: GMP = Good Manufacturing Practices. "Met" and "Not met" indicate conformity with the assessed GMP requirements; percentages were calculated within each component.

Vegetation/shrubs and animal activity were observed around the enterprise and could serve as environmental sources of dirt or contamination. The building generally had floors that were relatively easy to clean and an orderly production area, although some wall surfaces were not water-resistant. Sanitation facilities were limited because only one sink was available for both handwashing and utensil/equipment washing. A wooden stirrer with a rough surface was still used during processing, and the cooling fan was not optimally clean. Environmental and production-area conditions are shown in Figure 1.

Figure 1. Conditions at small-scale enterprise X: (A) environment surrounding the enterprise; (B) production area and worker during production.

Regarding food-handler hygiene, workers were reported to wash their hands and to refrain from working when ill, but the use of hygiene-related protective items was inconsistent. Routine maintenance and sanitation were performed but did not cover all areas and supporting equipment, as indicated by dust on the fan used in the cooling area. In contrast, raw materials, process control, vacuum packaging, and freezer storage showed better conformity with the GMP assessment criteria.

3.2 SSOP implementation and potential contamination pathways

The SSOP evaluation showed that enterprise X had separated clean-water and wastewater channels. Bore-well water was used for washing equipment, whereas commercially packaged drinking water was used for mixing and boiling processes. For food-contact surfaces, the rough wooden stirrer and dusty fan represented weaknesses because they were difficult to clean optimally and could become contamination sources. Raw materials and finished products were separated; however, non-water-resistant walls and incomplete use of food-handler hygiene equipment remained potential pathways for cross-contamination.

Handwashing and equipment-washing facilities were not separated because only one sink was available outside the production area. The toilet was observed to be clean and free of standing water. Worker-health control mainly consisted of allowing ill workers not to work and using masks when workers felt unwell; however, no structured routine worker-health recording system was evident in the observed practice. Product labels included the product name, composition, distribution permit, expiration date, storage instructions, and serving instructions. Pest control involved traps, spraying, and installation of screens, while cleaning chemicals were stored separately from the processing area.

3.3 Hazard identification and critical control points

Table 2. Description of frozen pempek dos produced by small-scale enterprise X

No.	Criterion	Description
1	Product/food name	Pempek dos

No.	Criterion	Description
2	Product description	Pempek dos is a fish-free pempek product produced by small-scale enterprise X and served with cuko (spiced vinegar sauce) and ebi (dried shrimp) as accompaniments.
3	Ingredients	Tapioca flour, wheat flour, rice flour, eggs, garlic, salt, monosodium glutamate, and beef-flavored seasoning.
4	Packaging	Vacuum-sealed plastic
5	Shelf life	6 months if the package remains intact and the product is stored in a freezer.

The evaluated product was frozen pempek dos packaged in vacuum plastic and reported to have a six-month shelf life when the package remained intact and the product was stored in a freezer (Table 2). Analysis of the production flow identified potential biological and physical hazards across 11 processing stages, from flour preparation, starter-paste preparation, ingredient mixing, shaping, boiling, draining, and packaging to storage and distribution (Table 3).

Table 3. Identification of potential hazards across frozen pempek dos production stages

No.	Stage	Potential hazard	Source/justification	Control measure
1	Flour portioning	Biological: Salmonella spp., Bacillus cereus; physical: plastic fragments, hair, insects/dirt	Raw materials from suppliers and worker contact	Inspect raw materials; store covered and dry; maintain food-handler hygiene
2	Starter-paste mixing	Biological: B. cereus, Staphylococcus aureus; physical: hair, insects, plastic/wood fragments	Workers and rough-surfaced stirrer	Maintain food-handler hygiene; inspect equipment and mixing area
3	Water boiling	Biological: pathogenic bacteria; physical: none identified	Inadequate heating	Boil water to approximately 100°C
4	Starter-paste cooling	Biological: S. aureus, B. cereus; physical: dust, hair, insects	Uncovered paste, workers, dusty fan	Cover the paste; maintain food-handler hygiene; clean the fan before use
5	Mixing eggs, garlic, and tapioca	Biological: Salmonella spp., S. aureus, B. cereus; physical: dust, hair, eggshell fragments	Raw eggs, ingredient condition, worker contact	Inspect ingredient condition and maintain food-handler hygiene
6	Pempek shaping	Biological: S. aureus, B. cereus; physical: dust, hair, plastic fragments	Direct hand contact and foreign objects	Handwashing and appropriate food-handler hygiene practices
7	Pempek boiling	Biological: S. aureus; physical: dust, gravel, insects, hair	Worker contact and cooking process	Heat in boiling water and protect against foreign objects
8	Draining	Biological: S. aureus; physical: dust and hair	Worker contact and draining environment	Maintain food-handler hygiene and protect the draining area
9	Packaging	Biological: S. aureus; physical: dust and hair	Worker contact, table, vacuum-sealing equipment, and packaging	Maintain food-handler hygiene and cleanliness of tables and vacuum-sealing equipment
10	Frozen storage	Biological: Listeria monocytogenes; physical: dust/ice fragments	Temperature fluctuations due to frequent freezer opening and worker contact	Minimize freezer opening; maintain cleanliness and stable storage conditions
11	Distribution	Biological: L. monocytogenes, Salmonella spp.; physical: dust/ice fragments	Non-refrigerated vehicle, package damage, exposure to ambient temperature	Distribute promptly; protect package integrity; control temperature during distribution

Note: The listed hazards are potential hazards identified according to the production stage, hazard source, and observed control conditions.

Recurring hazard sources included raw materials, worker contact, rough-surfaced equipment, dust/insects, an open cooling area, and temperature changes during storage and distribution. Four critical control points were identified: starter-paste cooling, pempek boiling, frozen storage, and distribution (Table 4).

Table 4. Critical control points (CCPs) in frozen pempek dos production

CCP	Stage	Basis for designation	Priority control
CCP 1	Starter-paste cooling	Exposure in an open area and use of a fan that was not optimally clean	Protect paste from dust/insects; maintain fan cleanliness; control cooling time
CCP 2	Pempek boiling	Heat-treatment stage for controlling biological hazards	Maintain consistent heating in boiling water and protect against post-cooking contamination
CCP 3	Frozen storage	Potential fluctuation of frozen conditions due to repeated freezer opening and product stacking	Maintain stable storage conditions; reduce freezer opening; organize product placement
CCP 4	Distribution	Distribution vehicle is not refrigerated and products may be exposed to ambient temperature	Minimize distribution time; maintain package integrity; implement temperature/cold-chain control

Note: CCP = Critical Control Point.

Starter-paste cooling was considered critical because the paste was left uncovered and cooled using a fan whose cleanliness was not optimal. Boiling represented an important stage for controlling biological hazards through heat treatment. Frozen storage was considered critical because frequent freezer opening and product stacking could affect the stability of frozen conditions. Distribution also required control because the delivery vehicle was not refrigerated, making it necessary to minimize delivery time and exposure to ambient temperature.

4 Discussion

The principal finding of this study is that food safety concerns in small-scale enterprise X were rooted primarily in basic hygiene and sanitation conditions rather than merely in the presence or absence of formal HACCP procedures. Overall GMP conformity of 71% indicated that several production practices were already in place; however, the components most closely related to environmental exposure pathways - sanitation facilities, processing equipment, food-handler hygiene, and maintenance and sanitation programs - still showed important gaps. This pattern is relevant to environmental health because food contamination may occur through water, surfaces, dust, insects, workers' hands, and equipment that is difficult to clean. Other studies of food-handling premises have likewise reported limitations in handwashing facilities, sanitation systems, and equipment cleanliness as recurrent hygiene-sanitation problems [3,4].

Building conditions and the surrounding production environment function as the first barrier against the entry of external contaminants. Non-water-resistant walls may retain moisture and complicate cleaning, while vegetation and animal activity around the premises may increase the environmental burden of dirt and contaminants. Guidance on food-premises design emphasizes surfaces that are easy to clean and non-absorbent, together with separation from areas that may serve as contamination sources [10]. Thus, physical improvement of small-scale food premises should be regarded not only as an aesthetic or production-quality issue but also as an environmental intervention to interrupt contamination pathways.

Sanitation facilities and the cleanliness of food-contact surfaces were among the most evident weaknesses. Using a single sink for both handwashing and equipment washing may facilitate transfer of contaminants between functions. The use of a rough-surfaced wooden stirrer and a dusty fan further demonstrates that sanitation should include both primary processing equipment and supporting equipment located within the production environment. Maintaining clean food-contact equipment is important for preventing microbial transfer, whereas incomplete maintenance may reduce the effectiveness of sanitation procedures [4,11].

Food-handler hygiene was only partially adequate. Handwashing and the practice of not working when ill were positive measures, but hygiene-related protective items were not used consistently and worker-health records were not systematically maintained. Food handlers provide a direct interface between the environment and food; therefore, hand practices, work clothing, health status, and adherence to procedures may influence the likelihood of cross-contamination. Evidence from food-service settings underscores the importance of worker-health policies and consistent personal-hygiene practices for maintaining food safety [12-14].

With respect to SSOP, the enterprise had implemented several protective measures, including separation of clean-water and wastewater channels, use of commercially packaged water for production, product labeling, pest control, and separate storage of cleaning chemicals. Nevertheless, the existence of procedures does not necessarily ensure effective control when basic facilities and daily practices remain inconsistent. SSOP implementation should therefore prioritize documented sanitation routines, separation of washing functions, scheduled cleaning of supporting equipment, and supervision of food-handler hygiene. This approach is consistent with SSOP implementation in food processing, where consistent sanitation practices serve as prerequisites for effective food safety management [15,16].

The HACCP-based assessment identified starter-paste cooling and pempek boiling as critical stages within the production area. Cooling occurred under open conditions with the assistance of a fan that was not optimally clean; therefore, exposure time and protection of the paste from dust and other environmental contact require control. Boiling, in contrast, serves as a heat-treatment step for biological-hazard control. In pempek production, boiling also affects the physicochemical properties of the product, highlighting the need for consistent heat control to achieve both cooking and food-safety objectives [17].

The other two CCPs were located after processing, namely frozen storage and distribution. This finding illustrates that the safety of frozen foods cannot be assured solely through kitchen hygiene. Products must remain under stable storage conditions, with freezer opening frequency and product stacking managed to maintain frozen conditions. During distribution, the absence of a refrigerated vehicle increases dependence on rapid delivery and protection from ambient temperature. Principles of low-temperature storage and cold-chain management identify temperature stability as an important component of maintaining food quality and safety until the product reaches consumers [6-8].

Overall, GMP, SSOP, and HACCP should not be viewed as three independent systems. From an environmental health perspective, GMP and SSOP establish the basic conditions needed to control contamination sources arising from the environment, while HACCP focuses control on process stages with the greatest consequences if control fails. The practical implication is that technical assistance for small-scale enterprises should prioritize sanitation facilities, equipment maintenance, food-handler hygiene, sanitation documentation, and temperature control during storage and distribution before promoting more formal HACCP implementation.

This study was based on observation, interviews, and documentation in a single small-scale enterprise. Accordingly, the findings primarily describe hygiene-sanitation conditions and potential hazards in the evaluated unit and should not be interpreted as estimates of contamination prevalence across all frozen

pempek enterprises. The findings are therefore most appropriately used to guide internal improvement and hygiene-sanitation support in comparable settings while considering differences in facilities and production processes.

5 Conclusion

Hygiene-sanitation conditions in small-scale frozen pempek enterprise X showed 71% overall GMP conformity, with the main gaps involving sanitation facilities, processing equipment, food-handler hygiene, and maintenance and sanitation programs. The SSOP evaluation indicated a need to strengthen separation of washing functions, cleanliness of supporting equipment, consistency of food-handler hygiene, and worker-health documentation. The HACCP-based assessment identified four critical control points: starter-paste cooling, pempek boiling, frozen storage, and distribution. Priority actions include improving sanitation facilities, equipment maintenance, worker compliance, procedural documentation, and cold-chain continuity to reduce contamination potential and strengthen consumer health protection.

6 Declarations

Ethics approval and consent to participate

The research protocol was reviewed by the Health Research Ethics Committee of Universitas Islam Negeri Alauddin Makassar and was granted ethical exemption under approval No. B.186/KEPK/FKIK/III/2025, issued on March 11, 2025. The ethical exemption was valid from March 11, 2025, to March 11, 2026. The study was conducted in accordance with applicable ethical principles, including confidentiality, privacy, risk–benefit considerations, and informed consent. Prior to data collection, all participants were informed about the purpose and procedures of the study, and their voluntary consent to participate was obtained.

Consent for publication

Consent for publication was obtained from the relevant individuals and/or responsible parties for any potentially identifiable photographs or materials included in the manuscript.

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Competing interests

The authors declare that they have no financial or non-financial competing interests that could have influenced the conduct, interpretation, or reporting of this study.

Author contributions (CRediT)

A.Syamsiah Adha: Conceptualization, methodology, investigation, data curation, formal analysis, and writing—original draft.

Zaskia Maharani: Methodology, investigation, data collection, data curation, formal analysis, and writing—original draft.

Rini Jusriani: Conceptualization, supervision, validation, interpretation of findings, writing—review and editing, and final approval of the manuscript.

Data availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request. The data are not publicly available because they contain information related to the operational practices of the participating small-scale food enterprise.

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Generative AI statement

Generative AI was used to assist with English-language translation, language editing, structural organization, and manuscript formatting. The authors reviewed the output and remain responsible for the accuracy, originality, citations, and integrity of the manuscript.

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