

Applying a hurdle-layered vulnerability assessment and critical control points framework to mitigate food fraud: a case study of a Taiwanese braised food small-sized enterprise

Chia-Sheng Yeh¹, Sih-En Liang², Hsin-Jung Chen^{2,*}

¹Department of Hospitality Management, Southern Taiwan University of Science and Technology, Nantai St, Yongkang District, Tainan City, Taiwan; ²Department of Food Science and Technology, Central Taiwan University of Sciences and Technology, Buzi Rd, Beitun District, Taichung City, Taiwan

*Corresponding Author: Hsin-Jung Chen, Department of Food Science and Technology, Central Taiwan University of Sciences and Technology, Buzi Rd, Beitun District, Taichung City, Taiwan. Email: 106706@ctust.edu.tw

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Abstract

Small- and medium-sized food enterprises (SMFEs) may face strong economic incentives that increase the risk of food adulteration, and be involved in serious nonconformities related to food fraud regulations in dual or triple audits. This study aims to provide a methodological framework and practical solutions to address these challenges. In this case, study of a Taiwanese braised food SMFE, a layered Vulnerability Assessment and Critical Control Point (VACCP) assessment and control framework, aligned with International Organization for Standardization 31010, Food Safety System Certification 22000 v6, and Codex Alimentarius Commission's (CODEX) Hazard Analysis & Critical Control Points, was established to identify vulnerabilities and mitigations. Six VACCPs were identified, each covering at least two fraud types defined by Global Food Safety Initiative, including substitution, unapproved enhancement, dilution, mislabeling, and concealed origin, spanning raw-material acceptance, spice/blended additive acceptance, mixing, final seasoning, and packaging/labeling. After implementation, nonconformities decreased 25%, turnover decreased from 9.0% to 5.7%, with improved verification coverage. This framework provides SMFEs a pathway for fraud mitigation in ready-to-eat foods.

Keywords: VACCP; food-safety culture; food fraud; vulnerability risk assessment; ISO 22000:2018/Amd 1:2024; FSSC 22000 v6; CODEX HACCP Code:2024

Introduction

Spink and Moyer (2011) proposed a food protection risk matrix dividing food protection management system risk into four fields based on behaviors and motivations: food safety (FS) and food quality (FQ) of unintentional contamination, and food fraud (FF) and food defense (FD) of intentional contamination. FF, as defined by

the Global Food Safety Initiative (GFSI) position paper, is the intentional substitution, addition, tampering, or misrepresentation of food/feed, ingredients, packaging, labeling, or product information for economic gain that could impact consumer health (GFSI BRv7, 2017). Unlike FF, FD aims to cause harm (economic, public health, or terror) from ideological or behavioral motives, not economic gain. Thus, prevention of FD and FF requires

different approaches, as FF is unlikely to be fully eliminated; actions should focus on minimizing vulnerability by reducing opportunities for fraudsters.

Scandal incidents worldwide frequently report economically motivated adulteration (EMA). Financial incentives, such as 'gain', drive the supply chain, causing harm, endangering public health, and creating social panic. Owing to a lack of effective monitoring and supervision, especially in small- and medium-sized food enterprises (SMFEs), suppliers (e.g., food manufacturers' raw material suppliers, and manufacturers that supply consumers) are economically attracted to FF. Elliott (2020) estimated that the annual scale of EMA could potentially reach approximately US \$50 billion. To strengthen risk-warning mechanisms and predict risk sources for FF, several countries aim for all food processes, from farm to table, to be monitored, tracked, and adequately addressed but often fail to do so. Such failure often results in the misidentification of EMA or FF. For example, the Food Safety Modernization Act of the US Food and Drug Administration (US FDA, 2016) considers FS, FD, and FF in its FS plan. It emphasizes risk-based prevention, control, and mitigation strategies. The GFSI (2018a) also updated its standards, adding new management requirements for FF and defining seven types of FF. This shift has caused China, Japan, Southeast Asian countries, the European Union (EU), New Zealand, Australia, and others to consider this issue. In addition to accelerating the adjustment of international FS regulations, governments of various countries are also paying more attention to the independent management of effectual food factories.

In Taiwan, food adulteration cases have spanned substitution (e.g., low-priced meats sold as beef in 2003; and restructured beef as steak in 2004), contamination (e.g., excessive preservatives in braised eggs in 2006; antibiotics and fipronil in eggs in 2014–2019), illegal additives (e.g., chloramphenicol in tribute pills in 2014; Sudan red in duck eggs in 2017–2018), and misrepresentation (e.g., forged expiration dates on frozen braised foods in 2014; and expired ingredients in Wagyu restaurants in 2024) (Taiwan Food and Drug Administration [TFDA], 2025), covering all seven GFSI-defined fraud categories. FF cases involved seven major categories defined by GFSI, often relying on single management measures lacking comprehensiveness. These incidents underscore the need for robust preventive measures in the braised food sector. Organizations thus need the strategy combination and mitigation implementation plan from Food Safety System Certification (FSSC) 22000 version 6 (FSSC 22000 v6), International Organization for Standardization (ISO) 22000, and ISO 22002-1: prerequisite program (PRP) similar to hurdle technology in food processing for layer-by-layer control. The Taiwan

Food and Drug Administration (TFDA) has tightened regulatory requirements, while the Industrial Bureau of the Ministry of Economic Affairs implemented the 'Food Industry Safety Protection Mechanism Establishment Plan' in 2016 (US FDA, 2016). Establishing food protection tools is a key indicator (Food Development Research Institute, 2024), although effects remain limited. Traditional Vulnerability Assessment and Critical Control Point (VACCP) tools (e.g., spider diagrams, 50-question checklists, and decision trees) often cause confusion, misinterpretation, and implementation gaps for food operators in practical applications, making it difficult to meet the requirements of dual or triple audits conducted by buyers (e.g., Costco) and certification bodies. A more practical and comprehensible VACCP-layered hurdle methodology aligned with international standards is therefore necessary. Such a methodology should incorporate directly relevant requirements and audit guidance from the latest international Food Safety Management System (FSMS) standards (FSSC 22000, ISO 22000, and ISO 22002-1: PRPs) to support organizations in addressing FF risks in practice. The development of a VACCP-layered hurdle methodology requires a structured framework, including methodology design, combined management strategies, 12 implementation steps, and integrated management of implementation plans.

Applying hurdle effects within comprehensive management frameworks may effectively mitigate FF risks, especially when employees prioritize FS over production efficiency and consistently make appropriate decisions even without supervision, despite potential increase in operational costs. FF cases correspond to seven major categories defined by GFSI that include dilution, substitution, concealment, unapproved enhancements, counterfeiting, mislabeling, and gray market production, theft, or diversion. These seven FF categories describe supplier behaviors driven by economic gains. VACCP focuses on identifying critical process steps within organizational operations where significant FF vulnerabilities driven by economic motivation exist, in accordance with requirements of international standards. These identified vulnerabilities serve as the basis for subsequent integrated control or mitigation strategies within an organization. VACCP and FF mitigation strategies cannot rely on a single method; rather, they involve multiple organizational dimensions. This approach is analogous to traditional food processing practices for controlling microbial hazards in final products, which apply sequential or simultaneous layered controls, such as blanching, water activity control, pH adjustment, vacuum packaging, thermal processing, and refrigeration or freezing. Hence, it is necessary to apply this layered control concept to FF through a hurdle-layered approach, such as FF risk awareness,

establishing FF teams with external expert support, personnel competency development, supplier strengths–weaknesses–opportunities–threats (SWOT) analysis, risk assessment and identification of high-risk suppliers, VACCP assessment within processing steps, conformity with international standards, developing FF worksheets, and formulating FF mitigation strategies.

Oftentimes, SMFEs are deficient in merely one measure of management that then undermines the entire system's comprehensiveness. Hence, SMFEs need strategy combination and mitigation plans introduced by FSSC 22000 v6, ISO 22000, and ISO 22002-1: PRP, which is similar to the hurdle technology used in food processing to provide layer-by-layer control. The TFDA has tightened regulatory requirements. Moreover, the Industrial Bureau of the Ministry of Economic Affairs implemented the 'Food Industry Safety Protection Mechanism Establishment Plan' in 2016 (US FDA, 2016). Establishing food protection tools is a key indicator (Food Development Research Institute, 2024), although effects remain limited. Applying hurdle effects in comprehensive management may effectively mitigate FF issues, especially when employees prioritize safety over production, they would make right decisions without supervision, despite potential increased costs.

Taiwan's braised food industry uses vegetables, aquatic products, meat, eggs, beans, and other ingredients, which have long been integrated into local food culture and become one of the country's most popular specialties. For example, red and white braised foods are two mainstream traditional flavors in Taiwan's food culture. Red braised sauce is developed with special compound spices. Taiwanese braised food is classified into three main supply models: (1) cold braised food: this is the most traditional model, and the ingredients are braised, cooled, shaped, and directly displayed for sale; (2) heated braised meat: customers first select pre-braised ingredients, and stores cook or heat them on-site; (3) frozen braised food: this is a relatively new model, emerged during the COVID-19 pandemic period. After the braised finished product is cooled, it is mixed with special key research and development (R&D). Marinade is used to add flavor and then frozen for storage and transportation. These three models form a diversified and coexisting supply, which not only meets the various needs of traditional and modern, ready-to-eat and take-out, snacks and catering channels. It also helps to extend shelf life and reduce the loss of food ingredients (FSSC 22000 v6 Clause 2.5.16—food loss and waste). This diversification has led to numerous issues related to EMA. In 2022, the TFDA issued 'Guidelines for Food Manufacturers to Establish Food Safety Monitoring Plans' with mandatory clause 5.4.4 requiring prevention measures against improper substitution, addition, or removal of raw materials or

products. Onarinde *et al.* (2023) noted that at the food business operator (FBO) level, especially SMFEs, 'inspection' dominates due to limited resources such as finance, knowledge, and time (Njage *et al.*, 2018). Current FF supervision focuses on reactive detection via intelligence, security gaps, and verification of laboratory, thus shifting to preventive strategies is essential. Hurdle technology, used in processing for microbial control, achieves high quality systematically. This study's management theory applies similar hurdle effects from FSSC 22000, ISO 22000, and ISO 22002-1: PRP, integrating systems such as PRP and Hazard Analysis & Critical Control Points (HACCP) for multiplied FF mitigation. Beyond detection, this braised food case refers to Brooks *et al.* (2021), employing a hurdle-based approach to identify significant vulnerabilities (VACCP) in supply chains. Integrating this with preventive management ensures FS and mitigates FF.

Research Methods and Research Structure

The case study involves a braised food company with a history of 16 years. Its main product types are vegetables, different parts of chicken or pig carcasses, and offal. The company operates 50 chain stores across Taiwan and reports an annual turnover of approximately NT\$140 million. The central factory, located in central Taiwan, employs about 80 staff members. The company's FS system is aligned with ISO 22000 and Codex Alimentarius Commission (CODEX, 1969) HACCP requirements and has adopted the FSSC 22000 management system.

In addition to product testing, the case company incorporated Taiwan's internal regulatory requirements, which were modeled after American-style retail standards, into its second audit. The case company referenced the FS management system standards FSSC 22000 v6 and ISO 22000: 2018/Amd 1:2024, including the associated Family Clause (ISO 22002-1: PRP). Compliance with FSSC 22000 v6 entails full adherence to ISO 22000 requirements, the PRP for specific sectors (ISO/TS2002-x series), and the additional requirements stipulated by FSSC 22000 v6. Following the seven categories of FF defined by GFSI, we conducted a vulnerability assessment of the supplier's raw materials and the manufacturer's processes. Using the nine-factor FF evaluation scale, this study identified process steps with higher risks of adulteration or counterfeiting. The VACCP framework integrates preventive and control measures, applying hurdle effects (Codes 1–9) as mitigation strategies. The case company uses assessment report to monitor and verify implementation at least annually and reviews the strategy on a regular basis. The research structure is presented in Figure 1.

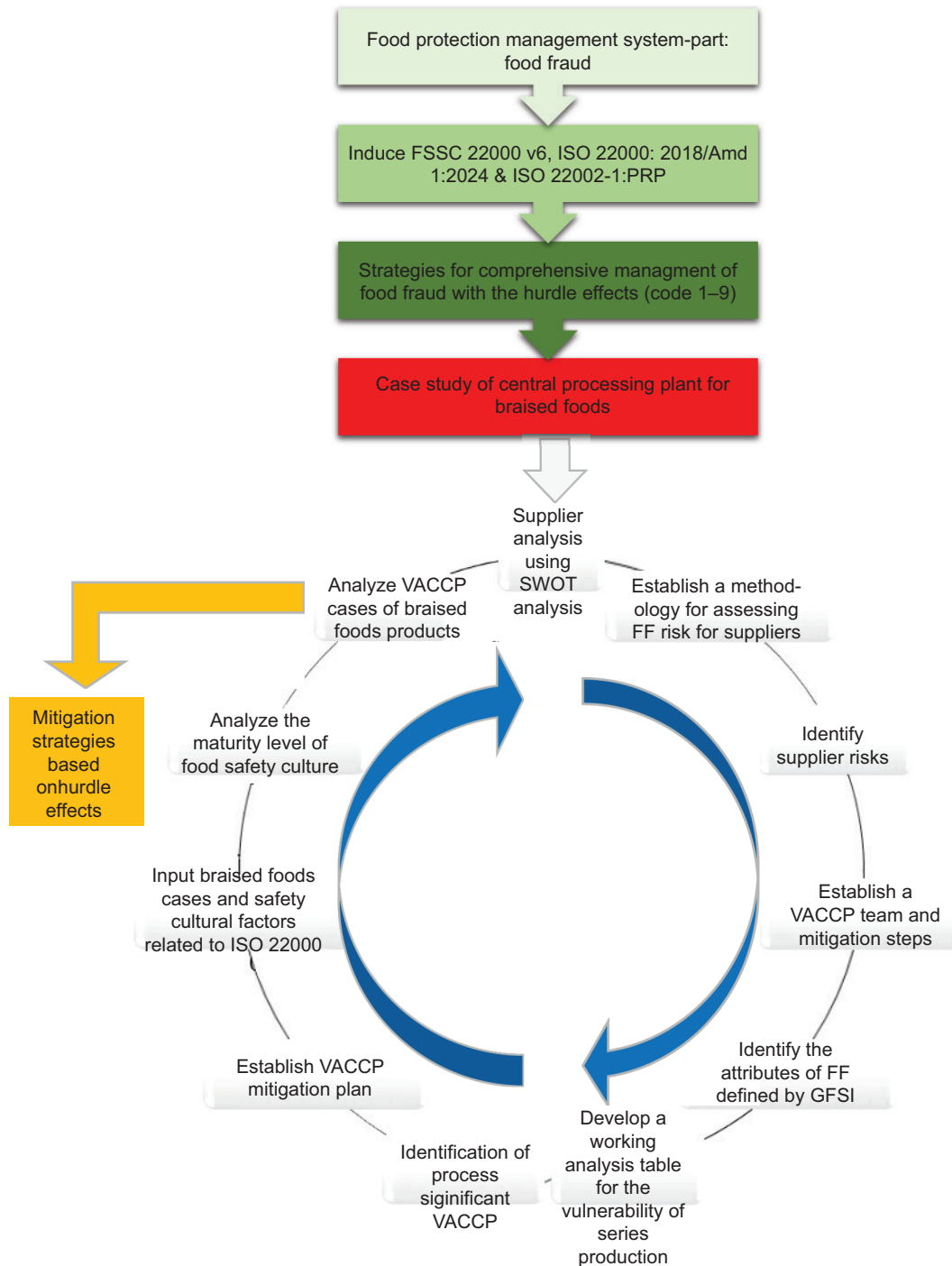


Figure 1. Research structure.

Results and Discussion

The hurdle effects implemented into the food protection management system

In this case study, the braised food company adopted several measures to mitigate FF. These measures incorporate the additional requirements of the FSSC 22000 standard,

which require full compliance with ISO 22000 and the manufacturing-specific ISO 22002-1: PRP as well as the provisions of the US Intentional Adulteration Rule (see Table 1).

The methodology, planning, and mitigation strategies introduced for the hurdle effects (Codes 1-9) were designed to better understand food adulteration by

Table 1. The methodology and key mitigation strategies aligned with the hurdle codes.

Hurdle code	Focus area	Key mitigation strategies
Code 1	Fraud risk management planning	Performed strengths–weaknesses–opportunities–threats (SWOT) analysis to identify fraud vulnerabilities; integrated new FSSC 22000 v6.0/ISO 22000 requirements into the Food Safety Management System (FSMS); established quarterly meetings to share fraud incident news and updates.
Code 2	Stakeholder risk assessment (supplier focus)	Identified high-/medium-/low-risk suppliers via structured vulnerability assessment (with external expert input); determined stakeholder needs; formed a food fraud (FF) team and provided targeted staff training.
Code 3	Supplier qualifications & controls	Implemented stricter supplier evaluation, audits, and site visits; required use of approved suppliers with third-party certifications; enhanced laboratory testing capability (proficiency testing and calibrated equipment) for raw materials.
Code 4	Team competence & communication	Provided specialized VACCP training for team members (including external expert guidance); ensured all sites (e.g., franchisees) received fraud-prevention education; established an internal reporting procedure for serious incidents (fraud and legal issues) within 3 days.
Code 5	Product information integrity & traceability	Verified accuracy of product labels/claims (compliance with all regulations); implemented a product design review procedure to ensure that new or changed products remain safe and legal; established a full traceability system linking raw materials to finished product batches; strengthened allergen management training.
Code 6	VACCP risk assessment & prerequisite program (PRP) verification	Established formal FF risk assessment procedures covering all processes; identified potential fraud hazards in each process step and documented vulnerability analysis; defined standard operating procedures (SOP) for VACCP, including monitoring intensity and a periodic sampling rotation plan; incorporated FF controls into the existing PRPs and verified these controls regularly.
Code 7	Nonconformity control & corrective action	Developed a VACCP monitoring plan (with scheduled monitoring and rotation of checks); appointed trained internal auditors for FF control; implemented a process to investigate causes of any VACCP nonconformities and promptly apply corrective/preventive actions; and ensured annual internal audits (or more frequent) to verify effectiveness of fraud mitigation measures.
Code 8	Management support & reviews	Assigned a fully authorized FF mitigation team; held quarterly FF team meetings to discuss implementation issues, emerging risks, and improvements; conducted management review at least semi-annually to evaluate the adequacy and effectiveness of fraud mitigation measures as part of the overall FSMS review, ensuring continuous improvement.
Code 9	Enhancement of food safety culture (FSC)	Established an FSC program emphasizing fraud prevention (regular communication, training, and employee feedback); set food safety (FS)/FF key performance indicators (KPIs) and a reward system to encourage reporting and compliance; promoted accountability through performance evaluations; and integrated FF topics into the case company's quality policy and objectives, thereby fostering voluntary employee participation in mitigation efforts.

identifying food adulterers, their operating modes, causal relationships, rationalization, and criminal motives. They implement multiple hurdles at the provider level within the context of social and criminal psychology of counterfeiting. Notably, the FF hurdle-based approach adopted by this study involves main internal regulations (Costco Wholesale, 2024) of well-known American chain stores when conducting audits. A competent auditor developed the assessment rating system for the case company. Employees use a quantitative scoring system to determine supplier eligibility.

Implementation steps of this study's strategy for mitigating food fraud

Step 1: Form a team of trained personnel in FF mitigation (quality control [QC], R&D, manufacturing, procurement, management, and legal) with external experts as needed; this study employed a senior PhD holder with 25 years of experience.

Step 2: Product characteristics should be described based on product usage and consumption targets, including the full name of the final product and possible vulnerabilities

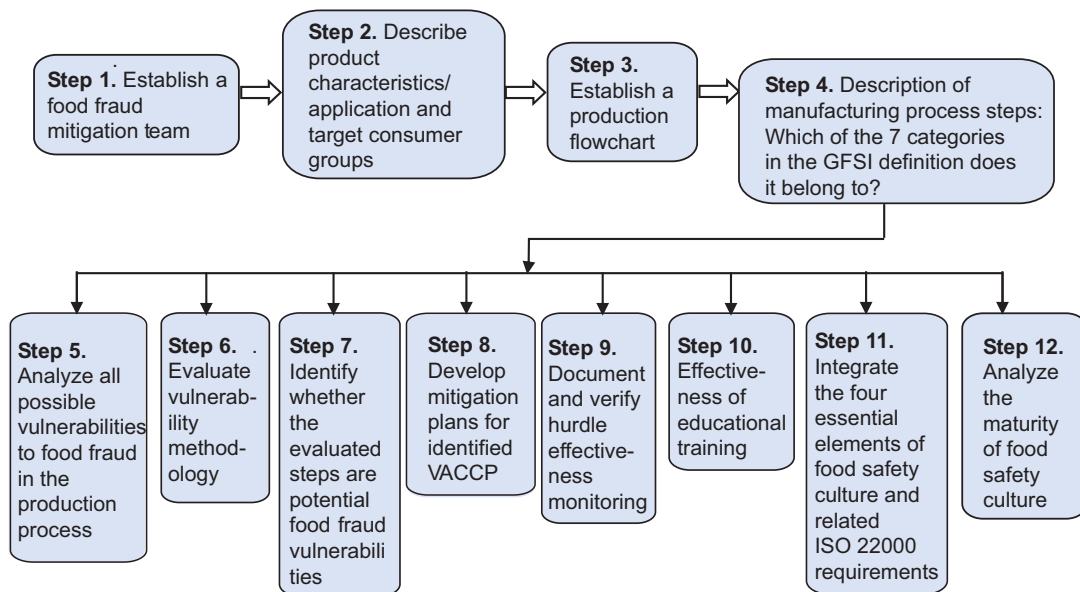


Figure 2. A 12-step mitigation plan to establish a food fraud (compiled by this study).

that may affect the detection or identification of FF. Any information that may be advantageous to consumers (to avoid mislabeling or document information fraud) should be included.

Step 3: To clearly describe the manufacturing flow of food, from acceptance to product shipment and transportation. The process includes a VACCP rework and traceability system.

Step 4: Each step should briefly describe food adulteration. Create vulnerability background information to assist in identifying significant food adulteration vulnerabilities.

Step 5: This stage is supported by a 50-item questionnaire, and an FF decision tree or a spider graph analysis, which may constitute vulnerability to adulteration, such as:

- What have other countries implemented to prevent FF?
- What strategies and measures are used?
- What strategic measures have been implemented to avoid and address commodity-based food adulteration in different industries?
- Which conditions are required for a food adulteration and counterfeiting prevention strategy to be successful?

Recent reviews have demonstrated that effective prevention depends on building a verification ecosystem that integrates risk assessment with targeted verification and intelligence-sharing, which is especially important for SMFEs with limited resources (Manning *et al.*, 2024).

Step 6: This study used nine factors to evaluate the vulnerability of FF. Develop an assessment method (similar to hazard analysis, such as CODEX HACCP Code: 2024) and verify its validity.

Step 7: The situation is assessed based on nine factors and divided into five categories: 1, 2, 5, 8, and 10. Grading: the total grade to evaluate the vulnerability of FF is 9–90 points. A score of ≥ 72 ($\geq 80\%$) indicates a critical vulnerability point. One issue is that this evaluation should be performed by a competent FF mitigation team or by entrusting external experts, if necessary, to identify significant FF vulnerabilities (VACCP). At the same time, they can identify high, medium, and low risks (such as low, medium, and high confidence) supplier lists and levels. This study operationalized an ordinal risk index (1–10 per factor; total 9–90) as an application of ISO 31010-consistent techniques within the ISO 31000 risk process. A threshold of $\geq 80\%$ as ‘significant’ functions as a governance decision rule to prioritize mitigations under SMFE resource constraints, analogous to severity \times likelihood matrices used in HACCP/Failure Mode & Effects Analysis (FMEA) adaptations. The index therefore serves as a calibrated and application-oriented

screening tool, rather than an industry-wide cut-off (Bouzembrak *et al.*, 2024; Manning *et al.*, 2024; Zhou *et al.*, 2024).

Step 8: Establish a mitigation plan to make effective use of hurdle effects (Codes 1–9) for significant adulteration and counterfeit vulnerabilities. Preventive control measures and mitigation strategies should be developed. In this paper, the term ‘hurdle’ refers to administrative and organizational barriers, such as governance, supplier assurance, audit cadence, and contractual controls, rather than microbial lethality hurdles, which include factors such as pH, water activity, and temperature.

Step 9: Monitor records and verify the effectiveness of hurdle effect by observing whether the strategy operates as expected. Owing to the low frequency of intentional FF, monitoring should be conducted at least once a year.

Step 10: Education and training personnel should have completed a standard training course approved by the US FDA (2016). Regularly direct food mixing meetings for all factory personnel. Conduct counterfeiting simulation exercises and retain supporting information.

Step 11: The four aspects of FS culture (communication, education and training, employee feedback, and performance measurement) correspond to the relevant requirements of the ISO 22000 standard.

Step 12: An FS culture maturity analysis questionnaire is used at all company levels, including the five dimensions of FS culture (vision and mission, people, consistency, adaptability, hazard, and risk awareness). Include the implementation of its key components (TFDA, 2015, 2022) as well as the display of key performance indicators (KPIs). An anonymous Likert-scale questionnaire covered five domains (vision/mission, people, consistency, adaptability, and hazard/risk awareness). Content validity was reviewed by two external auditors. Internal consistency (Cronbach’s α) and sampling adequacy with Bartlett’s test were assessed. Missing data (<5%) were handled via pairwise deletion. The full item list is provided in the Supplementary Material (Tables S1–S6) together with scoring instructions.

Step 13: We compared pre-implementation (HEB refers to the period before implementing the hurdle effects [January–December 2022]) versus post-implementation (HEa refers to the period from January 2023 to December 2024 [2-year average]) outcomes.

Binary detections used two-proportion z -test or Fisher’s Exact test; continuous levels used Welch’s t -test or Mann–Whitney’s U test. Complaint and non-conformity rates were analyzed with Exact Poisson or over-dispersed models; paired supplier risk scores used paired t -test or Wilcoxon Signed-Rank test. Family-wise error was controlled by Holm adjustment; effect size, and confidence intervals (CIs) are reported.

Case analysis of the hurdle effects

The case study involved the central kitchen of a well-known braised food enterprise in Taiwan. It is an SMFE with approximately 50 employees and operates about 50 chain stores nationwide. This study used braised pig ears, a high-volume item, as a monitoring sentinel for hazard and fraud-control evaluation. From January 2022 to December 2024 (HEb vs. HEa), this study evaluated the impact of the administrative hurdle framework on fraud-prevention performance.

In the post-implementation period (HEa, January 2023–December 2024), verification coverage for higher-risk herbs/spices expanded beyond supplier’s certificate of analysis (CoA), whereas in HEB (January–December 2022), herbs relied solely on supplier reports. In HEa, the company introduced batch sampling with randomized annual self-tests and third-party outsourcing, added routine screening for aflatoxins, sulfur dioxide, and organophosphate pesticides, and implemented a testing-cycle rotation with monitoring to reduce rapid-test errors, aligned with ISO/IEC 17025 and FSSC 22000 v6 (Codes 1, 2, 3, 6, and 7). Purchasing volumes of pig ears meant fixed sampling opportunities. Quarterly staff-turnover KPIs were 5%, 9%, and 3% in 2022–2024, with a Q2–Q3 2022 peak during COVID-19 and stability in 2023. Customer complaints showed a downward trend alongside improved overall satisfaction. Internal and external audits were executed per ISO 22000:2018 and FSSC 22000 v6 with structured sampling plans, and nonconformity tracking was in place as part of routine governance.

Provide consumers with disclosure of product characteristics

Table 2 summarizes the characteristics and intended uses of braised pig ear products. The proportion of auxiliary raw materials in this industry is a unique formula. Using Chinese medicinal materials from the main producing area (China) and compound food additives are essential factors determining consumer taste and sales performance (Codes 4 and 5).

Furthermore, it is necessary to avoid misrepresentations to consumers, including any marketing or labeling of products that inaccurately represent their quality, safety, origin, or freshness, and to ensure that management of such companies takes steps to prevent fraud. Making, using, or possessing false documents to sell or market fraudulent or substandard products should not occur. The goal is to communicate honestly with consumers while demonstrating the company's FS culture and corporate responsibility under Sustainable Development Goal 12 (SDG 12).

Manufacturing flow chart

The third type among the seven types of catering industry is: raw material acceptance \geq store \geq reprocessing \geq heating \geq cool down \geq refrigeration \geq serving meals (Chen *et al.*, 2019; GFSI, 2017, 2018b, 2019).

The flowchart in Figure 3 shows the relative relationship of the manufacturing process. The content includes the sequence and mutual influence of each step, indicating the raw materials, ingredients, processing aids, packaging materials, equipment, and intermediates. It illustrates the point where products enter the process, reprocessing and reworking processes, and the levels where final products, intermediate products, by-products, and waste are released or removed. This information facilitates subsequent analysis of the potential hazards in the process and identification of VACCP. Next, the hurdle effect can mitigate this critical vulnerability to a minimum or acceptable level. This study was conducted by competent members of the FF team and carefully hired external experts to assist in risk

assessment, analysis, and identification. The overall grade was determined based on the overall risk grade and the available costs, enforceability, and benefits to determine VACCP (Codes 1, 2, 6, and 7). Details are shown in Table 3.

Members of the FF mitigation team used the scoring criteria and parameters of all processing steps in the organization as a reference. This procedure varies depending on the food industry scale. The same processing steps in different food industries do not necessarily cause hazards and must be managed by competent FF mitigation teams (with external experts if necessary) based on each industry's experience (historical background, customer and consumer claims, and noncompliance), technical reports, and other considerations. Manning and Soon (2019) and ISO 31010 assigned a total score to each level based on the severity and possibility of FS hazards, adulteration, and counterfeiting. This methodology is similar to the HACCP risk assessment. For instance, Chen *et al.* (2022), Fernández-Segovia *et al.* (2014), and Soman and Raman (2016) examined the functioning of severity and probability of occurrence for hazard classification. All processes were covered and graded separately, and the grade of each 'processing step' was identified independently. This study used a nine-factor risk assessment method for suppliers. The key to assessing vulnerability is that 'it must be thought of as a crime' and profitability is an essential factor that may occur. The assessment includes the following factors: (1) Management of raw material categories or processes; (2) supplier relationships; (3) supervisory records of

Table 2. The product characteristics and intended uses of braised pig ears.

Item	Description
Process flow	Raw material acceptance \geq cold storage \geq thawing \geq pre-processing \geq pickling \geq marinating \geq cooling \geq cutting \geq seasoning/mixing \geq weighing \geq inner packaging/labeling \geq metal detection \geq refrigeration \geq frozen storage and distribution.
Product name	Braised pig ears (ready-to-eat product).
Product description	Fully cooked, seasoned, braised pig ears, sold refrigerated or frozen; ready to eat after appropriate thawing.
Ingredients	Primary: pig ears. Auxiliary: assorted spices and seasonings (garlic, chili, star anise, cinnamon, etc.), sugar, salt, soy sauce, oils. Additives: food-grade flavor enhancers and preservatives (e.g., monosodium glutamate, organic acids, and ethyl maltol).
Intended use	To be consumed after thawing. For example, thaw under refrigeration for ~24 h or at room temperature for ~30 min (or microwave briefly) before serving. Consume immediately after opening the package.
Consumer precautions	Do not consume if the package is damaged, swollen, or past the expiration date. Once opened, keep any unused product refrigerated and consume as soon as possible (do not eat if any off-odor develops).
Allergens	Contains ingredients from sesame, peanuts, soybeans, and wheat (gluten).
Packaging	Sealed in a polypropylene (PP) plastic box with a nylon/retort cast polypropylene (NY/R CPP) plastic film cover (airtight).
Shelf life	Up to 1 year when frozen and unopened (at -18°C or below).
Storage/transportation	Keep frozen ($\leq -18^{\circ}\text{C}$). May be transported or temporarily stored under refrigeration ($\leq 7^{\circ}\text{C}$) if consumed within 48 h.

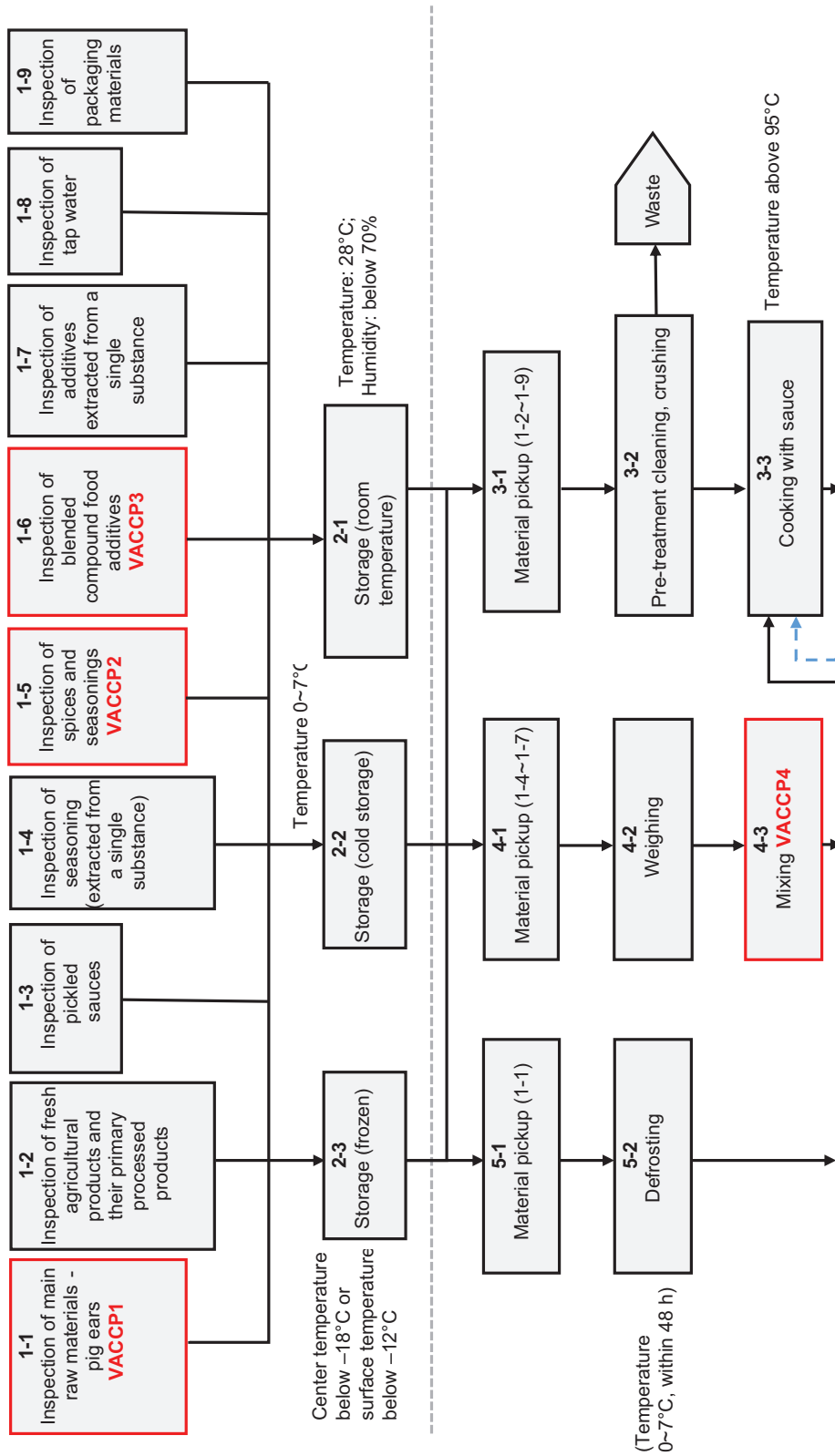


Figure 3. Flowchart of production of braised pig ears.

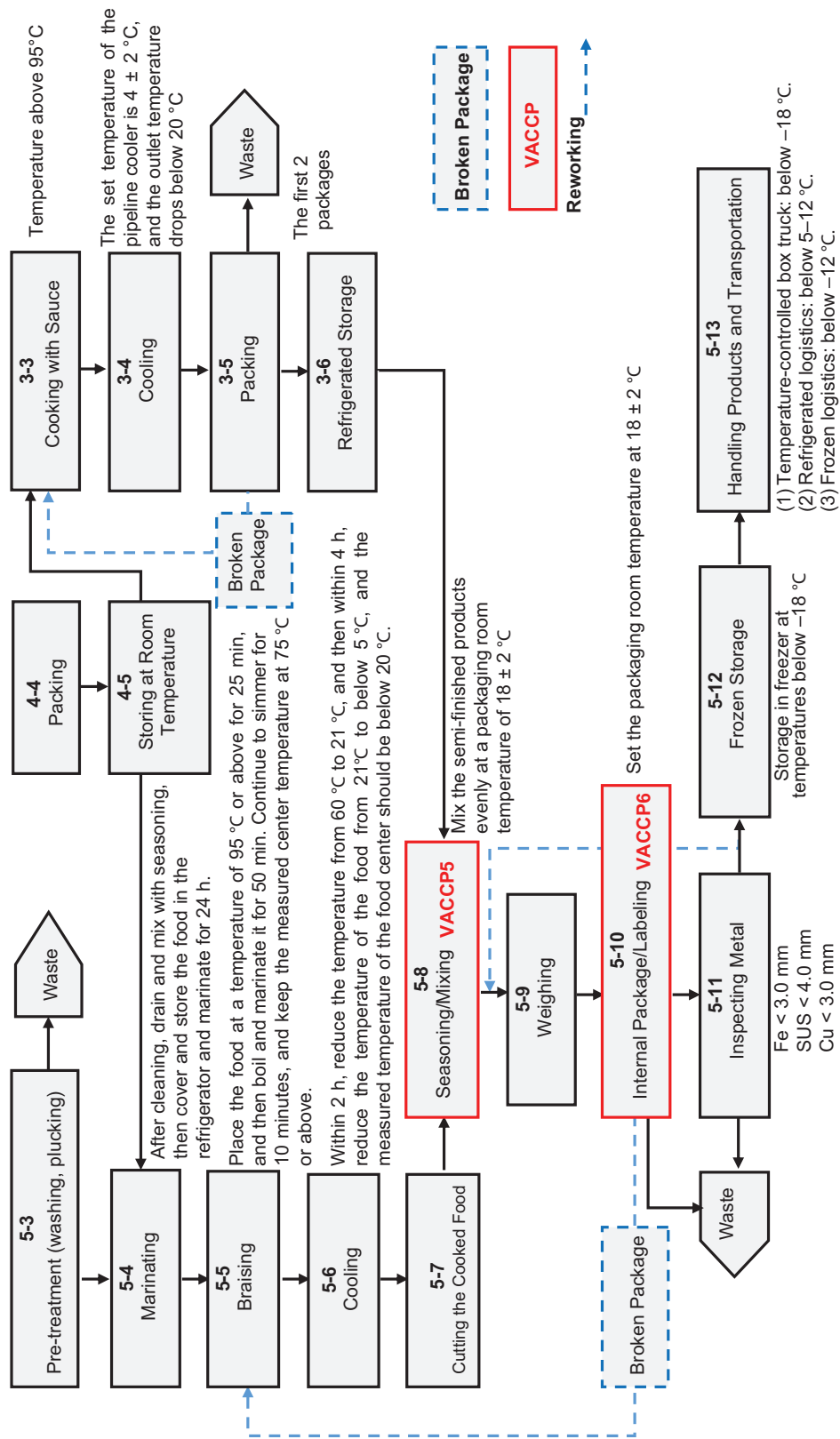


Figure 3. (Continued) Flowchart of production of braised pig ears.

Table 3. The critical vulnerability hazard analysis focus on selected ingredients.

Ingredient/material	Major vulnerabilities (hazards)
Pig ears (primary meat)	<p>Economically motivated adulteration risks: Presence of veterinary drug residues (e.g., antibiotics and sulfonamides) if withdrawal times are ignored; use of banned beta-agonist growth drugs (ractopamine) to cut costs.</p> <p>Food safety co-risk: This ready-to-eat product has a potential for <i>Listeria monocytogenes</i> contamination, requiring strict temperature control and sanitation to prevent bacterial growth.</p>
Dried spices and herbs	<p>Quality and contamination risks: High probability of heavy metal residues (e.g., arsenic, lead, and cadmium) from soil or processing contamination; pesticide residues from overuse of agrochemicals (chronic toxicity concern).</p> <p>Fraud risk: Mixing with inferior or substandard spice lots.</p> <p>Mycotoxins: Susceptible to mold growth during storage, leading to aflatoxins (e.g., B1) that are carcinogenic and heat-stable. Most spices are imported (often from mainland China), so source quality is variable and challenging to control increasing vulnerability.</p>
Compound food additives (blended seasoning powders)	<p>Adulteration risk: May contain unapproved or illegal additives added for economic gain; for example, the illegal dye Sudan red (an unapproved colorant) could be used to enhance appearance. These ingredients are also vulnerable to the same issues as individual spices, such as pesticide residues and heavy metals, depending on their components. Tight supplier oversight is required due to the compounded nature of these ingredients.</p>

quality or FS-related scandals; (4) prevention strategies for on-site inspections; (5) QC items and methods sensitivity; (6) detection technology and frequency; (7) consideration of geographical factor; (8) historical records of adulteration and counterfeiting; and (9) economic anomalies (Food Safety System Certification (FSSC), 2018; US FDA, 2016; van Ruth *et al.*, 2017).

This study conducted a risk assessment of vulnerabilities associated with the case company's raw material suppliers by categorizing them into high-, medium-, and low-risk levels (corresponding to low, medium, and high confidence) and compiling a comprehensive list of all suppliers. A deliberate analysis of potential FF vulnerability hazards was performed for each processing step to determine whether the identified risks matched to the FF categories defined by GFSI.

Based on the scoring systems and threshold criteria adopted in the existing assessment methodologies (Food Development Research Institute, 2017, 2024; TFDA, 2020), this study employed nonlinear scoring approaches, which were not standardized, for risk assessment, score definitions, and calculation methods. Previous studies utilized spider diagrams, 50-question checklists, and traditional scoring methods, which were not based on advanced statistical models but rather on evaluation factors, such as the organization's size and complexity, potential bottlenecks in testing technologies, any history of adulteration or fraud incidents, and geopolitical factors

affecting suppliers (e.g., corruption risks). While considering the importance of methodological principles, the risk assessment, scoring scales, and threshold values may vary across different sectors of the food industry (van Ruth *et al.*, 2017). The experts involved in this case study were two quality assurance (QA) managers of the company with FSSC 22000 Lead Auditor training certificates, together with an external expert. They fulfilled the criteria stipulated in the ISO 22000 Clause 7.2 (competence) and Clause 7.1.2 (qualification of external experts) as well as FSSC 22000 Clause 2.5.18 (competence requirements) and Clause 2.5.4 (food fraud audit guidance). The researcher also consulted the Food Industry Research and Development Institute (2017, 2024) and referenced FSSC (2018, 2024) and GFSI (2017, 2018a).

The overall risk level divisions were listed with five levels: 1, 2, 5, 8, and 10, with a total score of 9–90 points. A score of $\geq 80\%$ indicated a critical vulnerability point (Codes 1, 2, 3, 4, 6, and 7). This study identified risk assessment for potential vulnerabilities in FF across all braised food manufacturing processes as shown in Table 4. The potential vulnerability hazard analysis of FF is shown in Table 5. For example, the illegal Sudan red (unapproved enhancer) evident in Taiwan in 2024 is widely used in various food industries to provide seasonings and spices. The supplier in this case was from China and was often called a 'supplier–importer', importing in large quantities from suppliers with criminal motives for extremely high economic gains.

Table 4. Nine-factor food fraud vulnerability assessment criteria.

No.	Factor	Considerations for vulnerability
1.	Supply chain management	Complexity of the supply chain and extent of control over suppliers (e.g., number of intermediaries, and transparency of sourcing).
2.	Supplier relations	Strength of relationship and trust with suppliers (history of reliability, level of communication, and transparency).
3.	Incident history	Past records of quality or safety incidents, recalls, or regulatory violations associated with the ingredient or supplier.
4.	On-site inspection rigor	Effectiveness of on-site inspections and incoming goods checks (frequency and depth of inspection of materials upon receipt).
5.	Quality control (QC) capability	Technical acumen of QC methods used (availability of appropriate testing methods and the staff's proficiency in detecting adulterants).
6.	Detection technology & frequency	Availability and frequency of testing for fraud-related hazards (e.g., rapid test kits, laboratory analyses, and how often they are applied to batches).
7.	Geographical risks	Origin of materials and associated regional risks (countries or regions with higher known prevalence of adulteration or weak regulations).
8.	Historical adulteration	Known vulnerability of the product type to past adulteration or fraud cases (industry-wide knowledge of common fraud tactics for that material).
9.	Economic anomaly	Economic drivers that could motivate fraud (e.g., sudden price spikes or shortages of the authentic material, creating incentive for adulteration or counterfeiting).

Table 5. Identified significant VACCPs and their mitigation strategies.

VACCP (process step)	Primary vulnerability (fraud hazard)	Mitigation strategy (key control measures)
VACCP 1—raw material acceptance (pig ears)	Substitution with lower-cost or tainted meat; veterinary drug adulteration (undisclosed use of growth drugs or antibiotics in pigs). Defined by Global Food Safety Initiative (GFSI) as 'substitution', 'concealment', and 'unapproved enhancements'.	Source from approved domestic suppliers only; require supplier's certificate of analysis for each lot; conduct rapid screening of each batch for veterinary drug residues; implement a supplier accountability contract with incentives/penalties.
VACCP 2—spicy seasoning (herbs/spices) acceptance	Addition of unapproved additives or dyes to spices; concealment of poor-quality or contaminated spice lots (imported herbs/spices of variable quality). Defined by GFSI as 'substitution' and 'unapproved enhancements'.	Use only pre-qualified spice suppliers (with audits and third-party certifications); test incoming spice batches for pesticide, heavy metal, and dye adulterants (e.g., Sudan red); and enforce contract terms with a reward/punishment system for quality compliance.
VACCP 3—blended additive acceptance	Inclusion of illegal substances in compound food additives (e.g., unauthorized coloring or flavor enhancers); misrepresentation of additive ingredients. Defined by GFSI as 'substitution' and 'unapproved enhancements'.	Purchase blended additives from vetted manufacturers with full disclosure of ingredients; require each batch to come with an inspection report; perform in-house rapid tests for targeted adulterants; apply the same supplier evaluation and penalty system as for spices (VACCP 2).
VACCP 4—mixing step (batch preparation)	Intentional adulteration during production by staff (adding unauthorized substances or undeclared ingredients into the mix for economic gain or other motives). Defined by GFSI as 'dilution', 'concealment', and 'unapproved enhancements'.	Restrict access to the mixing area (authorized personnel only); implement a two-person oversight rule for each mixing batch; install CCTV monitoring over mixing operations; and institute an employee fraud-awareness program and confidential reporting system to deter malicious activity.
VACCP 5—final seasoning additions (post-cooking)	Similar insider fraud risk during final seasoning (possibility of workers adding undeclared oils, flavorings, or other adulterants to stretch or modify the product). Defined by GFSI as 'dilution', 'concealment' and 'unapproved enhancements'.	Apply the same controls as VACCP 4: controlled access and constant surveillance of the seasoning process; require dual sign-offs on added ingredients; conduct random spot-checks of batches and review surveillance footage; and reinforce staff accountability and whistleblower protections.
VACCP 6—packaging and labeling	Mislabeling or falsification of product information (e.g., incorrect ingredient origins or forged expiration dates or lot codes for economic advantage). Defined by GFSI as 'mislabeling', 'gray market production/theft/diversion', 'concealed origin', and 'counterfeiting'.	Perform label content verification for each packaging batch (check that ingredients, origin, and dates match approved records); cross-verify purchasing records for label claims (e.g., origin statements); require a second-person review of label artwork and coding; maintain traceability records for all label lots; and conduct periodic label audits.

Identifying significant vulnerabilities of food fraud to establish control limits and mitigation strategies based on hurdle effects
 The VACCP identified for all braised food processes includes the following steps:

- (1) Step 1.1: main raw material acceptance: pig ears (VACCP 1);
- (2) Steps 1–5: spicy seasoning acceptance (VACCP 2);
- (3) Steps 1–6: acceptance of blended spices (compound food additives) (VACCP 3);
- (4) Step 4.3: mix (VACCP 4);
- (5) Steps 5–8: seasoning and mixing (VACCP 5); and
- (6) Steps 5–10: inner packaging/labeling (VACCP 6), where ‘\$’ denotes economic benefits.

Comprehensive management of the hurdle effects was implemented accordingly, as shown in Table 6.

Among the identified VACCP, the ‘raw material acceptance’ step has been identified as the food processing industry’s latest possible FS critical control point (CCP). Chen *et al.* (2020) also suggest that the decision should be conditional as a CCP. Accordingly, two of the four fields of the food protection management system, FF and FS issues, were established. The food protection management system is an overlapping aspect of these two elements. This study identified the significance of steps, intersections, and the importance of VACCP and HACCP of FF, aligned with FSSC (2019), which has been applied by the food industry to both domestic and international sales. The acceptance step aligned with the CODEX’s HACCP principle in compliance with ISO 22000:2018 (Clause 8.5) to set control limits, acceptability levels, and corrective action. The organization uses the target limit

Table 6. Hurdle-layered VACCP mitigation plan.

VACCP (step)	Control limit (target)	Monitoring (frequency and method)	Verification (method and frequency)	Responsible role
VACCP 1—pig ears (raw intake)	No illegal veterinary drug residues (e.g., antibiotics ≤ legal ppm; beta-agonists: ND*)	Each batch: the supplier’s certificate of analysis (COA) is reviewed, and a rapid test is performed for drug residues.	Annual third-party laboratory testing of pig ear samples and periodic supplier re-evaluation audits.	Purchasing manager, quality control (QC) supervisor, and FF team leader.
VACCP 2—spices (dry herbs) intake	No pesticide or heavy metal levels above legal limits; no unapproved dyes present (ND for Sudan red).	Each batch: supplier’s certificate and in-house rapid screening for pesticides and dye adulterants.	Semiannual third-party testing of spice samples (pesticide and contaminant panel); regular supplier quality audits.	Procurement manager, QC supervisor, and FF team leader.
VACCP 3—compound additive intake	No unapproved additive in premix (all components must meet specifications).	Each batch: verify supplier lot analysis and perform rapid spot tests for known adulterants.	Annual third-party validation testing on additive premixes; periodic review of supplier ingredient transparency.	Procurement manager, QC supervisor, and FF team leader.
VACCP 4—mixing (batch preparation)	No unauthorized ingredients were added beyond the formula (recipe strictly followed).	Each batch: dual-employee supervision during ingredient mixing; CCTV real-time monitoring of the mixing area.	Monthly internal audit of mixing records and surveillance logs; unannounced spot inspection of the production floor.	Production supervisor, quality assurance (QA) manager, and FF team leader.
VACCP 5—seasoning (final mix)	No unauthorized substances were introduced during the final seasoning step.	Each batch: two-person sign-off on any added seasoning ingredients; continuous CCTV monitoring.	Monthly management review of seasoning batch records and camera footage; random product testing for undeclared additives.	Production supervisor, QA manager, and FF team leader.
VACCP 6—packaging/labeling	All label information is 100% accurate (correct ingredients, origin, and expiration date on each lot).	Each batch: label contents double-checked against product formulation and purchase records; visual inspection of date codes.	Quarterly label compliance audit (traceability exercise to verify label information vs. sourcing); routine verification of label approval process for new materials.	Research and development (R&D) and QA supervisors, purchasing supervisor, and FF team leader.

Notes: ND: not detected (below the method detection limit).

as a control limit. The value set to control hazards should typically be stricter than the standards stipulated in the regulations. This study identified six VACCPs in the areas of acceptance, mixing, seasoning, and labeling. For each VACCP, stricter control limits were set than legal thresholds, defined per batch or scheduled monitoring, and specified corrective actions. PRPs were reviewed monthly; effectiveness of VACCP is verified through sampling rotation and third-party testing.

Monitoring emphasizes three main principles: real-time monitoring, representativeness, and as much continuity as possible. For each VACCP control limit, the intensity and breadth of the monitoring system should be in accordance with the TFDA's revised announcement on 'food safety monitoring plans and inspection requirements for food businesses, minimum inspection frequency, and other related matters'. It should include monitoring targets, monitoring items, monitoring units, and inspection frequency (quarterly or per batch). It should also include relevant hazard analysis for inspection items, relevant hazard information, regulatory limits, and periodic rotation plans (self-inspection, outsourcing for an impartial third-party inspection, or inspection reports provided by suppliers). It should establish a systematic monitoring documentation as required. When products are non-conformities, corrective actions are taken. However, for SMFEs, many suppliers may only have a business registration certificate or have not undergone third-party certification; thus, they could not ensure the safety of products. Therefore, during the process of identifying supplier risks, based on the requirements of FSSC 22000 v6 Clause 2.5.13 for product development and design, the company must consider the supplier's financial status, production capacity, QC, and delivery timeliness while identifying high-risk (low reliability) suppliers and implement management based on mitigation strategies (Codes 1, 2, 3, and 7).

Furthermore, based on the requirements for material services and management in FSSC 22000 v6 Clause 2.5.1, reward and penalty clauses are established in the management of raw material procurement contracts to enhance suppliers' active cooperation with the company's quality requirements. After the implementation of hurdle effects, the records of raw material inspections were compared during receipt, as shown in Table 7. This table indicates that before and after implementation, all raw material items satisfied the target limits. The raw pig ear materials used by the braised Central Food Factory were sourced from Taiwan, and the Chinese medicinal herbs were brought from China. In addition to requiring suppliers to provide quarterly self-inspection reports, each batch of raw materials was subjected to rapid screening tests upon receipt. Furthermore, a batch is randomly sampled and tested for veterinary drug residues by a

third-party inspection company annually; cross-comparison ensures no chemical contamination of materials.

Chen *et al.* (2020) reported that CoAs provided by suppliers often do not accurately reflect whether the supplied materials conformed to specific requirements. After implementing the hurdle effect, the company strengthened self-screening for aflatoxins, sulfur dioxide, and organophosphate pesticides. Owing to laboratory capacity and high testing costs, it is not feasible to outsource testing of each batch of imported medicinal herbs. Therefore, the company selected suppliers that have passed qualification assessments, required self-inspection reports, and conducted random annual sampling for self-testing and third-party inspection. These measures were cross-check mechanisms for medicinal herb materials' safety and a confirmation of professional competence (FSSC 22000 v6, Clause 2.5.1) (FSSC, 2024).

The company's procurement and acceptance decisions are based on inspection reports provided by suppliers. The company periodically commissions impartial third-party testing and proficiency comparisons to verify compliance with supplier-provided reports. Moreover, supplier qualifications are regularly reviewed, and restrictive management measures are applied to approve suppliers. To enhance control over chemical hazards of raw materials, the company has increased inspection efforts and implemented a rotation plan for testing cycles while monitoring items to reduce rapid test screening errors, ensuring the accuracy and reliability of monitoring. Inspection work aims to prevent potential risks of chemical hazards from raw materials while complying with the requirements of ISO17025:2017 and FSSC 22000 v6, Clause 2.5.1 (Codes 1, 2, 3, 6, and 7).

In particular, if raw materials originate from high-risk geopolitical regions or major global production areas, the company applies the following measures: (1) rigorous supplier selection and qualification assessment; (2) once acceptance of key raw materials returns to a stable and consistent status, a reduction in testing frequency in accordance with the TFDA 'monitoring rotation plan', under which testing frequency is adjusted based on defined sampling plans; and (3) contractual management requirements combined with scheduled or unscheduled sampling inspections. These measures are intended to control risk while avoiding excessive cost burdens on SMFEs.

Scope and limitations

This application was implemented within a Taiwanese braised food SMFE, thus constrained by SMFE-specific resources, governance, and supplier portfolios.

The nine-factor index and the $\geq 80\%$ significance rule were calibrated for this context to prioritize mitigation within operational constraints. They should be regarded as decision heuristics, rather than universal thresholds. Owing to the low base rate of laboratory detections, which are predominantly not detected, this study employed verification coverage and various proxies related to audits and customer interactions. These metrics included third-party testing coverage, internal-audit nonconformities, complaint rates per 10,000 units, supplier re-rating, training hours per full-time equivalent, and staff turnover, all of which were used to demonstrate impact. The before–after design (HEb January–December 2022 vs. HEa January 2023–December 2024) does not incorporate randomized controls and is vulnerable to residual confounding factors, such as seasonality, supplier changes, and regulatory or market shifts, despite the application of consistent period definitions and standardized monitoring. The FS culture instrument received internal validation through content review, reliability assessment, and sampling adequacy evaluation; however, it lacked external validation. Additionally, self-report and social-desirability biases remain potential concerns, even with the assurance of anonymity. Transferability beyond Taiwan may differ due to regulatory and variations in supply chain; however, adherence to ISO/IEC 31010, CODEX HACCP and FSSC 22000 v6 is probably to support adaptation by comparable SMFEs. This approach offers SMFEs simplicity in application and prioritizes decisions under resource constraints, facilitating practical fraud mitigation.

Key Factors for Effectiveness of Vaccp Implementation

Audits

The current international FSMS standards have both advantages and disadvantages, but the effectiveness of their implementation depends on one essential factor: auditing. Independent and impartial third-party tools can significantly contribute to high levels of FS. Accredited certification bodies use their experience and expertise to support the food industry and are entrusted by supervisory authorities to perform official functions. To provide an alternative and cost-effective oversight service, these bodies must also bear the associated operational costs. Accreditation bodies, in turn, should strengthen the performance of certification bodies worldwide. Through an elimination mechanism, auditors are expected to have graduated from a formal food-related academic program, and their auditing competencies must be strictly assessed to ensure that audit quality is not diminished by competition among certification institutions. These issues contribute to why the credibility of certification results and the effectiveness of SMFEs' FSMS are frequently questioned.

Another key factor is the company's implementation of internal audits. Organizations must conduct fair and professional internal audit activities, and internal auditors often have a critical role in enhancing the effectiveness of FSMS. Internal auditors should meet the competency requirements specified in ISO 22000:2018 Clause 7.2 and FSSC 22000 v6, Clause 2.5.18, allowing them to identify nonconformities within the organization's quality system and support continuous improvement.

Regardless of the type of audit, both internal and external auditors are required to meet specified competencies, such as possessing Food Protection Management System (FPMS)'s 4-domain methodology and CCP identification capabilities, audit depth, process, scope, standards, criteria, independence, systematic procedures, formal sampling, purposive sampling, random sampling, risk-based sampling, suspicious-sample evaluation, and a supervision plan. First-, second-, and third-party audits, together with traceability evidence, may involve testing capabilities and instruments, reports, company inspections, on-site surveillance, indicators, and signage. Objective evidence may also include routine inspections, screening, scoring, snapshots, social media checks, spot checks, and real-world supplier assessments, as well as mechanisms that encourage employees to report FS incidents (Codes 7 and 8).

Implementing organization's food safety culture

During research period, the case company implemented the four elements of FS culture through a top-to-bottom approach. KPIs were established for each department, including the overall customer positive feedback (based on comparisons of production volumes and customer satisfaction surveys) and the overall customer negative feedback (based on product defect rates, customer complaint responses, and the number of exceptions handled). The trend analysis of KPIs after implementation of FPMS methodology is shown in Figures 4A–4F. For example, the product defect rate decreased by 25%, as seen in Figure 4A. The term 'nonconformity products' refers to the daily nonconforming weight divided by the total production weight. This number decreased from a monthly average of 513 kg in 2022 to 410 kg and 385 kg in 2023 and 2024, respectively. The analysis revealed that the majority of nonconformity items were rejected due to antibiotic residues (veterinary drug, unapproved enhancers) during acceptance testing. In accordance with the monitoring rotation plan stipulated by TFDA, one sample of raw meat product was found to be mixed with low-quality meat that contain veterinary drug residue (fraud and mislabeling).

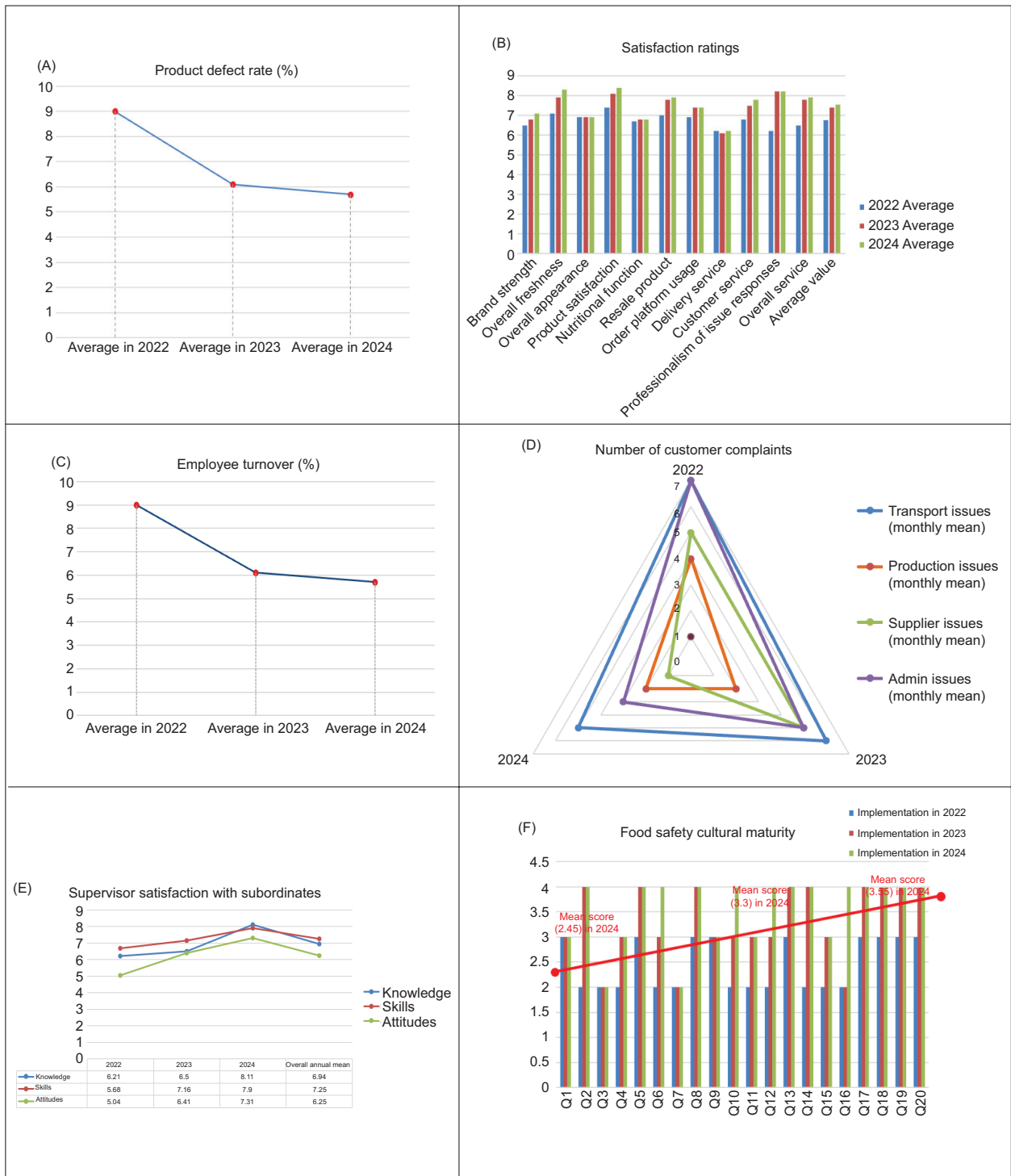


Figure 4. Trend analysis of key performance indicators (KPIs) after implementation of FPMS methodology. (A) product defect rate: expressed as a percentage (%); (B) satisfaction ratings: total score based on a 10-point scale; (C) employee turnover: number of employees who left divided by total number of employees, expressed as a percentage (%); (D) number of customer complaints: calculated as the total number of complaints in each category; (E) supervisor satisfaction with subordinates: each dimension and the overall score are based on a 10-point scale; (F) Food safety culture (FSC) maturity: based on the preliminary 20-item questionnaire covering various dimensions of corporate culture; total score was based on a 10-point scale.

The second highest rejection is the spicy seasoning acceptance (heavy metal content exceeds the standard), as the majority of Chinese medicinal herbs and spices come from China, which is an economically unstable and politically opaque region (one of the nine elements of adulteration risk assessment). Other rejections include mislabelling during manufacturing process (one of the seven types defined by GFSI). The methodology shown in Table 1, the nine-element FF vulnerability considered in Table 4, the process diagram in Figure 3, and Table 5 on identification of significant VACCPs and their mitigation strategies showed effectiveness in early stages. This finding is similar to the methodological benefits reported by Manning and Soon (2019) and Manning *et al.* (2024).

The KPIs trend analysis after implementation of FPMS methodology is shown in Figures 4A–4E.

Customer complaint refers to the average monthly number of complaints made by customers regarding various aspects of the company. It was found that there was no significant difference in transportation-related issues, as the company outsources its transportation services. The proposed solution is to conduct thorough external communication with transportation provider, identify alternative suppliers as backups, and strengthen contractual management to ensure compliance, as shown in Figure 4D. It is worth noting that the complaints related to suppliers refer to this company's complaints about abnormalities concerning its upstream suppliers, expressed as the average monthly frequency. The relatively low complaints in 2022 (before FSC implementation) were due to insufficient organizational awareness of the risks and hazards of FA and FF as well as the lack of adequate control or mitigation measures. The five cases recorded in 2022 were nonconforming products identified by audits or regulatory authorities (as mentioned earlier), which resulted in penalties. In contrast, the five cases recorded in 2023 occurred after the implementation, during which the company strengthened its control over FA and FF, hence detected more related issues.

After full implementation of FSC in 2024, the number decreased to only one case. The inverse relationship between these complaints and the satisfaction level demonstrates that the system began to show initial effectiveness after implementation. Customer satisfaction showed an upward trend (increasing from a score of 6.7 to 7.4 and 7.5), as illustrated in Figure 4B. It is worth mentioning that the annual employee turnover rate for 2022, 2023, and 2024 was 9.0%, 6.1%, and 5.7%, respectively. The turnover rate in the first and second quarters of 2022 reached 11% and 10%, respectively, bringing the annual average to 9% (during COVID-19), and then

dropped to 5.7% by 2024. The sales of frozen prepared foods (braised foods) improved during this period, but employees left due to the pandemic. After the pandemic ended in 2023, the FSMS system's implementation of preliminary assessment of FSC helped retain employees and reduce turnover. The turnover rate gradually stabilized, as shown in Figure 4C.

Employee turnover is a key KPI reflecting whether FSC has been effectively implemented. During the initial stage, following guidance and training from an external expert and enhanced internal communication from leadership, some senior employees with more passive personal traits may have found it difficult to adapt to additional responsibilities, resulting in a slight initial increase in turnover. However, the management promoted the initiative by setting examples for the staff. By 2024, the turnover rate had stabilized. The introduction of new system provided an opportunity for organizational rejuvenation, which in the long term was beneficial for the enterprise. Further observation over time is required to confirm sustained benefits. Supervisors' satisfaction with subordinates (in terms of risk knowledge, technical skills, and attitudes) showed an improving trend after implementation, as illustrated in Figure 3E.

Although individual personality traits remained a challenge, through expert training and guidance, shareholders recognized that employees with strong risk awareness and team spirit are the company's most valuable assets. They became willing to invest more substantially in employees, including allocating greater portion of profits and enhancing benefits, thereby improving retention rate. At the same time, the company established a clear accountability system, which is essential for FSC. The overall FSC maturity of the company was assessed using a 20-question survey instrument designed to cover five dimensions, namely, organizational vision and mission, personnel, consistency, adaptability, and hazard and risk awareness, along with their key components (GFSI, 2019).

Zanin *et al.* (2022) categorized FSC maturity into three stages: reactive, proactive, and generative. PAS 320:2023 (British Standards Institution [BSI], 2023) recommends a maturity scale ranging from levels 1 to 5. In this study, the maturity stages were defined as follows: Stage 1 is reactive; Stage 2 is compliant; Stage 3 is proactive; Stage 4 is preventive; and Stage 5 is resilient. These stages progressed from regulatory and standards-based compliance to risk- and knowledge-based prevention and continuous improvement. This model supports the food industry in adopting best practices to reduce FS risks and allows organizations to measure their maturity levels accordingly. The analysis of FSC

maturity for 2022 (pre-implementation) and 2023–2024 (post-implementation), as shown in Figure 3F, indicates that the company has advanced to a level between Stage 3 and Stage 4, demonstrating improvement after implementation. Nevertheless, there remains room for further advancement over time. For example, younger employees exhibited lower engagement compared to older employees, and individuals with an external locus of control demonstrated weaker normative beliefs than those with an internal locus of control. A stable workforce and cohesive teams are essential for building a consistent organizational culture.

Following implementation, the case company incorporated corporate integrity, employee turnover, communication, education and training, feedback, and active participation into its FS culture maturity assessment. Leadership integrity and commitment, together with the systematic involvement of frontline employees, influenced shared values, attitudes, beliefs, and behaviors toward FS. This outcome aligned with the findings of Alrobaish *et al.* (2023) and Anindya and Adhariani (2019).

A questionnaire was designed to assess corporate integrity and vulnerabilities related to food adulteration and counterfeiting by collecting demographic information, such as employee age, seniority, job function, and contract type. Organizational characteristics, including product type, service type, company size, and certification status, were also considered (Alrobaish *et al.*, 2023). This survey supported the company's efforts to ensure FS while reducing incidents related to food adulteration and counterfeiting (Code 9).

Workforce stability is a critical factor for ensuring FS in the food industry, as insufficient staffing may result in weakened controls and FS breaches. A stable workforce helps to retain talent and experience, increases operational efficiency, and reflects the case company's capacity to provide a satisfactory working environment, reasonable compensation and benefits, and sufficient training and development opportunities to meet employees' diverse needs. Burke *et al.* (2022) also suggested that training reduces the likelihood of financial fraud. Low turnover further indicates a solid corporate culture and values, fostering employees' sense of belonging, feedback, and voluntary participation, all of which contribute to the long-term development of FS culture.

Under the guidance of senior consultants, on-site employees' awareness of FS and hazard factors improved. Based on positive and negative feedback, the introduction of hurdle approach enhanced brand recognition and product quality awareness among

approximately 50 chain stores and their customers. Indicators such as product presentation, delivery service, and overall service satisfaction improved significantly each year, and the overall satisfaction increased notably. These improvements can be attributed to management's emphasis on implementing the hurdle effect strategy, which was reflected in declining counts of customer complaints (Codes 7–9).

Significant mitigation measures were observed during the 3-year period (2022–2024) examined in this study, providing practical guidelines and experience for identifying VACCPs. Although the food industry remains vulnerable to food adulteration and counterfeiting, prevention and mitigation strategies can be implemented effectively. Prevention strategies often involve high implementation costs, and measuring their effectiveness, regardless of whether threats actually occur, remains challenging. Moreover, striking a balance between prevention and detection strategies is difficult, as it largely depends on whether regulatory agencies or the food industry drive these initiatives. Companies must take responsibility and seek opportunities to enhance the effectiveness and efficiency of audit and governance systems (Kotsanopoulos and Arvanitoyannis, 2017).

In the short term, the case company invested in professional personnel, FSC training, and top-to-bottom implementation efforts, which required costs and resources. However, after long-term implementation, these practices became self-sustaining, supporting business growth and comprehensive quality management throughout the organization, thereby reducing customer complaints and expanding business performance. After implementation, quantitative improvements were observed in several areas: raw material rejection rate decreased by 50%, process defect rate decreased by 25%, customer complaints decreased by 25%, and customer satisfaction increased by 20%. Hence, effective implementation should follow this sequence to ensure a smooth process: establishing a solid FSC, emphasizing the importance of training (with full participation of all managers through a top-down approach), ensuring the legal awareness of responsible persons, and strengthening professional staffing.

This study also aligns with the principles of the CODEX HACCP Code:2024 amendment, which emphasizes that food companies should promote a robust FS culture. Accordingly, hurdle effects can be applied to independent management and integration of food operators. These measures contribute to combating FF and enhancing consumer trust in food services. Future research should prioritize multi-site or cross-sector validation of the hurdle-layered VACCP architecture to enhance generalizability.

Conclusions

Suppliers, including both raw material suppliers and manufacturers who provide products directly to consumers, often possess 'criminal motives' driven by EMA that may involve hidden gains. This study applied hurdle effects (Codes 1–9) to VACCP identification and mitigation strategies, including VACCP assessment methodologies, audit requirements aligned with international standards, relevant guidelines, and the planning of mitigation and improvement measures, in order to achieve integrated management of organization's FD system. For the braised food product examined in this case, six process steps, namely 'main raw material acceptance', 'spicy seasoning acceptance', 'blended compound food additive acceptance', 'mixing', 'seasoning/mixing', and 'inner packaging/labeling', were identified as VACCPs. Comprehensive implementation of strategies, methodologies, and planning required by ISO 22000:2018/Amd 1:2024 and FSSC 22000 v6 was carried out. This novel application of hurdle effects at organizational food management level is feasible for braised food industry, and can be extended to other product lines in the food sector.

The findings of this study provide a broadly applicable reference for SMFEs in diverse consumer food industry, such as frozen prepared foods, snack foods, and the food service sector, that must effectively address FF. It also offers general guidance for certification bodies, including auditor competency considerations, that hold quasi-regulatory authority over suppliers who are certified or preparing for certification.

However, small enterprises at an early stage of development are often constrained by limited financial resources, technical capacity, and cost considerations. In the case examined in this study, the leadership demonstrated awareness of FS culture and FF-related risks as well as a strategic intention to expand business operations. Prior to obtaining certification, such enterprises may strategically utilize public resources allocated by government agencies for upgrading and economic development of the food industry. In Taiwan, these include annual budgets administered by various governmental bodies, such as the Ministry of Education, Ministry of Science and Technology, Ministry of Agriculture, Ministry of Economic Affairs, and Ministry of Finance. Recurrent expenditure budgets are frequently used to support higher education institutions or enterprises through project-based subsidies, including workforce training programs, industry–academia collaboration initiatives, and engagement of external experts. Capital expenditure subsidies may support enterprises in establishing in-house laboratory testing capabilities, acquiring analytical equipment, upgrading

production facilities, or obtaining low-interest, long-term financing through financial institutions to support business development. By adopting the framework proposed in this study, enterprises may follow a phased, layered, and staged approach, beginning with the implementation and certification of FSSC 22000, ISO 22000, and HACCP systems, and progressively advance toward higher-level system certifications. This approach allows organizations to meet baseline requirements of major retail channels (e.g., Costco) and international standards while strengthening system execution and supporting business growth.

The case study demonstrates that implementation across chain stores, along with feedback from employees and customers, resulted in lessening of customer complaints and increase in customer satisfaction. When conducting supplier evaluations (as recommended in the FSSC 22000 auditing guidelines, which require verification of a supplier's capability through third-party validation), the implementation can extend across industries and even influence raw material suppliers, such as meat slaughtering operators and food additive providers. In this study, layered hurdle management using Codes 1–9 confirmed the breadth of coverage, while application of the TFDA-mandated monitoring rotation plan supported strategic responses aligned with enterprise conditions and testing risk levels, and the cost constraints faced by SMFEs was taken into consideration.

Mandatory Disclosure on Use of Artificial Intelligence

During the preparation of this manuscript, the authors used generative AI tools solely for language editing and improving readability. The AI tools were not used to generate scientific content, interpret data, or draw conclusions. All authors have reviewed and take full responsibility for the final content of the manuscript.

Data and Code Availability Statement

No new data were generated for the research described in the article.

Author Contributions

Hsin-Jung Chen: Conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, supervision, validation, visualization, writing—original draft, and final approval. Sih-En Liang: Data curation, formal analysis, writing—original draft, and final approval.

Chia-Sheng Yeh: Data curation, formal analysis, writing—review and editing, and final approval. All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ethics Statement

According to the institution's policy, the research plan of this study met exemption criteria (quality improvement/operational evaluation) and did not require formal IRB review. Informed consent was implied by voluntary survey completion.

Conflict of Interest

To the best of our knowledge, the named authors have no conflict of interest, financial or otherwise.

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Supplementary

Table S1. Methodology, plan, and mitigation strategies based on hurdle effects.

Hurdle effects/ code No.	Introduced item	Hurdle effect strategies	Methodology, strategy portfolio, and implementation plan
Code 1 1. FSSC 22000 V6.0 Clause 2.5.4.1 2. ISO 22000 Clause 6.1	Actions to address the risks and opportunities of food frauds	<ol style="list-style-type: none"> 1. Conduct a strengths–weaknesses–opportunities–threats (SWOT) situation analysis to reduce risks to acceptable levels and turn them into opportunities. 2. The change plan introduces the standard provisions of FSSC 22000 V6.0, ISO 22000: 2018, and ISO 22002-1: PRP. 	<ol style="list-style-type: none"> 1. Perform a SWOT analysis of this study. 2. The downstream distributors of 50 franchise stores in the braised food industry attach importance to positive and negative feedback from customers. They actively improve customer satisfaction and strengthen rolling adjustments to external communication. 3. Management and supervisors hold quarterly supervisory meetings to update and pay attention to collecting and reporting relevant food frauds news events and regulations. 4. Suppliers should strengthen external communication and pay attention to supplier and delivery information of raw materials.
Code 2 1. FSSC 22000 V6.0 Clause 2.5.4.1 2. ISO 22000 Clause 4.2	<ol style="list-style-type: none"> 1. Identify high-, medium-, and low-risk suppliers. 2. Understand the needs and expectations of stakeholders (suppliers and employees). 	<ol style="list-style-type: none"> 1. The company determines the stakeholders and stakeholder requirements related to FSMS and establishes a vulnerability assessment (supply chain). <ol style="list-style-type: none"> a. Perform and assess potential supply chain vulnerabilities according to defined methodologies; and b. Assessment should cover organization-wide processes and products. 2. Hire external experts to assist when necessary. 	<ol style="list-style-type: none"> 1. Conduct stakeholder reviews and evaluations with all suppliers regarding corporate risks (recruiting external experts to participate, using factor assessment supported by 50 questions or a CVP decision tree or spider chart). 2. Identify high-, medium-, and low-risk suppliers and make a list. 3. Establish a contract with the rights and obligations of stakeholders. 4. The notified organization will introduce FSSC 22000 and ISO 22000 standards and develop employee education and training plans. 5. Establish a food fraud mitigate team, and staff members receive training from internal and external professionals, and implement the system.
Code 3 1. FSSC 22000 V6.0 Clause 2.5.1 2. ISO 22000 Clause 7.1.6 and 8.7 3. ISO 22002-1:PRP Clause 5.5	<ol style="list-style-type: none"> 1. Supplier selection and management. 2. Regulation of externally supplied processes, products, or services. 3. Laboratory equipment. 	<ol style="list-style-type: none"> 1. Develop procedures and standards for supplier evaluation, frequency of audits, and factory visits. 2. Purchase raw materials with third-party certification. 3. Conduct capability comparison tests to determine the ability to produce accurate and reproducible test results. 4. The equipment used for measurement should be able to achieve the measurement accuracy and uncertainty required to provide valid results. Receive second- or third-party audits from laboratory at least once every 3 years. 5. Urgent procurement procedures are documented to ensure products still meet specified requirements and suppliers have been evaluated. 	<ol style="list-style-type: none"> 1. Supplier evaluation and decentralized procurement management of raw material suppliers and new remote video evaluation accordingly. 2. Raw material specifications are stricter than regulatory and standard requirements. Develop policies for purchasing animals that must be subjected to controls on prohibited substances (such as pharmaceuticals, animal medications, and pesticides). 3. Amend the procurement contract, formulate an accountability system and a reward system, adopt the capital turnover rate that the supplier needs most, and pay for the goods at the beginning of the next month once acceptance is passed, focusing primarily on CVP. 4. Raw materials should be inspected, tested, or contain a certificate of analysis (COA) and documented prior to acceptance or use. 5. To implement the shortage of specially purchased raw materials, and raw materials from other qualified suppliers must be selected to replace the shortage of raw materials and reduce the risk of insufficient raw materials. 6. Obtain a certificate of laboratory proficiency comparison test for quality controllers. The proportion of inspectors is increased by 10%, and the adulteration and counterfeiting of raw (auxiliary) materials is strictly enforced.

(continues)

Table S1. Continued.

Hurdle effects/ code No.	Introduced item	Hurdle effect strategies	Methodology, strategy portfolio, and implementation plan
Code 4 1. FSSC 22000 V6.0 Clause 2.5.17 and 2.5.18 1. ISO 22000 Clause 7.2 7.4, and 8.4	1. The professional capabilities of all company VACCP and HACCP team members. 2. Internal and external communication. 3. Notification and commitment of serious incidents.	1. External communication provides adequate information to stakeholders in food supply chain. 2. Internal communication establishes effective and good communication with employees on food safety issues. 3. FPMS imports external expert guidance. Arrange professional education and training for each requirement to ensure that personnel are competent for the job. 4. Requirements and education training for our company's chain stores (with multiple site certifications).	1. Hire external consultants and professionals with food-related disciplines in this case. 2. Professionals must have relevant certificates and practical experience to verify their effectiveness and manage the team's operation. 3. Establish a standard operating procedure (SOP) and leadership commitment to a required reporting system for serious incidents within 3 days—such as legal proceedings, prosecutions, malfeasance, negligence, and fraudulent activities and corruption. 4. Monthly supervisory meetings and quarterly employee meetings are held to announce the company's implementation philosophy on food fraud.
Code 5 1. FSSC 22000 V6.0 Clause 2.5.2 and 2.5.13 2. ISO 22000 Clause 8.2.4 and 8.3 3. ISO 22002-1:PRP Clause 10.3	1. Ensure product labeling and printed materials are correct. 2. Product design and development evaluation vendors. 3. Establishment and implementation of a traceability system. 4. Allergen management.	1. Ensure that finished products are labeled to meet al. applicable laws and regulations in the countries where they are intended to be sold and implemented in accordance with Clause 5.4.4 (Food Fraud) of TFDA [13] Guidelines for Food Manufacturers to Establish Food Safety Monitoring Plans. 2. The R&D department establishes new products and product, or process changes, establishes, implements, and maintains procedures for product design and development, and ensures the production of safe and legal products related to food fraud issues. 3. Establishment of traceability and tracking system. 4. Establish a training program.	1. Identify and formulate product characteristics and intended uses of braised pig ears. The product description is similar to Step 2 of the HACCP application. 2. When preparing for mass production after research and development, the supplier's assessment and inventory of high, medium, and low risks must cover processes and products within the scope of the organization. 3. Provide documented information for the management department to purchase printed labels to facilitate the accuracy of product labels and printed materials. 4. Establish the connection relationship between raw materials, ingredients, intermediate products, and final products in each batch of the manufacturing flow chart—and distribution channels for final products to facilitate traceability. 5. If a claim is made on product labeling or packaging, a verification plan must be in place. 6. Implement the TFDA regulations and electronic traceability and tracking registration. 7. R&D personnel, related employees, and external experts handle training on food frauds, and allergens.
Code 6 FSSC 22000 V6.0 Clause 2.5.4 and 2.5.12 2. ISO 22000 Clause 8.5 ISO 22002-1:PRP Clause 6.2, 7.3, 14, and 15	1. Establish a risk assessment methodology for food fraud. 2. Identify the hazards of food frauds in all manufacturing processes. 3. Establish VACCP standard operating procedures (SOP). 4. PRP verification directly related to food fraud.	1. Identify significant hazards that may occur. Document records of assessment data. 2. Introduce FF's risk assessment methodology, covering the company's processes and scope. 3. Interpretation of rework drawings and ability to establish and implement traceability systems, applications, or locations. 4. PRP review and validation and verification plan. 5. Through the company's establishment of auditing and evaluation standards for suppliers, it is required that its suppliers also have food fraud mitigation plan in place.	1. Convene quarterly food fraud team meetings to gain support from the company in implementing FSMS. 2. Analyze the criminal principles of VACCP and its 12 implementation steps. 3. Hazard identification, acceptability analysis, and establishment of vulnerability hazard analysis worksheet. 4. Clearly identify the significant VACCP and HACCP as well as the respective control measures and intensity. 5. Establish monitoring intensity and periodic rotation plan. 6. Detection technology combined with rapid test screening and regularly compares its experimental capabilities and validity. 7. In addition to raw material suppliers, we also establish a rework plan and finished product recall procedures for the company's water sources, waste management and removal, and formulate hazard control management strategies. 8. The PRP is reviewed once a week at the management review meeting.

(continues)

Table S1. Continued.

Hurdle effects/ code No.	Introduced item	Hurdle effect strategies	Methodology, strategy portfolio, and implementation plan
Code 7 ISO 22000 Clause 8.7, 8.9, 9.2, 10.1, and 10.2	<ol style="list-style-type: none"> Control of product and process nonconformities matters. Review corrective actions. Implement the company's internal audit. 	<ol style="list-style-type: none"> Monitoring of VACCP. Control of product and process noncompliance matters. Develop measures to eliminate the causes of nonconformities and prevent their recurrence. Appoint competent internal auditors. 	<ol style="list-style-type: none"> Establish a monitoring plan for VACCP and a monitoring rotation plan based on TFDA. After the food fraud mitigate team evaluates the reasons for nonconformities, external consultants and experts are consulted to propose improvement measures as soon as possible; follow-up assessments are conducted to determine whether the required measures and reviews are effective. The leader and technology of the food fraud mitigation team should meet the requirements of Clause 2.5.18. The centralized function and all sites are audited at least annually or more; the effectiveness of corrective action be demonstrated. Internal auditors should meet the requirements of FSSC 22000 Clause 2.5.18. Many employees of this company have more than 3 years of full-time work experience and have completed higher education courses. Two lead auditors have completed the FSSC 22000 lead auditor training course. 48-h training course covering ISO 22000:2018/Amd 1:2024, ISO/TS 22002-1, and FSSC 22000 V6.0 additional requirements. Internal audit reports are subject to a technical reviewer.
Code 8 1. FSSC 22000 V6.0 Clause 2.5.3.1 1. ISO 22000 Clause 9.3	<ol style="list-style-type: none"> The general manager shall authorize the assignment and regular meetings of members of the food fraud mitigation team. The general manager shall convene a management meeting to review and make resolutions. 	<ol style="list-style-type: none"> Capacity training, assignment, and complete authorization of members of the food fraud mitigation team. Ensure the appropriateness, adequacy, and effectiveness of management review inputs and outputs, connect them with the goals of FSMS, and continuously improve and update FSMS promptly. 	<ol style="list-style-type: none"> The food fraud mitigation team meeting will be held at least once quarterly to report relevant issues, such as findings during implementation, predictions of possible occurrences, new international information, statistics, and trend analysis, provide opportunities for continuous improvement, and integrate FSMS-related information. A management review meeting is held at least once every 6 months to conduct a general review of input and output of all required items in accordance with Clause 9.3 of the ISO 22000 standard, including issues of food frauds.
Code 9 1. FSSC 22000 Clause 2.5.8 1. ISO 22000 Clause 5 and 6.2 2. ISO 22000: 2018/ Amd 1:2024 requirements corresponding to food safety culture	<ol style="list-style-type: none"> Top-to-bottom food safety culture. Management leadership and commitment The goals of FSMS and plans to achieve them. 	<ol style="list-style-type: none"> Food safety culture encourages employees' voluntary participation, setting key performance indicators (KPIs), reward and promotion systems, accountability, and maturity trend analysis. Establishing food safety culture standard operating procedures (SOP) includes four elements: communication, training, employee feedback and participation, and implementing performance measurements. ISO 22000: 2018/Amd 1:2024 requirements corresponding to food safety culture (Cause 4.1, 4.2, 5.1d), 5.2.2(a) and (b), 5.3.1, 5.3.2, 7.4.3, 6.2, 6.3, and 7.2b), 7.1.2, 7.3, 7.5.1b), 8.9.19.1.29.3, 9.3.2, 10.2, and 10.3). 	<ol style="list-style-type: none"> Establish a quality control circle (3 to 15 individuals), establish reading clubs for different departments, and hold regular and irregular theme discussions (if necessary, organize the hiring of additional experts for assistance and evaluation). By encouraging employees to participate voluntarily, the basis for issuing year-end performance bonuses is included. Announce the organization's quality policy, quality objectives, and KPIs of each department. Implementation of accountability. Installation and regular review and supervision of monitors. All employees can use anonymous questionnaires to continuously improve and increase the maturity of the company's food safety culture each year. The general manager publicly encourages truthful internal reporting in line with TFDA's 2015 'Reward Measures for Handling Food Safety and Hygiene Reports'; verified reports are eligible for bonuses [13].

Table S2. Product characteristics and intended uses of braised pig ears (example).

Process description	Acceptance of primary (auxiliary) raw materials ≥ room temperature/refrigerated/frozen storage ≥ picking ≥ thawing ≥ pre-processing ≥ pickling ≥ marinating ≥ cooling ≥ cooking and cutting ≥ seasoning/mixing ≥ weighing ≥ inner packaging/labeling ≥ metal inspection ≥ refrigeration/freezing ≥ storage and transportation.
Product name	Braised pig ears
Product description	Braised products (ready to eat): fully cooked, refrigerated/frozen, ready to eat after opening.
Elements	Primary raw material: Pig ears. Auxiliary raw materials: sugar, salt, rice wine, chicken powder, meat tenderizer powder, pickling powder, pepper, braised rice powder, soy sauce, bean paste, fermented bean curd, garlic, chili, star anise, cumin, bay leaf, cloves, cinnamon twigs, Sichuan peppercorns, sesame oil, soybean oil, and canola oil. Compound food additives: L-sodium glutamate, glycolic acid, DL-aminopropionic acid, 5'-inosine nucleoside disodium phosphate, 5'-guanine nucleoside disodium phosphate, disodium succinate, citric acid sodium, ethyl maltol (spice), ammonium glycyrrhizinate (sweetener), capsicum essence (spice), Sichuan peppercorn oil (spice).
Label description	Braised products: fully cooked, refrigerated, and ready-to-eat after opening.
Intended usage and purpose of the product	1. Best way to eat: place it in a refrigerator and defrost it for 24 h, then unpack and eat. 2. Enjoy immediately: place at room temperature for 30 min, wait until the ice softens, and serve. 3. Microwave thawing: after each box is microwaved at 800 W for 30 s, it is ready to eat after unpacking.
Consumer objects and precautions	Do not eat if the product has expired or is swollen or if the packaging is damaged before opening. Eat as soon as possible after opening; do not eat if there is a smell of oil consumption. Keep refrigerated after opening and consume as soon as possible. For those that must be transported and sold under -18°C, the sales site must have refrigeration equipment. Allergens: the product contains allergens, such as sesame, peanuts, soybeans, gluten-containing cereals, and their products. Nutritional facts are labeled.
Packaging type	Polypropylene (PP) plastic box, NY+RCPP plastic sealing film.
Shelf life	Frozen and unopened: 1 year.
Storage and transportation	Storage: refrigerated/frozen; transportation: refrigerated/frozen.

Table S3. Food fraud vulnerability hazard-related analysis worksheet for braised pig ear inspection items (example).

Target	Braised pig ears	Factory raw material number	xxx
Supplier	xxx		
Items used	Pig ears		
Test items	Veterinary drug residues (antibiotics [sulfonamides], beta-receptor hormones, etc.).		
Related hazards analysis	<p>Related hazard 1: sulfonamides</p> <p>Cause of harm: failure to follow drug withdrawal period results in drug residues in livestock products.</p> <p>Harmful effects: the harm caused by drug residues to the human body is mainly chronic toxicity caused by long-term intake.</p> <p>Food safety impact score: 25</p> <p>Regulatory limits: according to the 'Veterinary Drug Residue Standards' stipulated by Taiwan's Ministry of Health and Welfare, the allowable amount (ppm) of residues in muscles, livers, kidneys, and lipids of livestock and poultry is 0.1 ppm.</p> <p>Effective dose: 0.1 ppm</p> <p>Monitoring frequency: each batch</p> <p>Related hazard 2: Beta receptor hormone</p> <p>Cause of harm: overdose may cause drug residues in animal products.</p> <p>Harmful effects: ractopamine must not be detected in domestic or imported meat products.</p> <p>Food safety impact score: 22</p> <p>Regulatory limits: Taiwan's Ministry of Agriculture lists ractopamine as a banned drug.</p> <p>Effective dose: negative</p> <p>Monitoring method: each batch</p>		

(continues)

Table S3. Continued.

Target	Braised pig ears	Factory raw material number	xxx
	<p>Related Hazard 3: Listeria</p> <p>Cause: Listeria monocytogenes has been detected in ready-to-eat meat in Taiwan. The infection is mainly caused by eating contaminated food. This bacterium can continue to grow and reproduce at 4°C in refrigerator and must be heated to above 72°C. It is resistant to dryness, high temperature, acidic environment, salt, and alcohol and is prone to secondary pollution because of food processing. Listeriosis is listed as a Category 4 infectious disease under Taiwan's 'Infectious Disease Prevention and Control Act'.</p> <p>Food safety impact score: 25</p> <p>Effective dose: negative</p>		
Target	Spices: bay leaves, star anise, fennel, cloves, cinnamon twigs, Sichuan peppercorns, chili peppers	Factory raw material number	xxx
Supplier	xxx		
Items used	xxx		
Test items	<p>Heavy metals, pesticides, and aflatoxin residues</p> <p>Note: more than 98% of Chinese medicinal materials are imported from abroad and 90% from mainland China. The source is difficult to control, and the medicinal materials on the market are of mixed quality.</p>		
Related hazards analysis	<p>Related hazards 1: Heavy metals, such as arsenic (As), lead (Pb), cadmium (Cd), mercury (Hg).</p> <p>Cause of hazard: heavy metals remain due to contamination in the soil or during processing.</p> <p>Hazardous effects: the harm by heavy metal residues to the human body is mainly chronic toxicity caused by long-term ingestion.</p> <p>Food safety impact score: 20</p> <p>Regulatory limits: 'Limits of heavy metals in Chinese medicinal materials' stipulated by Taiwan's Ministry of Health and Welfare.</p> <p>Influence dose: ranging from 0.2–5 ppm</p> <p>Monitoring frequency: every 6 months</p> <p>Related hazards 2: Pesticides</p> <p>Cause of harm: excessive use may cause drug residues on Chinese herbal medicines.</p> <p>Hazardous effects: the harm caused by pesticide residues to the human body is mainly chronic toxicity caused after long-term ingestion.</p> <p>Food safety (FS) impact score: 22</p> <p>The regulatory limits are based on the Taiwan Ministry of Agriculture's 'Pesticide Residue Limit Standards for Chinese Medicinal Materials'.</p> <p>Influence dose: ranging from N.D. –0.2 ppm</p> <p>Monitoring frequency: each batch</p> <p>Related hazard 3: Total aflatoxin/aflatoxin B1</p> <p>Cause of harm: pork is introduced by eating feed, corn, and other cereals in feed. Aflatoxins are secondary metabolites produced by molds. They are resistant to high temperatures and cannot be removed by high-temperature cooking. Aflatoxins mainly include B1 and B2, G1 and G2, etc., among which B1 is the most toxic one.</p> <p>Harmful effects: the toxin is hepatotoxic and carcinogenic to humans.</p> <p>Food safety impact score: 22</p> <p>The regulatory limits are based on the 'Hygienic Standards for Contaminants and Toxins in Food' stipulated by Taiwan's Ministry of Health and Welfare.</p> <p>Influence dose: ranging from N.D. –10 ppb</p> <p>Monitoring frequency: each batch</p>		

Table S4. Potential vulnerability and hazard risk assessment worksheet for food fraud (example).

Nine-Factor risk assessment	Potential vulnerability hazards	Risk prevention and control standards (≥80% of the total score)	Overall risk score (H, M, L)	Risk level (H, M, L)	Supply chain management	Supplier relations	Regulatory records, quality, or safety-related incidents	Prevention strategies for on-site inspections	Quality control project/method acumen	Detection technology and frequency	Geographical considerations	Historical records of adulteration	Economy abnormal	Global Food Safety Initiative (GFSI) defined types
Ex: 1-1 Acceptance of primary raw materials: pig ear	Mixing/substituting/adding unapproved fortifiers with low-priced or inferior quality or expired frozen meat raw materials.	72	74	H	10	10	8	8	10	10	5	8	5	B, C, D, and E

Notes: 1. Abbreviations of GFSI defined types: A. dilution, B. substitution, C. concealment, D. unapproved enhancements, E. mislabeling, F. gray market production/theft/diversion, and G. counterfeiting.
 2. Nine-factor vulnerability risk assessment method for food fraud, coupled with 50 Q or decision tree or spider diagram analysis.

Table S5. Potential vulnerability hazard analysis worksheet for food fraud (example).

Process step	Operating area	Process step descriptions	Potential significant food fraud hazard standard (total score)	Risk fraction	Does this potential hazard significantly affect product safety? (Yes/No)	Reasons for determining the left column	Significant harm prevention and control measures	This step is VACCP
Ex: 1-5 Acceptance of spicy seasonings	Zone 3	Acceptance: Item and quantity Appearance (color, packaging, completeness of labeling). Third-party certification Statutory inspection items for biological, physical, and chemical hazards.	≥72	76	Yes	1. When the total score is ≥72, it is significantly vulnerable. 2. GFSI's Food Fraud types B, C, D, and E. B – substitution process may use other low-unit-price raw materials (or parts) to replace high-unit-price raw materials or products. C – concealing low-quality food ingredients or products hidden in the process. D – unapproved fortification process, to increase quality characteristics, unknown, undeclared or unapproved raw materials or products are added. E – for financial gain, document forgery and fraud, and false claims on the packaging, such as the place of origin and product name.	Use qualified suppliers, supplier evaluation and auditing, third-party certification, contract management, testing technology, etc.	VACCP2

Table S6. The hurdle affects the comprehensive management of food fraud: VACCP mitigation plan.

Processing steps	Significant vulnerability hazard specification	Mitigation strategies			Monitoring			Correction action	Record	Verification plan		
		Project	Method	Frequency	Operator	Method	Frequency			Person responsible		
VACCP 1-1 Acceptance of primary raw materials pig ear	B – substitute C – conceal D – unapproved enhancer E – make false claims on packaging for financial gain	1. Avoid replacing high-unit-price raw materials or products with other low-unit-price raw materials or partial products during the process. 2. Prevent noncompliant raw materials from entering the process. Establish a food raw material management database	Antibiotics and other chemical hazards.	1. The supplier provides inspection reports. 2. Rapid screening.	Per batch	Quality controller	1. If the product fails to pass the inspection, it will be rejected. 2. Increase the number of random inspections. 3. Supplier evaluation. 4. Contract management: reward and punishment system.	1. Supplier list and evaluation record form. 2. Raw material supplier contract management. 3. Raw material acceptance record form. 4. Abnormal corrective measures record form.	1. Confirm whether the raw material acceptance record form is qualified. 2. Confirm the validity of the inspection report provided by the manufacturer. 3. Irregular random testing.	Per batch	Purchasing manager, Quality assurance supervisor, Food fraud mitigation team leader.	
VACCP 1-5 Acceptance of spicy seasonings	D – unapproved enhancer E – make false claims on packaging for financial gain	1. Do not exceed pesticide and heavy metal residue limit standards. 2. Avoid replacing high-unit-price raw materials or products with other low-unit-price raw materials or partial products during the process. 3. Establish a food raw material management database.	Chemical hazards, such as pesticides and unapproved enhancers (such as Sudan red).	1. The supplier provides inspection reports. 2. Rapid test screening.	Per batch	Quality controller	1. If the product fails to pass inspection, it will be rejected. 2. Increase the number of random inspections. 3. Supplier evaluation. 4. Contract management and reward and punishment system.	1. Supplier list and evaluation record form. 2. Raw material supplier contract management. 3. Raw material acceptance record form. 4. Abnormal corrective measures record form.	1. Confirm whether the raw material acceptance record form is qualified. 2. Confirm the validity of the inspection report provided by the manufacturer. 3. Irregular random testing.	Per batch	Purchasing manager, Quality assurance supervisor, Food fraud mitigation team leader.	

(continues)

Table S6. Continued.

Processing steps	Significant vulnerability hazard specification	Mitigation strategies	Project	Monitoring			Correction action	Record	Verification plan			
				Method	Frequency	Operator			Purpose	Method	Frequency	Person responsible
VACCP 3 1-6 Acceptance of blended spices (compound food additives)	D – unapproved enhancer E – make false claims on packaging for financial gain	1. Do not exceed pesticide and heavy metal residue limit standards. 2. Avoid replacing high-unit-price raw materials or products with other low-unit-price raw materials or partial products during the process. 3. Establish a food raw material management database.	Chemical hazards, such as pesticides and unapproved enhancers (such as Sudan red).	1. The supplier provides inspection reports. 2. Rapid screening.	Per batch	Quality controller	1. If the product fails to pass inspection, it will be per batch. 2. Increase the number of random inspections. 3. Supplier evaluation. 4. Contract management and reward and punishment system.	1. Supplier list and evaluation record form. 2. Raw material supplier contract management. 3. Raw material acceptance record form. 4. Abnormal corrective measures record form.	Ensure prevention of food adulteration from high-risk suppliers.	1. Confirm whether the raw material acceptance record form is qualified. 2. Confirm the validity of the inspection report provided by the manufacturer. 3. Irregular random testing.	Per batch	Purchasing manager, Quality assurance supervisor, Food fraud mitigation team leader.

(continues)

Table S6. Continued.

Processing steps	Significant hazard specification	Mitigation strategies	Monitoring			Correction action	Record	Verification plan				
			Project	Method	Frequency			Operator	Purpose	Method	Frequency	Person responsible
VACCP 4 4-3 Mix	B – substitute C – conceal D – unapproved enhancer	1. The working area is subjected to access control, and monitors are installed. 2. In principle, two workers should work with supervisors to conduct inspections. 3. Avoid adding B, C, and D substances that shareholders or responsible persons may authorize.	1. The security monitoring system is connected to the mobile phone of the relevant manufacturing supervisor. 2. Each mixing requires two people to work at the same time. 3. Checking the usage amount of food additives.	1. Visual inspection and monitor. 2. Three specialized management of food additives.	Per batch	Operator	1. In accordance with the 'Process and Quality Control Operating Procedures' system. 2. The batch will be detained, and the persons will be questioned one by one, and the suspicious persons will be identified and their behavior and purpose will be questioned. 3. Check the monitor immediately to see if anyone is deliberately approaching the contaminated product. 4. Personnel rewards, punishments, and accountability systems are combined with ISO 22000: 2018/ Amd 1:2024 to introduce a food safety culture. 5. Establish an employee reporting system.	1. Daily work record sheet. 2. Check the surveillance system. 3. Attendance record sheet. 4. Abnormal corrective measures record form. 5. Is there any abnormal economic records or information? 6. Enterprise food safety maturity analysis table.	Ensure protection against food fraud vulnerabilities of high-risk suppliers.	1. Review the daily work record sheet. 2. Check food fraud monitor operation regularly. 3. Special personnel conduct irregular inspections. 4. Always pay attention to relevant news events and issues. 5. Update of external regulatory documents. 6. Notify the certification body and supervisory authorities of the improvement of the mechanism.	Per batch	Manufacturing supervisor, Quality assurance supervisor, Food fraud mitigation team leader.

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Table S6. Continued.

Processing steps	Significant vulnerability hazard specification	Mitigation strategies	Monitoring			Correction action	Record	Verification plan				
			Project	Method	Frequency			Operator	Purpose	Method	Frequency	Person responsible
VACCP 5-8 Seasonings	B – substitute C – conceal D – unapproved enhancer	1. The working area is subjected to access control, and monitors are installed. 2. In principle, two workers should work with supervisors to conduct inspections. 3. Avoid adding B, C, and D substances that shareholders or responsible persons may authorize.	1. The security monitoring system is connected to the mobile phone of the relevant manufacturing supervisor. 2. Each mixing requires two people to work at the same time. 3. Checking the usage amount of food additives.	1. Visual inspection and monitor. 2. Three specialized management of food additives.	Per batch	Operator	1. In accordance with the 'Process and Quality Control Operating Procedures'. 2. The batch will be detained, and the persons will be questioned one by one, and the suspicious persons will be identified and their behavior and purpose will be questioned. 3. Check the monitor immediately to see if anyone is deliberately approaching the contaminated product. 4. Personnel rewards, punishments, and accountability systems are combined with ISO 22000: 2018/ Amd 1:2024 to introduce a food safety culture. 5. Establish an employee reporting system.	1. Daily work record sheet. 2. Check the surveillance system. 3. Attendance record sheet. 4. Abnormal corrective measures record form. 5. Is there any abnormal economic records or information? 6. Enterprise food safety maturity analysis table.	Ensure prevention of food adulteration from high-risk suppliers.	1. Review the daily work record sheet. 2. Check monitor operation regularly. 3. Special personnel conduct irregular inspections. 4. Always pay attention to relevant news events and issues. 5. Update of external regulation documents. 6. Notify CB and supervisory authorities of the improvement of the mechanism.	Per batch	Manufacturing supervisor, Quality assurance supervisor, Food fraud mitigation team leader.

(continues)

Table S6. Continued.

Processing steps	Significant vulnerability hazard specification	Mitigation strategies	Monitoring			Record	Verification plan					
			Project	Method	Frequency		Operator	Correction action	Purpose	Method	Frequency	Person responsible
VACCP 6 1-1 Inner packaging/ labeling	Forgery of documents (labels), resulting in ingredients: B – substitute C – conceal D – unapproved enhancer E – make false claims on packaging for financial gain	1. The raw materials used in product development and design require risk assessment. 2. The labeled artwork must be verified. 3. Verification of transparency information (origin, ingredients, and items). 4. The effective date is printed correctly.	1. Supplier label review. 2. Supplier List (HLM). 3. Valid date printing.	1. Visual Instructions. 2. Review. 3. Verification.	Per batch	1. R&D personnel and purchasing personnel. 2. Quality control and purchasing personnel. 3. Operators.	1. Training of R&D, quality control, and purchasing personnel. 2. Correction of artwork. 3. Printing correction of the effective date.	1. Risk assessment form for raw materials used in R&D and design. 2. Create a review record sheet for marked artwork. 3. Process record sheet. 4. Traceability record sheet. 5. Process record sheet. 6. Abnormal corrective measures record form.	Ensure prevention of food adulteration from high-risk suppliers.	1. Review the form on the left. 2. Confirm the effectiveness of education and training in each department. 3. Random testing. 4. Confirmation of transparency of purchasing information (origin, ingredients, and items).	Per batch	Research director, Quality control supervisor, purchasing supervisor, Food fraud mitigation team leader, Manufacturing supervisor.