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# FOOD SAFETY RISK ANALYSIS BASED ON AN IMPROVED HACCP METHODOLOGY: AN APPLIED STUDY

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***Abstract***

*Food safety is a core objective of the modern food industry, directly affecting consumer health and trust in the food supply chain. This paper presents an applied food safety risk analysis based on an improved Hazard Analysis and Critical Control Points (HACCP) methodology that addresses the limits of traditional qualitative approaches. The proposed method integrates a semi-quantitative framework that differentiates between inherent process risk and residual risk after control measures are applied. Hazards are assessed by probability and severity, while the performance of the food safety management system is evaluated separately using a Control Capacity Index (CCI), which considers monitoring automation level and human reliability factors. The methodology is demonstrated through a case study covering key production stages in bread manufacturing. The results show that differentiating between hazard assessment and control performance allows for clearer prioritization of risks and more precise identification of vulnerabilities. By incorporating indicators based on automation and human quality, HACCP evolves from a static compliance tool into a more complex, dynamic risk management system. The approach supports the requirements of ISO 22000 and Codex Alimentarius and promotes continuous improvement and evidence-based decision-making in the agri-food sector.*

***Key words****: Food safety, HACCP, risk analysis, Control Capacity Index (CCI), food industry.*

## INTRODUCTION

Food safety represents one of the major concerns of the modern agri-food industry, having a direct impact on public health, consumer confidence, and the sustainability of the food supply chain (Rossi et al., 2025). Market globalization, increasing complexity of supply chains, diversification of raw materials, and growing regulatory and consumer requirements have driven the need for increasingly robust and effective food safety management systems (Michel et al., 2024).

In this context, the Hazard Analysis and Critical Control Points (HACCP) methodology remains the cornerstone of food safety management, being internationally recognized and promoted by the Codex Alimentarius Commission (Codex Alimentarius, 2003), the World Health Organization (WHO), and the Food and Agriculture Organization of the United Nations (FAO) (Herrera, 2004). International standards such as ISO 22000, FSSC 22000, and BRCGS incorporate HACCP as a central element of food safety management systems, enforcing a preventive approach based on the identification, evaluation, and control of significant hazards (Bomba & Susol, 2020).

The scientific literature highlights that, in practice, HACCP implementation is often limited to predominantly qualitative risk assessments based on simple probability and severity scoring (Ricci et al., 2017). Recent studies indicate that such approaches may lead to subjective results, over- or underestimation of certain hazards, and difficulties in clearly distinguishing between critical control points and operational prerequisite controls (Pal et al., 2016). Moreover, the actual performance of control measures is frequently assumed to be constant, without systematic or quantifiable evaluation.

The current regulatory framework places clear responsibility on food business operators to demonstrate effective hazard control. European

Union legislation, such as Regulation (EC) No 178/2002 (Reg. 178, 2002), and Regulation (EC) No 852/2004 (Reg. 852, 2004), requires not only hazard identification but also evidence of the effectiveness of applied control measures. Nevertheless, there is a notable lack of integrated risk analysis approaches that correlate the inherent level of hazard with the real capacity of food safety management systems to prevent, detect, and correct deviations in a timely manner, particularly in food processing units with complex or semi-automated operations (Glevitzky et al., 2025).

The food industry faces multiple challenges and risks, including microbiological contamination, emerging chemical hazards, foreign bodies, human error, process variability, and increasing dependence on organizational and technological factors (Hooda et al., 2025). While HACCP offers undeniable benefits - such as incident prevention, regulatory compliance, and enhanced consumer trust - its limitations become apparent when control performance, automation level, monitoring reliability, and human factors are not explicitly considered (Zarid, 2025).

Within the scientific community, diverging perspectives exist regarding the future evolution of HACCP (Popa et al., 2021), some authors advocate maintaining the simplicity of the methodology to ensure practical applicability, whereas others support the integration of semi-quantitative tools and performance-based indicators to transform HACCP into a dynamic risk management system (Zhao et al., 2025). This ongoing debate underscores the need for methodological solutions that preserve HACCP's fundamental principles while providing a more objective and reproducible assessment of food safety risks.

The main aim of this study is to propose and validate an improved HACCP methodology based on a semi-quantitative risk analysis approach that separates hazard assessment from the evaluation of control measure performance. The original contribution of this work lies in the introduction of a Control Capacity Index (CCI), designed to quantify the effectiveness of food safety management systems by integrating factors such as level of automation, and human factors. The proposed methodology is demonstrated through a case study covering key stages of a food production process.

## MATERIALS AND METHODS

The applicative study aims to validate the functionality of the improved HACCP methodology by comparing traditional qualitative risk classification with the semi-quantitative CCI approach.

### Classical Risk Analysis (HACCP Approach)

In the traditional HACCP methodology, risk evaluation is based on the combined assessment of two fundamental parameters: severity and probability of occurrence (Table 1). This qualitative approach aims to estimate the potential impact of a hazard on consumer health and the likelihood of its presence in the final product. Risk classification is determined by analysing: Severity (S) – the magnitude of the adverse effect caused by the hazard; Frequency/ Probability (F) – the likelihood that the hazard occurs or persists in the final product. Severity reflects the potential consequences for consumer health, ranging from minor quality defects to serious food safety incidents. Frequency represents how often the hazard may occur under normal operating conditions (Marin & Vultur, 2007).

Table 1. Risk Matrix (Decision Diagram)

| Severity | Frequency | | |
|---|---|---|---|
| | Low | Medium | High |
| High | 3 | 4 | 4 |
| Medium | 2 | 3 | 4 |
| Low | 1 | 2 | 3 |

The classical HACCP method uses a decision matrix that combines severity and frequency scores to determine the overall risk class.

Methodologically, the classical HACCP matrix functions primarily as a qualitative, with limited semi-quantitative features, tool built on a conservative structure that tends to favour precautionary risk classification; it provides limited differentiation between intermediate levels of severity and likelihood, does not incorporate an explicit evaluation of control measure effectiveness, and relies on a static assessment of hazards without accounting for process dynamics or operational variability over time.

### Definition of Risk Assessment Components

The proposed methodology is based on four core components used to evaluate food safety risks: Severity (G), Frequency (F), Personnel

Reliability (P), and Automation Level (A). Each component is assigned a numerical score on a three-level scale, allowing the calculation of the CCI.

This structured scoring system enables a semi-quantitative differentiation between intrinsic hazard magnitude and the operational capacity of the system to control that hazard.

a) Severity (G) represents the potential impact of a hazard on product quality and consumer safety. Severity is evaluated using the following scale: 1 – Low: The hazard has a minor effect and does not significantly compromise product quality or safety; 2 – Medium: The hazard may produce noticeable effects and may require corrective actions; 3 – High: The hazard has a severe impact and may lead to product safety compromise or regulatory non-compliance. Severity reflects the intrinsic seriousness of the hazard, independent of control measures.

b) Frequency (F) represents the probability of occurrence of a hazard within the production process. Frequency is classified as: 1 – Low: The hazard occurs rarely under normal operating conditions; 2 – Medium: The hazard occurs occasionally; 3 – High: The hazard occurs frequently and requires continuous monitoring. Frequency captures the likelihood of hazard manifestation before considering control system effectiveness.

c) Personnel Reliability (P) reflects the influence of human factors, including competence, experience, training level, and adherence to operational procedures. The scoring criteria are: 1 – High reliability: Personnel are well-trained, motivated, and consistently comply with established procedures, minimizing risk; 2 – Moderate reliability: Personnel are technically competent but show reduced engagement or inconsistent procedural compliance, potentially affecting control efficiency; 3 – Low reliability: Personnel are insufficiently trained or inexperienced, significantly increasing operational risk. This parameter introduces the human factor as a measurable component of control capacity.

d) Automation Level (A) reflects the degree to which the production process depends on human intervention. The classification is defined as: 1 – Fully automated: The process is highly automated, and risk is minimally influenced by human intervention; 2 – Semi-automated: The process combines automation with operator involvement, and risk may be influenced by human interaction; 3 – Manual process: The process depends entirely on human operation, increasing variability and potential risk. Automation level quantifies technological control capacity and its impact on risk stability.

These four parameters form the analytical basis for calculating the CCI, enabling a structured and semi-quantitative assessment of both hazard intensity and control system performance within the food safety management framework.

**Mathematical Formulation of the CCI**

The CCI was developed to integrate intrinsic hazard characteristics with operational control performance into a single semi-quantitative indicator. The model combines hazard severity and occurrence probability with human and technological control factors, enabling a more comprehensive risk evaluation framework. The CCI is defined as:

$$CCI = (G \times F) \times (1 + A + P)$$

where: G represents hazard severity; F - frequency (probability of occurrence); P - personnel reliability; A - the level of automation. The model is structured in two distinct components:

a) Intrinsic Risk Component (G × F). The product of severity and frequency represents the baseline hazard intensity. This component reflects the inherent risk level independent of control measures.

b) Control Adjustment Component (1 + A + P). The additive term adjusts the intrinsic risk according to system control capacity. Higher values of P (lower personnel reliability) increase overall risk. Higher values of A (lower automation level) increase process variability and risk exposure. The constant "1" ensures that intrinsic risk remains present even under optimal control conditions.

This multiplicative structure allows differentiation between structural hazard magnitude and operational control performance.

**CCI Risk Classification and Interpretation**

The resulting CCI values are interpreted according to the following intervals: 3-20: Low Risk. Risks are considered controlled and manageable through standard operational procedures and routine monitoring. 21-36: Medium Risk. Risks require enhanced

supervision, periodic corrective actions, and performance verification measures. 37-63: High Risk. Risks demand immediate intervention, strengthened control mechanisms, and potential redesign of the process or control strategy.

This classification enables quantitative prioritization of critical stages and supports dynamic decision-making within the food safety management system. Unlike traditional qualitative HACCP matrices, the CCI provides numerical differentiation that facilitates monitoring over time and evaluation of improvement strategies (Mitrea et al., 2003).

## APPLICATIVE STUDY

### Comparative Risk Analysis – Classical HACCP vs. CCI

Table 2 presents a comparative assessment of selected representative stages in the bread production process, aiming to contrast the qualitative hazard classification provided by the classical HACCP matrix with the semi-quantitative CCI. This comparison highlights the differences in residual risk evaluation arising from personnel reliability and automation levels, illustrating how operational controls modulate the overall risk beyond intrinsic hazard severity.

Table 2. Comparative Risk Assessment – Bread Production Stages

| Production Stage | Main Hazards | Classical | Classical Interpretation | CCI | CCI Interpretation |
|---|---|---|---|---|---|
| Flour Reception | Microbiological contamination, damaged packaging | 3 | High | 24 | Medium |
| Flour Storage | Mold, insect infestation | 3 | High | 36 | Medium |
| Sieving | Foreign bodies, contamination | 3 | High | 30 | Medium |
| Mixing | Non-uniform dough, contamination | 3 | High | 20 | Low |
| Baking | Undercooked products, microbiological risk | 3 | High | 12 | Low |
| Distributio n | Contamination during transport | 3 | High | 12 | Low |

***Raw Material Stages (Reception and Storage)****:* Classical HACCP classifies all raw material stages as high risk. In contrast, the CCI framework reduces the risk to medium, reflecting the mitigating influence of personnel and automation. This demonstrates that control factors such as training and monitoring can meaningfully lower residual risk even when intrinsic hazards are high.

***Processing Stages (Mixing, Baking)****:* While classical HACCP assigns uniformly high risk due to hazard severity, CCI shows risk levels reduced to low or medium, accounting for partial automation and trained personnel. This indicates that operational management significantly mitigates risk, and that the classical matrix tends to overestimate hazards.

***Post-Processing Stages (Distribution)****:* Both classical HACCP and CCI show lower risk in these stages, but CCI introduces quantitative differentiation (e.g., CCI = 12–16). This enables more precise monitoring and prioritization over time, rather than a simple binary classification.

The classical HACCP matrix offers a conservative, qualitative snapshot that is useful for regulatory compliance and initial hazard identification.

The CCI framework integrates operational control factors (Personnel and Automation), allowing numerical differentiation, dynamic monitoring, and more precise prioritization of preventive actions. The observed discrepancies underscore the added value of semi-quantitative assessment, particularly in production stages with strong monitoring or partial automation.

### Sensitivity Analysis of the CCI Model

A one-factor-at-a-time (OAT) sensitivity analysis was conducted to evaluate the robustness of the CCI. Each parameter (G, F, P, A) was varied individually by ±1 unit while keeping the others constant. The resulting CCI values and percentage changes were calculated as:

$$\Delta\% = (CCI_{modified} - CCI_{initial}) / CCI_{initial} \times 100$$

Using the initial values of G = 3, F = 1, P = 2, and A = 1, the CCI calculation proceeds as follows: $CCI_i = (3 \times 1) \times (1 + 2 + 1) = 12$.

Table 3 presents the sensitivity analysis of baking parameters on the CCI index, highlighting how individual variations of each parameter affect the final value and the percentage difference compared to the reference value.

Table 3. Sensitivity Analysis - Baking

| Parameter | Initial Value | Value (±1) | Applied CCI Formula | Final CCI | Difference | Δ% |
|---|---|---|---|---|---|---|
| Baseline | G=3,F=1,P=2,A=1 | — | (3×1)×(1+2+1) | 12 | 0 | 0 |
| G | 3 | 2 | (2×1)×(1+2+1) | 8 | −4 | −33.3 |
| G | 3 | 4* | (4×1)×(1+2+1) | 16 | +4 | +33.3 |
| F | 1 | 0* | (3×0)×(1+2+1) | 0 | −12 | −100 |
| F | 1 | 2 | (3×2)×(1+2+1) | 24 | +12 | +100 |
| P | 2 | 1 | (3×1)×(1+1+1) | 9 | −3 | −25 |
| P | 2 | 3 | (3×1)×(1+3+1) | 15 | +3 | +25 |
| A | 1 | 0* | (3×1)×(1+2+0) | 9 | −3 | −25 |
| A | 1 | 2 | (3×1)×(1+2+2) | 15 | +3 | +25 |

*Values 0 or 4 are hypothetical for sensitivity testing beyond the 1-3 scale.

Frequency (F) is the dominant driver of CCI, and a baseline low frequency (F = 1) makes the process highly sensitive, so any increase effectively doubles the risk. Severity (G) retains a proportional impact of ±33.3%, directly influencing the baseline hazard, while Personnel (P) and Automation (A) exert a moderate influence of ±25%, highlighting that managerial control can meaningfully reduce residual risk in partially automated stages. The baking stage exemplifies operational sensitivity: although intrinsic hazards are moderate, deviations in process control or monitoring produce disproportionate effects on overall risk.

Table 4. Key Insights

| Parameter | Influence Type | Managerial Leverage |
|---|---|---|
| Frequency (F) | Structural × operational | High |
| Severity (G) | Structural | Moderate |
| Personnel (P) | Operational | Moderate |
| Automation (A) | Operational | Moderate |

Table 4 summarizes the key insights regarding the influence of baking parameters on performance and the corresponding level of managerial control for each.

For safety-critical stages such as baking, maintaining a low frequency of deviations is essential. Personnel training and partial automation offer actionable levers to stabilize risk without altering intrinsic hazard characteristics. The CCI model clearly highlights where monitoring and control efforts should be concentrated.

## DISCUSSIONS

The sensitivity analysis confirms that the CCI model behaves multiplicatively with respect to intrinsic hazard magnitude, that control parameters gain strategic importance in low-frequency environments, and that the framework effectively distinguishes between structural and operational vulnerability.

The results show that distinguishing between inherent risk and residual risk enables clearer hazard prioritization and more accurate identification of critical control points.

The proposed HACCP–CCI framework transforms traditional hazard classification into a dynamic, performance-sensitive evaluation system. By separating intrinsic hazard from control capacity, the model enables evidence-based prioritization, resource optimization, continuous improvement in alignment with ISO 22000, and enhanced managerial decision-making transparency. Unlike classical qualitative matrices, the CCI approach introduces measurable elasticity, scalability, and analytical depth while preserving operational simplicity.

In the context of food safety management, HACCP remains the foundational risk assessment framework mandated by regulatory authorities worldwide for systematic identification, evaluation, and control of hazards linked to food production processes (Rizzo et al., 2025). Its qualitative or semi-quantitative nature has driven researchers and practitioners to explore alternative or complementary methodologies that enhance prioritization, detection capability, and continuous improvement (Marhavilas, 2011).

One commonly integrated method is Failure Mode and Effects Analysis (FMEA), originally developed in engineering but increasingly applied in food systems for risk identification and quantification (Li et al., 2023). FMEA systematically reviews potential failure modes within a process and ranks them based on severity, occurrence, and detectability, often yielding a Risk Priority Number (RPN) that can guide corrective actions. Studies have shown that pairing FMEA with HACCP can deepen analytical insight: for instance, in edible-coated orange processing, both a qualitative risk matrix and FMEA identified critical hazards, but

FMEA provided additional emphasis on the detection capability of controls, thus offering enhanced prioritization of failure modes and validation of hazard analyses (Segovia Bravo, 2026). In pastry processing and other food production contexts, FMEA has been integrated alongside ISO 22000 standards to quantify processing risks and monitor the effectiveness of control actions. The application of FMEA allowed identification of the most significant failure modes and demonstrated that corrective measures could substantially reduce RPN values, reinforcing its role as a complementary tool in structured food safety management systems (Varzakas, 2011; Lee et al., 2021). Another study on ready-to-eat vegetable processing found that FMEA combined with cause-and-effect analysis identified key high-risk stages, and subsequent corrective measures brought RPN values below acceptable thresholds, corroborating the method's utility in structured risk assessment (Varzakas & Arvanitoyannis, 2009).

Beyond FMEA, continuous improvement methodologies like Kaizen and Lean principles are increasingly used to support risk assessment frameworks (Díaz Reza et al., 2025). Although not risk assessment tools per se, Kaizen emphasizes incremental, data-driven problem solving and waste elimination across the value chain, thereby enhancing process stability and quality outcomes (Lizarelli et al., 2025). In food safety contexts, Kaizen has been proposed as a means to strengthen HACCP implementation by fostering an organizational culture oriented toward systematic improvement of controls and preventive measures throughout production and distribution stages (Mureşan et al., 2020). A specific application of Kaizen principles to food safety quality management from wheat to bread illustrates how continuous improvement techniques can reinforce analytical frameworks by focusing on root causes and process optimization, leading to safer and more efficient operations (Hill, 2014).

The results obtained in this study are consistent with existing literature on semi-quantitative and hybrid food safety risk assessment approaches (Arvanitoyannis & Varzakas, 2008; Soman & Raman, 2016; Trafialek & Kolanowski, 2014; Shirani & Demichela, 2015; Surareungchai et al., 2022). In particular, the observed dominance of frequency and the significant role of operational factors such as personnel reliability and automation align with findings reported in FMEA-based HACCP extensions and human reliability studies in food production systems. Moreover, the demonstrated benefit of separating intrinsic hazard from residual risk confirms previous evidence that integrated frameworks improve hazard prioritization and support more effective control strategies. These similarities strengthen the validity of the proposed HACCP–CCI model and highlight its applicability within modern risk-based food safety management systems.

Comparatively, standard risk matrices like the classical HACCP chart provide a qualitative baseline for hazard classification, which is accessible, easy to interpret, and widely mandated in food safety legislation (Popa et al., 2023). In contrast, methods such as FMEA add granularity by examining failure detection capability and supporting semi-quantitative prioritization, while Kaizen and Lean tools operationalize ongoing control improvements rather than discrete hazard ranking (Gomaa et al., 2025). These approaches complement rather than replace HACCP; in integrated food safety management systems, combining HACCP with FMEA, Ishikawa diagrams, Pareto analysis, and continuous improvement tools has been shown to result in more robust hazard identification, validation of control measures, and actionable performance metrics (Lee et al., 2021).

The literature suggests that while classical HACCP remains central due to its regulatory acceptance and preventive orientation, the integration of FMEA and continuous improvement methodologies enhances the depth, responsiveness, and operational relevance of risk assessment in modern food production systems. These hybrid approaches align with holistic risk management standards such as ISO 22000, which emphasize both hazard analysis and performance evaluation throughout the supply chain (Szczyrba & Ingaldi, 2024).

## CONCLUSIONS

The semi-quantitative HACCP–CCI framework improves risk discrimination compared to the classical HACCP matrix by integrating human

reliability and automation levels. This allows a distinction between intrinsic hazard magnitude and residual risk after operational controls, shifting HACCP from a static compliance tool into a dynamic risk management system aligned with ISO 22000 and Codex Alimentarius requirements and supportive of continuous improvement in the agri-food sector.

Sensitivity analysis highlights stage-specific behaviour: intrinsic hazard parameters dominate in flour storage, while operational factors such as personnel reliability and automation have greater influence in baking. This enables targeted interventions where they are most effective, optimizing monitoring, training, and automation efforts.

The HACCP–CCI model provides quantitative rigor, actionable insight, and alignment with ISO 22000 and Codex Alimentarius. It supports evidence-based prioritization, continuous improvement, and enhanced food safety governance in the agri-food sector.

The present study is based on a semi-quantitative modelling approach and relies on assumed parameter ranges for human reliability, automation levels, and hazard classification. As such, the results may be sensitive to the quality and representativeness of input data. In addition, the HACCP–CCI framework was not validated on large-scale industrial datasets, which may limit its generalizability across different agri-food sectors and production environments.

Future work should focus on validating the HACCP–CCI model using real industrial case studies and large-scale empirical datasets across different food production systems. Further research could also explore the integration of real-time monitoring technologies, such as IoT-based sensors and machine learning approaches, to dynamically update risk parameters. Additionally, extending the model to incorporate economic cost analysis and supply chain variability could further enhance its practical applicability and decision-support capability.

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