

Original Article

Readiness Analysis of ISO 22000:2018 Implementation at Rumah Tempe Indonesia, Bogor: Clauses 9 and 10

Alya Maysha Safina, Hesti Ayuningtyas Pangastuti*

Departement of Food Technology, Faculty of Industrial Technology, Sumatera Institute of Technology, Lampung Selatan, 35365, Indonesia

* Corresponding email: hesti.pangastuti@tp.itera.ac.id

Abstract: The implementation of an effective food safety management system (FSMS) is essential to ensure product safety and to meet international standards in the food industry. This study aimed to evaluate the readiness of Rumah Tempe Indonesia (RTI), Bogor, in implementing ISO 22000:2018, with particular emphasis on Clause 9 (Performance Evaluation) and Clause 10 (Improvement). A qualitative case study approach was employed based on ISO 22000:2018 requirements. Data were collected through document review, direct observation, and informal interviews with relevant personnel. The results indicated that RTI has implemented several foundational elements of an FSMS, including hazard analysis documentation and procedures for handling nonconforming products. However, the performance evaluation system has not yet been fully established, as evidenced by incomplete monitoring records, the absence of scheduled internal audits, and the lack of formal management review practices. Furthermore, although continual improvement initiatives have been initiated, documentation and verification of corrective actions remain inconsistent. Overall, RTI demonstrates partial readiness for ISO 22000:2018 certification. Strengthening documentation, formalizing performance evaluation processes, and enhancing top management involvement are recommended to improve FSMS effectiveness and support continual improvement.

Keywords: continous improvement, factory, iso 22000, tempeh

INTRODUCTION

The global food industry is currently undergoing rapid transformation driven by changes in consumer lifestyles, increasing health awareness, and growing demands for environmental sustainability. In this context, plant-based protein products have gained substantial attention, particularly among young and urban consumers worldwide. Fermented soybean products, such as tempe, are increasingly recognized not only as traditional foods but also as functional foods with potential health benefits, aligning well with global trends toward sustainable and nutritious diets (Ahnman-Winarno et al., 2021).

Indonesia plays a strategic role in the global soybean-based food sector, as tempe represents one of the country's most distinctive fermented food products. Despite its strong domestic demand, Indonesia remains highly dependent on imported soybeans. According to national statistics, soybean imports reached approximately 2.16 million tons, valued at around USD 1.15 billion during January–September 2024, reflecting both the scale of consumption and the importance of soybean-based products in the Indonesian food system [2]. Tempe is considered a flagship product due to its high protein content, dietary fiber, essential amino acids, and bioactive compounds resulting from fermentation.

Tempe is a traditional Indonesian fermented food produced through the fermentation of dehulled soybeans using molds of the genus *Rhizopus* [3]. The production involves multiple processing stages, including soaking, dehulling, inoculation, fermentation, and storage, which are highly dependent on environmental conditions and process control. As a result, tempe production is susceptible to microbial contamination, process variability, and product inconsistency if not properly managed. Such characteristics require not only the application of hazard control measures but also a well-established food safety management system (FSMS) capable of systematic monitoring, performance evaluation, and continuous improvement. In this context, the readiness of food producers to implement ISO 22000:2018 becomes critical, particularly in ensuring that evaluation and improvement mechanisms are effectively established to maintain food safety and process consistency.

With the increasing global demand for healthy and sustainable foods, tempe has significant potential to be developed as a competitive export commodity. However, successful internationalization of traditional fermented foods requires not only nutritional and sensory acceptance but also strict compliance with international food safety and quality standards. Food safety incidents, inconsistent product quality, and inadequate hygiene practices remain critical barriers for small- and medium-scale traditional food producers seeking access to global markets.

Rumah Tempe Indonesia (RTI) was established as a pioneer in hygienic tempe production in Indonesia, aiming to improve the image of tempe as a safe, high-quality, and environmentally responsible food product. RTI has positioned itself as a model for traditional tempe producers by implementing improved sanitation, standardized processing, and quality control systems. The tempe produced by RTI has obtained Hazard Analysis and Critical Control Points (HACCP) certification from an accredited certification body and complies with the Indonesian National Standard for tempe quality (SNI 3144-3:2015). These achievements indicate RTI's commitment to food safety and quality assurance at the national level.

Nevertheless, for tempe products to compete in international markets, additional challenges must be addressed, particularly those related to product consistency, process hygiene, traceability, and compliance with food safety regulations of importing countries. While HACCP provides a preventive approach to identifying and controlling critical hazards, it does not fully encompass the broader management system elements required for global supply chains. In this regard, the implementation of ISO 22000:2018, an internationally

recognized Food Safety Management System (FSMS) standard, represents a strategic step forward.

ISO 22000:2018 integrates the principles of HACCP with prerequisite programs and a management system approach aligned with risk-based thinking and continuous improvement. Structurally, the standard adopts a High-Level Structure (HLS) consisting of ten interrelated clauses, where Clauses 1 to 3 provide the scope, normative references, and terms and definitions. Clause 4 addresses the organizational context, Clause 5 emphasizes leadership and top management commitment, Clause 6 focuses on planning including risk-based thinking and food safety objectives, and Clause 7 covers support processes such as resources, competence, and communication. Clause 8 represents the operational core, including prerequisite programs (PRPs), hazard analysis, and hazard control plans. Subsequently, Clauses 9 (Performance Evaluation) and 10 (Improvement) function as evaluation and improvement mechanisms to ensure the effectiveness and continual development of the FSMS. However, Clauses 9 and 10 are often less rigorously implemented than operational control requirements, particularly in small and medium-sized food enterprises, as they rely heavily on systematic evaluation, documentation, and strong management commitment, thereby highlighting the importance of focusing specifically on their implementation.

The implementation of ISO 22000:2018 requires organizations not only to establish preventive food safety controls but also to ensure the effectiveness and sustainability of the food safety management system (FSMS) through systematic evaluation and improvement. In this context, ISO 22000 Clause 9 (Performance Evaluation) plays a critical role in assessing FSMS performance through monitoring and measurement activities, internal audits, and management review, providing evidence-based input for decision-making. Furthermore, ISO 22000 Clause 10 (Improvement) emphasizes the organization's responsibility to manage nonconformities, implement corrective actions, and drive continual improvement to enhance the conformity, adequacy, and effectiveness of the FSMS. Despite their strategic importance, these two clauses are often less thoroughly implemented compared to operational control requirements, particularly in small and medium-sized food enterprises. Therefore, this study focuses on evaluating the implementation and readiness of Clause 9 (Performance Evaluation) and Clause 10 (Improvement) at Rumah Tempe Indonesia, aiming to identify challenges, and opportunities for strengthening FSMS effectiveness in alignment with ISO 22000:2018 requirements.

Despite the growing importance of food safety management systems, studies examining the implementation of ISO 22000:2018 in traditional fermented foods, particularly tempe, remain limited. Existing research has largely focused on general compliance or prerequisite programs, while comprehensive evaluations of specific clauses especially Clauses 9 (Performance Evaluation) and 10 (Improvement) are rarely conducted in a detailed and systematic manner. This gap is even more evident in small- and medium-scale enterprises, where resource limitations and informal practices often hinder structured monitoring and continuous improvement processes. Therefore, assessing the readiness of Rumah Tempe Indonesia for the implementation of ISO 22000:2018 is crucial to identify existing gaps, strengths, and improvement opportunities within its current food safety practices. Such an assessment is expected to contribute not only to the enhancement of RTI's competitiveness in the global market but also to provide valuable insights for the broader tempe industry and other traditional fermented food producers in developing countries seeking international market access.

MATERIALS AND METHODS

Materials and Methods

This study employed a qualitative case study approach to assess the readiness of Rumah Tempe Indonesia (RTI), Bogor, in implementing a food safety management system (FSMS) based on ISO 22000:2018. Data collection was conducted between 2-30 June 2025. The study evaluated the conformity of RTI's existing practices with selected ISO 22000 clauses, particularly Clause 9 (Performance Evaluation) and Clause 10 (Improvement), enabling an in-depth assessment of organizational practices, documentation, and operational controls.

The study was conducted at Rumah Tempe Indonesia (RTI), a tempe production facility located in Bogor, Indonesia. Data were collected through observations, document analysis, and interviews with four key managerial personnel, namely the Quality Assurance Manager, Food Regulatory Officer, PPIC Manager, and HRGA Manager. These roles were selected to represent cross-functional perspectives in food safety management, including quality control, regulatory compliance, production planning, and organizational support systems. The assessment was conducted using a clause-based checklist developed from ISO 22000:2018 requirements. Each requirement under Clause 9 and Clause 10 was evaluated based on the presence of documented information, evidence of implementation, and consistency of application. The level of conformity was categorized as:

- **Conformity:** Requirement fully met and supported by documented evidence
- **Partial conformity:** Requirement partially met but lacking full documentation or consistent implementation
- **Non-conformity:** Requirement not met or no evidence available

Data Analysis

Data analysis was performed using qualitative descriptive analysis by comparing information obtained from document reviews, observations, and interviews against ISO 22000:2018 requirements. Each clause (Clause 9 and Clause 10) was evaluated based on three sub-criteria, with equal weight assigned to each. A finding was classified as conformity if all three sub-criteria were fulfilled. Partial conformity was assigned when one or two sub-criteria were fulfilled, indicating incomplete implementation, while non-conformity was defined as the absence of all required sub-criteria.

The level of readiness for ISO 22000:2018 implementation was determined based on the proportion of conformity and partial conformity findings across the evaluated clauses. A higher proportion of conformity findings indicates a higher level of readiness, whereas the presence of non-conformities reflects gaps requiring improvement. The overall assessment was then interpreted qualitatively to identify strengths, gaps, and priority areas for improving FSMS implementation at RTI.

RESULT AND DISCUSSION

Rumah Tempe Indonesia (RTI) is a hygienic tempeh producer that demonstrates a strong commitment to food safety and product quality, as reflected by its certifications, including BPOM distribution permit, Halal certification, compliance with SNI 3144:2015, and HACCP. These certifications indicate that RTI has implemented essential prerequisite programs and hazard control measures, forming a solid foundation for food safety assurance. However, to achieve a more integrated and internationally recognized system, RTI needs to prepare for ISO 22000:2018 implementation, which extends beyond hazard control by

incorporating management system elements such as organizational context, leadership, performance evaluation, and continual improvement.

The readiness analysis indicates that RTI is progressing toward the adoption of an internationally standardized FSMS. Nevertheless, several critical elements require further strengthening to fully comply with ISO 22000:2018 requirements. These include the systematic development of FSMS documentation, such as food safety manuals, procedures, and records aligned with ISO clauses; identification and evaluation of internal and external issues that may affect food safety objectives; and the formal establishment of food safety policies and measurable objectives consistent with the organization's strategic direction (ISO, 2018).

In addition, ISO 22000:2018 places strong emphasis on leadership and organizational accountability, requiring top management to actively demonstrate commitment to food safety culture and system effectiveness. RTI must also implement a structured internal audit program to periodically assess conformity and effectiveness of the FSMS, followed by management review meetings to evaluate performance and define improvement actions. The application of corrective actions and continual improvement mechanisms is essential to ensure long-term system sustainability and resilience against emerging food safety risks (Wallace et al., 2018).

Overall, the existing certifications held by RTI provide a strong platform for transitioning toward ISO 22000:2018. With targeted improvements in management system documentation, risk-based planning, internal auditing, and performance evaluation, RTI is well positioned to achieve ISO 22000 certification and enhance its competitiveness and credibility in both national and international markets. Sudah The detailed results of the readiness analysis are presented in Table 1 for Clause 9 Performance Evaluation and Table 2 for Clause 10 Corrective Action.

Table 1 Readiness Analysis of ISO 22000:2018 Clause 9 Performance Evaluation

No	Clauses	Readiness	Problem and Suggestions
9.1	Monitoring, Measurement, Analysis and Evaluation		
9.1.1	General		
	The organization shall determine:		
	a) what needs to be monitored and measured;		
	b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;		
	c) when the monitoring and measurement shall be performed;		
	d) when the results from monitoring and measurement shall be analyzed and evaluated;		
	e) who shall analyze and evaluate the results from monitoring and measurement.		
	The organization shall retain appropriate documented information as evidence of the results.		
		Partial conformity	Based on the available records reviewed, the completed check sheets were not directly verified, not all required parameters were filled in, and the soybean soaking check sheets were left incomplete. This condition requires attention and immediate on-site verification to ensure that the production process is carried out in accordance with the established standards and that the records can be effectively used for traceability, problem analysis, and evaluation to support continual improvement of the food safety management system. In addition, there is no updated sanitation check sheet or sanitation summary record (as of May 2025) available for analysis and evaluation. Consequently,

No	Clauses	Readiness	Problem and Suggestions
9.1.2	The organization shall evaluate the performance and the effectiveness of the FSMS. Analysis dan Evaluation The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement, including the results of verification activities related to PRPs and the hazard control plan (see 8.8 and 8.5.4), internal audits (see 9.2), and external audits. The analysis shall be carried out: a) to ensure that the overall performance of the system meets the planned arrangements and the FSMS requirements established by the organization; b) to identify the need for updating or improving the FSMS; c) to identify trends that indicate a higher incidence of potentially unsafe product or process failures; d) to establish information for planning the internal audit programme related to the status and importance of the areas to be audited; e) to provide evidence that corrections and corrective actions are effective. The results of the analysis and the resulting activities shall be retained as documented information. These results shall be reported to top management and used as input to management review (see 9.3) and to the updating of the FSMS (see 10.3). NOTE — Methods to analyze data can include statistical techniques.		there is insufficient documented evidence to demonstrate that sanitation activities have been effectively implemented and are capable of maintaining the effectiveness of the food safety management system. Suggestions: ☐ Implement mandatory verification of all monitoring check sheets and ensure all required parameters are fully completed before record filing. ☐ Conduct regular on-site verification of critical processes, including soybean soaking, to ensure compliance with established standards. ☐ Establish and maintain updated sanitation check sheets and sanitation summary records as objective evidence to support FSMS effectiveness and continual improvement.
9.2	Internal Audit		
9.2.1	The organization shall conduct internal audits at planned intervals to provide information on whether the FSMS:	Non-conformity	The Internal Audit SOP of Rumah Tempe Indonesia does not specify planned time intervals for conducting internal

No	Clauses	Readiness	Problem and Suggestions
9.2.2	a) conforms to: - the organization's own requirements for its FSMS; - the requirements of this document; b) is effectively implemented and maintained. The organization shall : - plan, establish, implement and maintain an audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the FSMS, and the results of monitoring, measurement and previous audits; - define the audit criteria and scope for each audit; - select competent auditors and conduct audits to ensure objectivity and the impartiality of the audit process; - ensure that the audit results are reported to the food safety team and relevant management; - retain documented information as evidence of the implementation of the audit programme and the audit results; - make the necessary corrections and take the necessary corrective actions within the agreed timescale; - determine whether the FSMS meets the intent of the food safety policy (see 5.2) and the FSMS objectives (see 6.2). Follow-up activities by the organization shall include the verification of the actions taken and the reporting of verification results.		audits to ensure that the food safety management system conforms to applicable requirements and is effectively maintained. Furthermore, RTI does not have documented internal audit reports for audits that have been conducted. Suggestion: During the implementation of internal audits, audit team members shall be independent of the production team and the management directly responsible for fresh tempe production in order to ensure objectivity and impartiality of the audit process.
9.3	Management Review		Rumah Tempe Indonesia has not yet established a documented and structured food safety management system (FSMS) performance evaluation system. Internal audits have not been conducted on a regular basis, and the results of performance evaluations have not been documented as inputs
9.3.1	General Top management shall review the organization's FSMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.	Non-conformity	
9.3.2	Management Review Inputs The management review shall consider:		

No	Clauses	Readiness	Problem and Suggestions
	a) the status of actions from previous management reviews; b) changes in external and internal issues that are relevant to the FSMS, including changes in the organization and its context (see 4.1); c) information on the performance and effectiveness of the FSMS, including trends in: 1. the results of system updating activities (see 4.4 and 10.3); 2. the results of monitoring and measurement; 3. analysis of the results of verification activities related to PRPs and the hazard control plan (see 8.8.2); 4. nonconformities and corrective actions; 5. audit results (internal and external); 6. inspections (e.g. regulatory, customer); 7. the performance of external providers; 8. the review of risks and opportunities and the effectiveness of actions taken to address them (see 6.1); 9. the extent to which FSMS objectives have been met; d) the adequacy of resources; e) any emergency situations, incidents (see 8.4.2) or withdrawals/recalls (see 8.9.5) that have occurred; f) relevant information obtained through external communication (see 7.4.2) and internal communication (see 7.4.3), including requests and complaints from interested parties; g) opportunities for continual improvement.		for decision-making or system improvement. In addition, there is no formal management review agenda that addresses the achievement of food safety objectives, audit results, customer feedback, or resource requirements. Suggestion: To fulfill the requirements of this clause, it is recommended that RTI establish a scheduled and documented internal audit program, prepare internal audit reports, and follow up on the risks and opportunities identified during audit activities.
9.3.3	Management Review Outputs The outputs of the management review shall include:		

No	Clauses	Readiness	Problem and Suggestions
	a) decisions and actions related to opportunities for continual improvement; b) any need for updates and changes to the FSMS, including resource needs and revisions to the FSMS food safety policy and objectives. The organization shall retain documented information as evidence of the results of management review.		
	Total		
	Non conformity		2
	Partial conformity		1
	Conformity		0
	Overall Clause 9		Non conformity

Table 2 Readiness Analysis of ISO 22000:2018 Clause 10 Corrective Action

No	Clauses	Readiness	Problem and Suggestions
10.1	Nonconformity and Corrective Action		
10.1.1	When a nonconformity occurs, the organization shall: a) react to the nonconformity and, as applicable: 1. take action to control and correct it; 2. deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: 1. reviewing the nonconformity; 2. determining the cause(s) of the nonconformity; 3. determining whether similar nonconformities exist, or could potentially occur; c) implement the necessary actions; d) review the effectiveness of any corrective action taken; e) make changes to the FSMS, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	Partial conformity	Rumah Tempe Indonesia has developed a hazard analysis document as part of its efforts to identify and manage nonconformities. However, nonconformity reporting mechanisms and follow-up verification activities have not yet been implemented consistently or documented within an integrated system. Suggestion: To fulfill the requirements of this clause, RTI is advised to establish formal procedures for nonconformity management and reporting, and to systematically document all corrective actions, verification of results, and evaluation activities.

No	Clauses	Readiness	Problem and Suggestions
10.1.2	The organization shall retain documented information as evidence of: a) the nature of the nonconformities and any subsequent actions taken; b) the results of any corrective action.		
10.2	Continual Improvement The organization shall continually improve the suitability, adequacy and effectiveness of the FSMS. Top management shall ensure that the organization continually improves the effectiveness of the FSMS through the use of communication (see 7.4), management review (see 9.3), internal audits (see 9.2), analysis of the results of verification activities (see 8.8.2), validation of control measures and combinations of control measures (see 8.5.3), corrective actions (see 8.9.3), and updating of the FSMS (see 10.3).	Partial conformity	Rumah Tempe Indonesia has partially improves the effectiveness of the FSMS through some documents and events. However, nonconformity reporting mechanisms and follow-up verification activities have not yet been implemented consistently or documented within an integrated system. Suggestion: Establishing a continual improvement plan and maintaining formal documented records of the follow-up actions taken.
10.3	Updating of the Food Safety Management System Top management shall ensure that the FSMS is continually updated. To achieve this, the food safety team shall evaluate the FSMS at planned intervals. The team shall consider whether there is a need to review the hazard analysis (see 8.5.2), the established hazard control plan (see 8.5.4), and the established PRPs (see 8.2). Updating activities shall be based on: a) inputs from communication, both external and internal (see 7.4); b) inputs from other information concerning the suitability, adequacy and effectiveness of the FSMS; c) outputs from the analysis of the results of verification activities (see 9.1.2); d) outputs from management review (see 9.3). The updating activities of the FSMS shall be retained as documented information and reported as input to management review (see 9.3).	Conformity	

No	Clauses	Readiness	Problem and Suggestions
	Total		
	Non conformity		0
	Partial conformity		2
	Conformity		1
Overall Clause 10			Partial conformity

Clause 9: Performance Evaluation

Clause 9 of ISO 22000:2018 addresses the requirements for performance evaluation of the food safety management system (FSMS), including monitoring and measurement activities, internal audit implementation, and management review. Performance evaluation is essential to determine whether organizational processes and controls are functioning as intended, meeting established objectives, and providing reliable input for continual improvement of the FSMS [5].

At Rumah Tempe Indonesia (RTI), a documented and structured performance evaluation system for the FSMS has not yet been fully established. Based on the available records reviewed, several monitoring documents, such as production and sanitation check sheets, were not consistently completed or verified. Some required parameters were left unfilled, and soybean soaking check sheets for certain production dates were incomplete. This condition indicates weaknesses in monitoring and measurement activities, which may limit the effectiveness of traceability, problem analysis, and data-based evaluation required under Clause 9.1.

In addition, no updated sanitation check sheets or sanitation summary records (as of May 2025) were available for review. The absence of such documented information limits the organization's ability to analyze sanitation performance and demonstrate that prerequisite programs (PRPs) are effectively implemented and maintained. Consistent and verified records are a fundamental requirement for performance evaluation and serve as objective evidence of FSMS effectiveness [6], [7].

Regarding internal audits (Clause 9.2), the Internal Audit SOP of RTI does not specify planned audit intervals, which are required to ensure that the FSMS conforms to both organizational requirements and ISO 22000:2018, and that it is effectively implemented and maintained. Furthermore, RTI does not possess documented internal audit reports, indicating that audit outcomes have not been formally recorded or used as inputs for system evaluation and improvement. ISO 22000 also emphasizes auditor independence; therefore, internal audit personnel should be independent of production activities and management directly responsible for fresh tempe production to ensure objectivity and impartiality of the audit process [8].

With respect to management review (Clause 9.3), RTI has not yet established a formal management review agenda to evaluate FSMS performance. Key inputs such as the achievement of food safety objectives, internal audit results, customer feedback, sanitation performance, and resource adequacy have not been systematically reviewed by top management. Management review is a critical mechanism to ensure that performance evaluation results are translated into strategic decisions and actions for improvement [9].

To fulfill the requirements of Clause 9, RTI is recommended to develop a comprehensive performance evaluation framework that includes: (i) verified and complete monitoring and measurement records; (ii) a scheduled and documented internal audit program with defined scope, criteria, and competent auditors; and (iii) regular management review meetings supported by meeting minutes and performance data. Active involvement of top management in reviewing FSMS performance is essential to ensure that the system operates as planned and continuously improves in response to identified gaps, risks, and opportunities [10].

Clause 9 of ISO 22000:2018 emphasizes the importance of performance evaluation to ensure that the food safety management system (FSMS) operates effectively through monitoring and measurement, internal audits, and management review. Based on the assessment at Rumah Tempe Indonesia (RTI), the implementation of Clause 9 can be categorized as non-conformity, as critical elements of performance evaluation have not been systematically established. Monitoring records, such as production and sanitation check sheets, were found to be incomplete and inconsistently verified, while key documents, including updated sanitation records (as of May 2025), were unavailable. In addition, internal audit practices were not supported by defined audit intervals or documented audit reports, and no formal management review mechanism was identified.

These gaps have significant implications for the effectiveness of the FSMS. Incomplete monitoring records weaken traceability and limit the organization's ability to perform data-driven evaluation and corrective actions. The absence of structured internal audits reduces the organization's capacity to detect system failures and ensure compliance with ISO 22000 requirements. Furthermore, without management review, critical performance data—such as food safety objectives, audit results, and customer feedback—are not translated into strategic decisions. If left unaddressed, these issues may increase the risk of undetected nonconformities, recurring operational failures, and reduced confidence in the reliability of the FSMS.

These findings are consistent with previous studies indicating that inadequate documentation, irregular internal audits, and weak management involvement are among the most common barriers in FSMS implementation, particularly in small and medium-sized food enterprises [6], [7]. ISO 22000 also emphasizes that performance evaluation must be evidence-based and supported by documented information to ensure system transparency and continual improvement [5]. Compared to organizations with mature FSMS implementation, RTI's current condition reflects a gap in integrating monitoring data, audit outcomes, and management review into a cohesive evaluation system.

To address these issues, RTI should establish a structured performance evaluation framework that integrates verified monitoring records, a scheduled and documented internal audit program, and regular management review meetings supported by performance data. Strengthening top management involvement is essential to ensure that evaluation results are effectively translated into improvement actions and strategic decisions.

Clause 10: Improvement

Clause 10 of ISO 22000:2018 addresses requirements related to nonconformity management, corrective actions, and continual improvement of the conformity, adequacy, and effectiveness of the food safety management system (FSMS). This clause emphasizes the organization's responsibility to respond to nonconformities, eliminate their root causes, verify the effectiveness of corrective actions, and continuously improve the FSMS through systematic updates, including hazard analysis review and consideration of internal and external inputs [11], [12].

Based on the assessment conducted at Rumah Tempe Indonesia (RTI), the organization has demonstrated partial compliance with Clause 10. RTI is supported by documented reports related to the handling of nonconforming products and product withdrawal or recall activities. These documents provide initial evidence that RTI has mechanisms to respond to food safety incidents and to implement subsequent actions in accordance with established standard operating procedures (SOPs). The availability of such records is essential to demonstrate control over nonconforming outputs and to ensure consumer protection in the event of food safety risks [6].

In addition, RTI has initiated efforts toward continual improvement by establishing a continual improvement plan. However, the follow-up actions arising from this plan have not yet been consistently documented in a formal and structured manner. ISO 22000 requires that corrective actions and improvement activities be supported by documented information, including records of implementation, verification of effectiveness, and evaluation outcomes, to ensure traceability and systematic learning within the FSMS [11].

Furthermore, RTI has developed a hazard analysis document as part of its preventive approach to food safety management. While this document reflects the organization's awareness of potential food safety hazards, the mechanisms for reporting nonconformities, conducting root cause analysis, and performing follow-up verification have not been fully integrated into a unified FSMS framework. The absence of a consistent and documented nonconformity management system may limit the organization's ability to prevent recurrence of similar issues and to effectively demonstrate continual improvement [13], [14], [15].

To fully comply with Clause 10, RTI is advised to formalize procedures for nonconformity reporting, corrective action implementation, and verification of results. All stages—from identification of nonconformities, execution of corrective actions, verification of effectiveness, to evaluation and system update—should be systematically documented. Such an approach will strengthen traceability, support evidence-based decision-making, and ensure that continual improvement of the FSMS is achieved through a structured and measurable process. Through consistent documentation and integration of improvement activities, RTI can enhance the robustness and long-term effectiveness of its food safety management system.

Clause 10 of ISO 22000:2018 focuses on the organization's ability to manage nonconformities, implement corrective actions, and drive continual improvement of the FSMS. Based on the assessment results, RTI demonstrates partial conformity, as several elements of improvement have been initiated but not yet fully implemented in a systematic and integrated manner. The organization has documented procedures and records related to nonconforming product handling and product recall, indicating the presence of basic response mechanisms. RTI has also developed a continual improvement plan and hazard analysis document, reflecting an initial commitment to preventive and corrective approaches.

However, the implementation of these elements remains incomplete. Follow-up actions from improvement plans are not consistently documented, and there is no integrated system for reporting nonconformities, conducting root cause analysis, and verifying the effectiveness of corrective actions. This lack of structured documentation and integration limits the organization's ability to ensure that corrective actions are effective and that similar issues do not recur. As a result, the FSMS may become reactive rather than preventive, increasing the risk of repeated nonconformities and reducing overall system reliability.

This condition aligns with findings from previous studies, which highlight that partial implementation of corrective action systems particularly the absence of root cause analysis and verification can significantly hinder continual improvement in FSMS [11], [12]. ISO 22000 explicitly requires that organizations maintain documented information for all stages of nonconformity handling and improvement processes to support traceability, accountability,

and organizational learning [13][15]. Compared to fully compliant systems, RTI's current approach lacks integration between hazard analysis, corrective action, and performance evaluation processes.

To achieve full conformity with Clause 10, RTI should formalize a comprehensive nonconformity management system that includes structured reporting, root cause analysis, corrective action implementation, and effectiveness verification. All processes should be consistently documented and integrated into the FSMS to ensure traceability and continuous, measurable improvement.

Overall, based on the evaluation of Clause 9 and Clause 10, Rumah Tempe Indonesia (RTI) cannot yet be considered fully ready for ISO 22000:2018 certification. While the organization has demonstrated initial efforts in establishing food safety practices and improvement mechanisms, critical gaps remain in performance evaluation, internal audit implementation, management review, and the integration of corrective action processes. These shortcomings indicate that the FSMS has not yet been implemented in a fully systematic, consistent, and evidence-based manner as required by ISO 22000:2018. Therefore, RTI is currently at a preparatory stage, requiring significant improvements to achieve full compliance and certification readiness.

CONCLUSION

The evaluation of Clause 9 (Performance Evaluation) and Clause 10 (Improvement) of ISO 22000:2018 indicates that Rumah Tempe Indonesia (RTI) has initiated several elements of a food safety management system (FSMS) but has not yet achieved full conformity with the standard requirements. In Clause 9, the absence of a documented and structured performance evaluation system—evidenced by incomplete and unverified monitoring records, the lack of scheduled internal audits, and the absence of formal management review activities—limits RTI's ability to assess FSMS effectiveness and to use performance data as a basis for systematic improvement.

Similarly, the assessment of Clause 10 shows partial compliance. RTI has demonstrated responsiveness to food safety incidents through documented handling of nonconforming products and product withdrawal or recall activities, as well as the existence of a hazard analysis document and a continual improvement plan. However, deficiencies remain in the consistency and integration of nonconformity reporting, corrective action follow-up, verification of effectiveness, and formal documentation of improvement activities. These gaps may hinder the organization's capacity to prevent recurrence of nonconformities and to demonstrate continual improvement in a structured and measurable manner.

Overall, the findings indicate that Rumah Tempe Indonesia (RTI) is not yet fully ready for ISO 22000:2018 certification, particularly when evaluated based on Clauses 9 and 10. While RTI demonstrates a foundational level of food safety management through existing certifications and initial control practices, significant gaps remain in performance evaluation and improvement processes, including incomplete monitoring records, the absence of structured internal audits and management review, and limited integration of corrective actions. It should be noted that this study focuses specifically on Clauses 9 and 10, while other clauses (Clauses 4–8) were beyond the primary scope of this analysis; therefore, the conclusion reflects a partial assessment of ISO 22000 readiness. Addressing these gaps is essential to strengthen FSMS effectiveness and support progression toward full certification.

ACKNOWLEDGEMENT

The authors would like to express their sincere appreciation to Rumah Tempe Indonesia (RTI), Bogor, for granting access to facilities, documents, and operational data required for this study. The cooperation and openness provided by the management and staff of RTI were invaluable in enabling the assessment and analysis of the implementation and readiness of the food safety management system based on ISO 22000:2018. Their support significantly contributed to the completion of this research.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this article. The authors have no financial, personal, or professional relationships with any parties that could have influenced the outcomes or interpretations of this study.

AUTHOR'S CONTRIBUTION

Alya Maysha Safina: conceptualization, methodology, investigation, formal analysis, writing – original draft. **Hesti Ayuningtyas Pangastuti:** supervision, writing – review & editing.

REFERENCES

- [1] A. D. Ahnan-Winarno, L. Cordeiro, F. G. Winarno, J. Gibbons, and H. Xiao, “Tempe: A semicentennial review on its health benefits, fermentation, safety, processing, sustainability, and affordability,” *Compr Rev Food Sci Food Saf*, vol. 20, no. 2, pp. 1717–1767, Mar. 2021, doi: 10.1111/1541-4337.12710.
- [2] BPS-Statistics Indonesia, “Imports of Soybean by Major Country of Origin, 2017-2024,” <https://www.bps.go.id/en/statistics-table/1/MjAxNSMx/imports-of-soybean-by-major-country-of-origin--2017-2023.html>.
- [3] A. Romulo and R. Surya, “Tempe: A traditional fermented food of Indonesia and its health benefits,” *Int J Gastron Food Sci*, vol. 26, p. 100413, Dec. 2021, doi: 10.1016/j.ijgfs.2021.100413.
- [4] Z. J. Tan, M. F. Abu Bakar, S. Y. Lim, and H. Sutimin, “Nutritional composition and sensory evaluation of tempe from different combinations of beans,” *Food Res*, vol. 8, no. 2, pp. 138–146, Mar. 2024, doi: 10.26656/fr.2017.8(2).088.
- [5] M. J. Hassan, A. A. Alsabbagh, and S. J. Abdel Hussein, “Evaluating the reality of food safety management in accordance with ISO 22000:201 8 and its role in improving supply chain operations,” *SN Business & Economics*, vol. 5, no. 10, p. 157, Sep. 2025, doi: 10.1007/s43546-025-00927-3.

- [6] C. A. Wallace, W. H. Sperber, and S. E. Mortimore, *Food Safety for the 21st Century: Managing HACCP and Food Safety Throughout the Global Supply Chain*. . USA: Wiley-Blackwell, 2018.
- [7] M. Glykas, “Quality management implementation maturity assessment in the food industry: Glykas Quality Compass Assessment on ISO 22000,” *International Journal of Productivity and Quality Management*, vol. 41, no. 3, pp. 289–336, 2024, doi: 10.1504/IJPQM.2024.137320.
- [8] S. Mortimore and C. A. Wallace, *HACCP: A practical approach (3rd ed.)*. . USA: Springer, 2013.
- [9] C. Escanciano and M. Leticia Santos-Vijande, “Implementation of ISO-22000 in Spain: obstacles and key benefits,” *British Food Journal*, vol. 116, no. 10, pp. 1581–1599, Sep. 2014, doi: 10.1108/BFJ-02-2013-0034.
- [10] B. Rihawi, “The impact of ISO 22000: 2018 on food facilities performance with multiple production lines,” *CyTA - Journal of Food*, vol. 22, no. 1, Dec. 2024, doi: 10.1080/19476337.2024.2431281.
- [11] International Organization for Standardization (ISO), *ISO 22000:2018 Food safety management systems — Requirements for any organization in the food chain*. Geneva, 2018.
- [12] E. L. Psomas and D. P. Kafetzopoulos, “HACCP effectiveness between ISO 22000 certified and non-certified dairy companies,” *Food Control*, vol. 53, pp. 134–139, Jul. 2015, doi: 10.1016/j.foodcont.2015.01.023.
- [13] H. Chen, S. Liu, Y. Chen, C. Chen, H. Yang, and Y. Chen, “Food safety management systems based on ISO 22000:2018 methodology of hazard analysis compared to ISO 22000:2005,” *Accreditation and Quality Assurance*, vol. 25, no. 1, pp. 23–37, Feb. 2020, doi: 10.1007/s00769-019-01409-4.
- [14] H. Chen *et al.*, “Implementation of food safety management systems that comply with <scp>ISO</scp> 22000:2018 and <scp>HACCP</scp> : A case study of a postpartum diet enterprise in Taiwan,” *J Food Saf*, vol. 42, no. 2, Apr. 2022, doi: 10.1111/jfs.12965.
- [15] I. Fernández-Segovia, A. Pérez-Llácer, B. Peidro, and A. Fuentes, “Implementation of a food safety management system according to ISO 22000 in the food supplement industry: A case study,” *Food Control*, vol. 43, pp. 28–34, Sep. 2014, doi: 10.1016/j.foodcont.2014.02.042.