



The HACCP Flexibility Approach in Small and Medium-Sized Food Businesses: A Comparison between the European Union and Türkiye

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ABSTRACT

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This study comprehensively examines the implementation of Prerequisite Programs (PRPs) and the Hazard Analysis and Critical Control Points (HACCP) flexibility approach in small and medium-sized food enterprises (SMEs) within the context of legislation implemented in the European Union (EU) and Türkiye. Based on the guidance documents and communications issued by the European Commission and the legal framework in force in Türkiye, the audit, implementation, and evaluation aspects of flexibility applied without undermining HACCP principles are examined. The study examines the role of PRPs and Operational Prerequisite Programs (OPRPs) controls in ensuring food safety in enterprises, determining whether Critical Control Points (CCPs) are limited or not possible; furthermore, it emphasizes the need for a standardized assessment approach to ensure uniformity in implementation during official controls. Based on literature findings and legislative analysis, it was concluded that the HACCP flexibility approach is a feasible and effective model for ensuring food safety in SMEs. It was further concluded that the approach of strengthening PRPs and OPRPs instead of CCPs, aligning the documentation burden with the capacity of the enterprise, and basing audits on actual practices contributes to the sustainable development of food safety culture. In order to better understand the flexibility provisions published in EC 852/2004, EC 853/2004, and other relevant directives/guidelines in Türkiye, and to utilize them in conjunction with sectoral good hygiene practice guides, a control checklist and implementation guide based on the HACCP Flexibility Approach was prepared. Some of these documents were included in this study, and initiatives have been undertaken to share them with the official authority.

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Introduction

Food safety refers to the effective control of foodborne hazards throughout each food supply chain, and the implementation of necessary measures to protect consumers from foodborne health risks (Zhou and Zhiduan, 2022). Preventing foodborne illnesses requires the establishment of scientifically based systematic, sustainable, and implementable food safety management systems. Herein, food safety practices affect direct and indirect effects on individuals' quality of life, as well as on public health, health systems, the national economy, tourism, and trade (Scharff, 2012). According to World Health Organization (WHO) data, approximately 600 million people contract foodborne diseases annually, and approximately 420.000 of these cases result in death. If a food intended for consumption contains unwanted bacteria,

viruses, parasites, or toxic chemicals, it can lead to more than 200 foodborne illnesses. Foodborne infections and intoxications not only cause acute health problems but also result in the loss of healthy life years in the long term, thereby increasing the socio-economic burden on societies (WHO, 2024).

Because they represent many food businesses and operate at the point of direct consumer interaction, small and medium-sized retail food enterprises have a decisive influence on food safety outcomes. The number of SMEs among all food business operators (FBOs) in Türkiye is approximately 84.22% in 2025. These food business activities cover restaurants and cafeterias, catering businesses, bakery production sites, butcher shops, and retail sales points. For these FBOs, compliance with

general and specific hygiene principles (Prerequisite Programs; PRPs), and controlling applications for foodborne hazards is evaluated as a fundamental preventive tool in the protection of public health (OG, 2014; GDFC, 2023).

The prevalence of small and medium-sized food businesses (SMEs) is much more than the other food sectors (e.g., meat and meat processing plants, dairy processing plants, food contact material and equipment manufacturers). In Türkiye, the number of SMEs was 84.22% of all food business operators (FBOs) in 2025. Therefore, the high proportion of small businesses in the sector makes them strategic actors not only economically but also in protecting public health. For these FBOs, compliance with general and specific hygiene principles (Prerequisite Programs; PRPs), and controlling applications for foodborne hazards is evaluated as a fundamental preventive tool in the protection of public health (OG, 2014; GDFC, 2023). For this reason, risk-based official controls, development of Good Hygiene Practices, and flexible and effective HACCP principles must be focused on standard criteria and evaluations.

Within the framework of harmonization with the European Union (EU), with the adoption of the “Law on Veterinary Services, Plant Health, Food and Feed” No. 5996 in 2010, the obligation to establish and implement a food and feed safety system based on Hazard Analysis and Critical Control Points principles was introduced as one of the basic requirements for FBOs (Law No. 5996, Article 29, Paragraph 3) (OG, 2010). Issues regarding the establishment of systems for hazard analysis and the determination of critical control points (CCP) in enterprises are comprehensively addressed in the Regulation on Food Hygiene (OG, 2011a; 2011b), the Procedure for Official Control of Food and Administrative Sanctions (GDFC, 2023), the Regulation on Specific Hygiene Rules for Food of Animal Origin (OG, 2011c), the Regulation Determining Specific Rules for Official Controls on Products of Animal Origin (OG, 2011d), and the Turkish Food Codex Regulation on Microbiological Criteria (OG, 2025).

Guidance documents and communications published by the EU Commission state that flexibility in implementation can be provided without compromising HACCP principles. Law No. 5996 and secondary legislation also allow for flexible applications for SMEs. In the official controls of SMEs, audits consider the HACCP Flexibility Approach, which includes PRPs and the control of foodborne hazards, as the basis, rather than a full HACCP system audit (OG, 2010; GDFC, 2023). However, the absence of a standardized control tool, such as a checklist form and/or a guide for the implementation of this approach, complicates uniformity in application during audits.

It is not a deviation from HACCP principles; rather, it is a form of risk-based and proportionate application clearly defined by legislation (EC 2004; EC 2016). The study reveals that flexibility can only be applied to low-risk activities and provided that PRPs are effective. Literature and EU guidelines indicate that it is the fitness for purpose, not the quantity of records, that determines auditability. The deviation-based recording approach facilitates the

monitoring of food safety performance, particularly in SMEs.

In this study, the HACCP Flexibility Approach has been evaluated in relation to EU legislation, Current laws in Türkiye, and the European Commission’s communications, relevant regulations, and guidelines regarding flexibility applications within HACCP-based food safety management systems for enterprises in which the determination of critical control points is impractical or limited. Practical and applicable suggestions aiming to develop a useful and standardized assessment approach compatible with EU practices, to reduce conceptual uncertainties in audits, to limit interpretation differences among practitioners during official controls, and to contribute to uniformity in implementation have been presented.

A Brief Methodology

This study is based on qualitative document analysis and comparative legal assessment. Primary legal sources were examined, including Regulation (EC) No 852/2004, Regulation (EC) No 853/2004, and the Law No. 5996 on Veterinary Services, Plant Health, Food and Feed, together with related secondary legislation and official guidance documents issued by the European Commission and the Turkish competent authority. A comparative framework was developed to assess similarities and differences between the legislations of EU and Türkiye according to legal requirements of flexibility provisions, scope of PRP and foodborne hazards-based control and official audit methodology.

Conceptual Framework of the HACCP Flexibility Approach

The EU accession negotiations concerning agriculture and fisheries are organized into three chapters: Chapter 11 (Agriculture and Rural Development), Chapter 12 (Food Safety, Veterinary and Phytosanitary Policy), and Chapter 13 (Fisheries). Negotiations under Chapter 12 began in mid-2010. To meet the first of the six opening benchmarks established for this chapter, Law No. 5996 on Veterinary Services, Plant Health, Food and Feed (OG, 2010), in conformity with the relevant EU *acquis*, was enacted as the framework statute to underpin further legislative alignment. A transitional period is provided for establishments to adapt to the new regime. Based on Law 5996, secondary legislation fully transposes the EU Hygiene Package (EC 852/2004, 853/2004, 854/2004, and 882/2004) and substantially harmonizes EU farm animal welfare requirements (Directive 98/58/EC), calf protection (Directive 2008/119/EC), and laying-hen protection (Directive 99/74/EC) was enacted in 2011 (Ropkins and Beck, 2000; OG, 2010; Schleinng, 2007; OG, 2010; OG, 2011a; OG 2011c; EC, 2016; GDFC, 2023).

The HACCP system, which constitutes the foundation of food legislation in both the EU and Türkiye, provides a scientific and systematic framework for the prevention of foodborne hazards (OG, 2010; GDFC, 2023). However, in practice, particularly within small and medium-sized retail food businesses, the full and comprehensive implementation of all elements of the HACCP system is

associated with significant technical, operational, and documentation-related challenges. SMEs have a limited staffing capacity, deficiencies in technical expertise, and administrative burdens constrain the effective application of HACCP's structure, which relies on detailed record-keeping and systematic hazard analysis. Consequently, SMEs need more flexible and simplified HACCP implementation models to ensure adequate and effective food safety under these limited operating conditions (Ehiri and Morris, 1995; EC, 2022). However, the effective application of HACCP depends on the complete sustainability of Pre-request Programmes (PRPs) (Schleinnig, 2007; OG, 2011a; OG, 2011b). HACCP principles are integrated into the national food safety legislation of many countries today, and their application forms may vary according to the regulatory structure, audit system, and characteristics of the food sector.

The traditional and highly detailed implementation model of the HACCP system may pose significant challenges for SMEs with limited human resources and technical capacity. For this reason, the "Flexibility Approach to HACCP Requirements," which is based on proportional application in accordance with the scale of the establishment and the level of risk associated with its activities, without compromising the core principles of HACCP, has been developed (FAO, 2003; GDFC, 2023). This approach acknowledges that, in cases where critical control points cannot be identified or are not required, prerequisite Programmes (PRPs) and operational controls may be sufficient to ensure food safety (EC, 2022a; EC, 2022b). The EU hygiene package and the supporting guidelines allow for the flexible application of HACCP-based procedures for certain categories of FBOs (EC, 2004; EC, 2008; OG, 2011a; EC, 2016; EC, 2020; EC, 2022a).

The HACCP flexibility approach recognizes compliance with GHP and GMP as a practical alternative to the systematic identification and monitoring of CCPs in the prevention of foodborne hazards. By allowing hazards to be managed through PRPs and OPRPs in small-scale, traditional, and low-complexity operations, it reduces documentation and administrative burdens while facilitating regulatory compliance and strengthening food safety culture (Ehiri and Morris, 1995; EC, 2004; EC, 2016; EC, 2020).

Flexibility Approach Regarding PRPs and HACCP in SMEs

Flexibility Approach Regarding PRPs

This study presents a flexibility-based application of HACCP principles, based on prior to the application of HACCP to any step of the product processing chain, those steps must be supported by PRPs based on good hygienic practices (GHP) for food safety in SMEs.

This study presents a flexibility-based application of HACCP principles supported by PRPs and hazard analysis in SMEs. In this concept, there is no need for extensive CCPs monitoring (Esterhuyzen and Louw, 2019). In accordance with EU legislation (EC No 852/2004) and supporting guidance, specific food businesses are afforded regulatory flexibility, allowing hazards to be managed primarily through PRPs when the identification of CCPs is not deemed necessary.

Flexibility approach in HACCP-based procedures

Hazard Analysis and Risk Assessment

Foodborne hazards are sources of physical, chemical (including allergens), and biological agents that cause adverse health effects. Hazard analysis is the process of identifying hazards in raw materials, other components, the environment, processes, or the food itself, examining the conditions that give rise to them, developing appropriate control measures, and determining their significance (EC, 2002; Esterhuyzen and Louw, 2019; Ozcakmak and Var, 2019). In SMEs, hazard analysis plays a critical role in risk assessment and the effective implementation of prior food safety practices. Foodborne hazards are evaluated in the context of the establishment's scope of activities and capacity, with control measures determined based on impact and probability (EC, 2004; ISO, 2018). In 2016, the EC published guidance (2022/C 355/01) (EC, 2016) to the extent to which GHP and HACCP-based procedures could be applied flexibly in SMEs. Within the HACCP flexibility approach, hazard analysis occupies a central position in ensuring food safety.

When assessing potential physical, chemical, biological, or allergenic hazards, all raw materials and ingredients, previous customer complaints including their frequency and nature, water, ice, or air used, the design and layout of machinery and equipment in contact with food, all production process stages (as defined in process flow diagrams), microbial load, personnel health and hygiene, intended use, target population, and packaging, storage, and distribution conditions must be considered (EC, 2004; Fielding et al., 2005; Wallace et al., 2014; ISO, 2018; GDFC, 2023).

In official food inspections, the technical and hygienic conditions of the enterprises (such as the requirements of general and specific hygiene conditions, transportation, food waste, water supply, equipment, personnel hygiene, provisions applicable to food, food packaging, heat treatment and training) and the implementation of food safety management systems, including procedures based on HACCP principles are evaluated (EC, 2004; Fielding et al., 2005; Wallace et al., 2014; ISO, 2018; GDFC, 2023).

The HACCP Flexibility Approach allows SMEs to implement simplified HACCP procedures that adapt to the risk and scale of their operations, emphasizing effective PRPs and operational controls over complex CCP identification, thereby reducing administrative burdens while maintaining food safety (FAO, 2003; EC, 2016; Ozcakmak and Var, 2019). As provided for in Article 15 of Regulation No 852/2004, where CCPs cannot be identified, procedures based on hazard analysis combined with reinforced PRPs and GHPs are considered sufficient to control foodborne hazards (EC, 2004; EC, 2022). The HACCP flexibility approach sample applications were prepared according to the EU directives and Law No. 5996 in Table 1.

Official Auditing Practices According to the Flexibility Approach in the EU and Türkiye

Auditing is a process in which an authorized inspector visits a food establishment to assess its compliance with food safety requirements. During audits, the implementation of PRPs, food processing practices, activities aimed at identifying critical hazards, evaluation of customer complaints, and food safety documentation are examined (OG, 2010, Anonymous 2016; GDFC, 2023).

Table 1. Application samples of the HACCP flexibility approach for SMEs.

Requirement	HACCP Flexibility Approach	Application samples	References
Process: Cleaning and disinfection of equipment			
Food contact equipment should be cleaned and disinfected as needed to prevent microbiological contamination.	Detailed microbiological verification tests, specific microorganism targets, or complex written procedures are not required to document cleaning and disinfection activities. Instead, it is sufficient to have information regarding when, by whom, and by what general method cleaning and disinfection were performed, the removal of visible dirt, the prevention of cross-contamination, and the existence of simple, implementable, and recordable controls to ensure food safety.	In a restaurant, knives (using a knife sterilizer, cutting boards, and countertop surfaces that come into contact with raw poultry are cleaned immediately after using hot water and appropriate detergent; then treated with a food-safe disinfectant. Authorized personnel mark the cleaning process as "routine cleaning at the end of the shift" on a short checklist. Detailed microbiological analysis is not performed; however, visually clean equipment, the use of separate equipment for different product groups, and the avoidance of reuse of contaminated equipment are implemented as basic preventive measures.	<ul style="list-style-type: none"> Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. Regulation on Food Hygiene Commission Notice providing guidance on food safety management systems for food retail activities, including food donations (2020/C 199/01)
Process: Raw Material Acceptance			
Determination of microbiological hazards regarding raw materials and ingredients used by the FBOs in the production process.	It is not obligatory to create comprehensive hazard lists prepared at a detailed and scientific level for the evaluation of microbiological hazards. Conducting a detailed scientific hazard analysis that includes specific microorganism names (e.g., Salmonella spp.) is not required; Adequate awareness of hazard groups, together with the implementation of appropriate preventive controls, is considered sufficient.	A restaurant operator is not required to prepare a detailed list regarding microbiological hazards (e.g., pathogenic bacteria) of poultry meat or a scientific risk analysis containing specific microorganism names (e.g., Salmonella spp.). Instead, controls regarding approved supplier selection, packaging integrity, labeling and traceability, maintaining the cold chain, conducting sensory controls, and ensuring hygienic storage and transport conditions are considered sufficient.	Commission Notice on the Implementation of Food Safety Management Systems Covering Good Hygiene Practices and Procedures Based on HACCP Principles, Including the Facilitation and Flexibility of Implementation in Certain Food Businesses
Process: Establishment of the HACCP Team			
Establishment of a formal HACCP team comprising members from different disciplines and the issuance of appointment letters.	The FBOs may represent the team individually. In complex situations, support from external consultants or guidance manuals is sufficient.	It is sufficient for the owner of a café with three employees to adopt a "Good Hygiene Practice Guide" and state, "I am implementing this," rather than establishing a formal HACCP team.	Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses (2016/C 278/01)
Process: Hazard Analysis			
Calculation of Biological, Chemical, Physical, and Allergen risks for each step by scoring (Probability x Severity).	Pre-prepared Analyses: Utilization of hazard analyses found in sectoral Good Hygiene Practice guides. A qualitative approach (e.g., "Present/Absent" or "Must be Controlled") is adopted instead of quantitative scoring.	A boutique patisserie accepts the guideline information stating "Egg = Salmonella risk = Controlled by cooking" directly, instead of conducting risk scoring for each raw material.	Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses (2016/C 278/01)
Process: Cooking Temperature Control			
Measurement of internal temperature by inserting a probe thermometer into a specific number of products per batch or per day.	Visual Control (Color/Texture): Reliance on sensory attributes such as the meat juices running clear or the color of the bread crust.	A doner kebab chef decides that the meat is cooked by observing the color of the meat and its texture during cutting, rather than inserting a thermometer.	Guidelines For the Validation of Food Safety Control Measures (CAC/GL 69-2008)
Process: Traceability			
The establishment of end-to-end traceability across production, processing, and distribution.	It is not mandatory to install complex digital systems or detailed software for traceability. Simple and feasible records suitable for the scale of the business, which allow the product to be traced from the supplier and one step forward, are considered sufficient.	A restaurant files the invoices and label information (product name, supplier, lot/batch number, use-by date) of the pre-packaged food products purchased. When the product is received into the warehouse, only the "product name-supplier-delivery date" information is recorded on a simple form. When the product is opened in the kitchen, the date of use is marked on the daily production list. In the event of a potential recall or non-conformity, the supplier from whom the product was purchased and the date on which it was used can be determined via these simple records.	Commission Notice on the Implementation of Food Safety Management Systems Covering Good Hygiene Practices and Procedures Based on HACCP Principles, Including the Facilitation and Flexibility of Implementation in Certain Food Businesses.

Table 2. The comparison of HACCP flexibility legislation between the EU and Türkiye.

Comparative Criteria	European Union Framework	Türkiye Framework
Legal Basis	EU hygiene package (Reg. 852/2004, 853/2004) and related guidance documents.	Law No. 5996 on Veterinary Services, Plant Health, Food and Feed, and related secondary legislation.
Audit approach	Risk-based and sustainability-oriented. Emphasis on the effectiveness of actual practices rather than the volume of documentation.	Risk-based official control system; however, practical implementation may vary depending on the interpretation of the HACCP flexibility approach.
Flexibility for SMEs	Explicit flexibility is provided in guidance documents. PRP effectiveness prioritized; qualitative hazard analysis acceptable.	Flexibility approach applied in practice; however, no clearly differentiated standardized control form specifically for SMEs applying HACCP flexibility.
Audit Focus	Evaluation of PRP effectiveness, adequacy of hazard analysis, implementation continuity, and corrective action effectiveness.	HACCP audit forms and PRP-based inspections are used; flexibility-based inspections are not clearly defined.
Documentation Approach	Proportional documentation. Practical compliance and operational control are prioritized over extensive written records.	Formal audit forms applied. Documentation expectations may differ between inspectors, potentially affecting consistency.
Inspection Frequency Determination	Determined according to risk categorization, compliance history, and business profile.	Determined under a risk-based inspection procedure considering sector classification, business history, reliability of self-control, and hygiene management.
Identified Structural Gap	Clear distinction between HACCP-based systems and flexible application for SMEs.	Failing to clearly distinguish between businesses subject to HACCP system audits and SMEs that practice flexibility can lead to inconsistent audit results.

In EU practices, audits are conducted based on the compliance and sustainability of actual operations rather than the mere presence of documentation. HACCP audits are risk-based and guidance-oriented, with flexibility particularly afforded to SMEs (Moy et al., 1994; EC, 2022; Radu et al., 2023). In SMEs, official controls focus on the effectiveness of PRPs and the adequacy of hazard analysis. EU regulations and guidance documents (EC directives 852, 853/2004, Regulation 2016/C 278/01, 2020/C 199/01, 2022/C 355/01 EC, CAC GL 69-2008) (EC, 2004; EC, 2008; EC, 2016; EC 2020; EC, 2022) provide flexibility in the application of HACCP-based procedures for specific establishments, emphasizing practical implementation over the quantity of records. Audits assess whether establishments adopt the HACCP flexibility approach, maintain continuity of hygiene practices, implement practical control of hazards, and ensure the effectiveness of corrective actions. Table 2 presents the comparative analysis of EU and Türkiye legislation on the HACCP flexibility approach.

In Türkiye, official audits for HACCP systems are conducted in accordance with Law No. 5996 (OG, 2010; GDFC, 2023) using an official control form for HACCP System Audits. However, there is no control form containing audit criteria for food businesses that fall under the scope of the HACCP Flexibility approach. The lack of a clear distinction between businesses undergoing HACCP audits and those applying the flexibility approach leads to ambiguity in practice and negatively affects the consistency of audit results.

In Türkiye, official controls are conducted under Law No. 5996 (OG, 2010), using dedicated forms for HACCP system audits or PRP-based flexibility approach inspections. However, SMEs' audit criteria and application consistency are not clearly defined, which may lead to divergent evaluation outcomes for similar establishments. The lack of clear differentiation between HACCP-audited establishments and those applying the flexibility approach introduces uncertainty in practice and undermines the consistency of inspection results. HACCP system audits are conducted in all businesses defined in Law No. 5996, and prior notification is given. For businesses to be audited, the "HACCP Requirements Flexibility Approach" (Annex-3) is reviewed, considering factors such as the size, risk

status, and capacity of the business. Following this review, the "Official Control Form for Approved/Registered Businesses" (Annex-4) and the "Official Form for HACCP System Audit" (Annex-5) are used. (GDFC, 2023). Developing procedures, guidelines, or checklists similar to EU practices could enhance uniformity in audits of small and medium-sized retail food businesses in Türkiye. This would allow the establishment of a standardized official inspection system that clearly defines traceability, record-keeping, and audit criteria within the PRP- and hazard analysis-based flexibility approach, thereby ensuring both the sustainability of food safety and consistency in audits (SafeFood, 2013; EU, 2017; Beykaya, 2020; Dabbene et al., 2014).

In Türkiye, as part of the European Union Twinning Project (TR72004/IB/AG/02) aimed at restructuring and strengthening the food safety and control system, the "Procedure for Determining the Frequency of Risk-Based Inspections of Businesses" (OG, 2004) was prepared. This procedure, which entered into force on January 10, 2008, was revised on June 6, 2021. According to this procedure, the results of four main criteria (sector class, business history, reliability of self-controls, and hygiene management) are decisive in determining the frequency of risk-based inspections of food businesses. When evaluating the reliability of the business's self-controls, HACCP procedures, product controls, and temperature controls are used as sub-criteria with a 5-point scoring system (Very Good (0), Good (3), Sufficient (6), Medium (9), Insufficient (12)) (GDFC, 2022). However, this practice has not yet been adopted according to the Official Food Control and Administrative Sanctions Procedure.

The 'Procedure for Determining the Risk-Based Inspection Frequency of Businesses' of the General Directorate of Food Control of the Ministry of Agriculture and Forestry is used to determine the inspection frequency of businesses according to their risk levels. Inspection frequency is determined according to the risk level identified based on factors such as the type of business, past inspection results, and production processes. Evaluation is made via the GGBS system using a 5-point scoring system (Very Good: 0, Good: 3, Sufficient: 6, Medium: 9, Insufficient: 12). This approach ensures more efficient use of resources. Administrative sanctions are also applied in accordance with this procedure (GDFC, 2022).

Results

This study evaluated food safety practices in SMEs where Critical Control Points (CCPs) could not be clearly identified, through the application of the HACCP Flexibility Approach. The implementation of PRPs, GHPs, and hazard analysis procedures in the EU and Türkiye was examined from technical, legal, and administrative perspectives. A review of the scientific literature findings and regulatory practices indicates that strengthening PRPs and GHPs can ensure the maintenance of food safety even in situations where the classical HACCP framework cannot be fully implemented. In this context, the HACCP Flexibility Approach is an effective model for achieving food safety objectives, particularly for SMEs and traditional food production establishments.

Furthermore, the development of a national guideline, procedure, or structured checklist for establishments operating under the HACCP Flexibility Approach, based on and adapted from European Union guidance documents, would enable a clearer and more transparent definition of official control criteria. Such a document would not only standardize the criteria applied by official control authorities during inspections but also provide FBOs with clearer guidance on preventive measures against foodborne hazards. Ultimately, the implementation of these measures is expected to make a significant contribution to strengthening a sustainable, risk-based, and European Union-aligned food safety inspection and control system in Türkiye.

Discussion

The implementation of standardized inspection policies within official food control systems is fundamental to ensuring consistency, legal certainty, and transparency in regulatory enforcement. Clear and structured inspection frameworks reduce interpretative discrepancies among inspectors, facilitate uniform application of legislation, and strengthen the credibility of competent authorities. In risk-based food safety systems, standardization does not imply rigidity; rather, it provides a harmonized structure within which proportional and flexible approaches can be applied objectively. When the European Union food safety framework is examined, particularly the guidance developed for establishments operating under the HACCP Flexibility Approach, it becomes evident that inspections are embedded within a clearly defined risk-based assessment model. The emphasis is placed on the effectiveness of implemented control measures, especially PRPs, GHPs, and hazard analysis adequacy rather than solely on the volume of documentation. This structured yet flexible approach enables inspectors to evaluate compliance against objective and transparent criteria while preserving proportionality for SMEs and traditional establishments.

In contrast, although Türkiye has adopted a risk-based inspection system under national legislation, the practical implementation of official controls for establishments applying the HACCP Flexibility Approach appears less clearly differentiated from full HACCP audits. The absence of a specifically defined national guideline,

standardized checklist, or scoring framework tailored to flexibility-based establishments may result in variations in inspection outcomes. Such variability can create uncertainty for Food Business Operators (FBOs), who may face differing expectations depending on the inspector's interpretation, and may also challenge the consistency of enforcement practices across regions. Moreover, the lack of a clearly articulated distinction between classical HACCP implementation and the flexibility-based approach may inadvertently increase the administrative burden on SMEs. In practice, inspectors may rely on conventional HACCP audit criteria even where CCP-based systems are not fully applicable. This situation risks undermining the core rationale of the flexibility principle, which is to maintain food safety objectives through strengthened PRPs and proportionate hazard control mechanisms rather than through rigid documentation requirements.

From a governance perspective, the establishment of a nationally harmonized inspection framework aligned with European Union guidance would contribute to greater procedural clarity and institutional coherence. A structured and transparent evaluation model potentially incorporating qualitative scoring or rating mechanisms could enhance accountability, comparability of inspection results, and trust between regulatory authorities and food businesses. Such harmonization would not only support legal alignment with EU practices but also reinforce the sustainability of risk-based food safety management within SMEs. Ultimately, the comparative analysis indicates that while both systems formally recognize risk-based control principles, the operational clarity and standardization of the flexibility approach remain more systematically articulated within the EU framework. Strengthening procedural guidance and inspection tools in Türkiye would therefore represent a critical step toward improving consistency, reducing interpretative ambiguity, and enhancing the overall effectiveness of official food safety controls.

Conclusion

In European Union Member States, guidance documents and inspection manuals developed for establishments applying the HACCP Flexibility Approach are based on a risk-based assessment framework, enabling inspection outcomes to be evaluated against objective criteria. This study highlights the necessity of developing a national guidance document, a standardized checklist, and a uniform scoring or grading system aligned with European Union practices for SMEs implementing the HACCP flexibility approach in Türkiye. Establishing such a framework would strengthen measurable and traceable food safety management in SMEs, thereby mitigating potential public health risks. Furthermore, these developments would significantly contribute to the sustainability of Türkiye's Official Food Control System and further its harmonization with the European Union.

Declarations

Not applicable. This study did not involve human participants, animals, or personal data.

Author Contribution Statement

Sibel Ozcakmak: Project administration, supervision, conceptualization, methodology, review and editing

Uğur Buber: Data collection, investigation, formal analysis, and writing the original draft

Nihal Atmaca Tamer: Review, investigation, and editing.

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Conflict of Interest

The authors declare no conflict of interest.

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