



Warsaw University of Life Sciences

Institute of Human Nutrition Sciences

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## **Assessment of ensuring food safety among stakeholders of organic food products**

Ocena zapewnienia bezpieczeństwa żywności wśród interesariuszy  
żywności ekologicznej

Doctoral thesis

Rozprawa doktorska

Doctoral thesis prepared under the supervision of

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## **Abstract**

Safety, health, and sustainability consumer perceptions are increasing the global need to provide organic food products, and hence the need to maintain a high level of food safety in the organic industry. This research set out to assess the level of ensuring food safety among selected organic stakeholders.

The study was designed as a multi-phase study. Phase I identified microbiological hazards associated with organic foods. Phase II was food safety risk assessment of HACCP audit results using FMEA method among Indian organic food enterprises. Phase III evaluated the factors influencing HACCP compliance in organic food processing enterprises in India. Phase IV involved comparative assessment of food safety rules, quality management and sustainability approaches among organic food stakeholders in different countries.

The findings has confirmed that microbiological hazards are a major food safety issue in organic food production. The assessment of the outcome of the HACCP audits indicated that all of the inspected organic food processing plants had implemented a food safety management system that complied with regulatory requirements and the results showed that the application of risk-based assessment methodologies helps to identify food safety issues in organic food systems. The results identified that food safety audits are an effective tool to verify whether food safety systems are properly implemented and functioning and enterprise characteristics such as company size and product type affect the level of compliance with food safety. The findings also confirmed the importance of regulatory capacity and stakeholder practices in the attainment of food safety in the organic industry.

**Keywords:** Organic food, food safety, risk assessment, HACCP, compliance, sustainability

## **Abstrakcyjny**

Percepcja konsumentów w zakresie bezpieczeństwa, zdrowia i zrównoważonego rozwoju zwiększa globalne zapotrzebowanie na produkty żywnościowe pochodzenia organicznego, a tym samym konieczność utrzymania wysokiego poziomu bezpieczeństwa żywności w branży ekologicznej. Celem niniejszego badania była ocena poziomu zapewnienia bezpieczeństwa żywności wśród wybranych interesariuszy branży ekologicznej.

Badanie zostało zaprojektowane jako wieloetapowe. W fazie I zidentyfikowano zagrożenia mikrobiologiczne związane z żywnością ekologiczną. W fazie II dokonano oceny ryzyka bezpieczeństwa żywności na podstawie wyników audytu HACCP z wykorzystaniem metody FMEA w indyjskich przedsiębiorstwach produkujących żywność ekologiczną. W fazie III oceniono czynniki wpływające na zgodność z HACCP w przedsiębiorstwach przetwórstwa żywności ekologicznej w Indiach. W fazie IV dokonano oceny porównawczej przepisów dotyczących bezpieczeństwa żywności, zarządzania jakością i podejścia do zrównoważonego rozwoju wśród interesariuszy branży żywności ekologicznej w różnych krajach.

Wyniki potwierdziły, że zagrożenia mikrobiologiczne stanowią istotny problem bezpieczeństwa żywności w produkcji żywności ekologicznej. Ocena wyników audytów HACCP wykazała, że wszystkie skontrolowane zakłady przetwórstwa żywności ekologicznej wdrożyły system zarządzania bezpieczeństwem żywności zgodny z wymogami regulacyjnymi, a wyniki pokazały, że stosowanie metodologii oceny opartej na ryzyku pomaga w identyfikacji problemów z bezpieczeństwem żywności w systemach produkcji żywności ekologicznej. Wyniki wskazały, że audyty bezpieczeństwa żywności są skutecznym narzędziem weryfikacji, czy systemy bezpieczeństwa żywności są prawidłowo wdrożone i funkcjonują, a cechy przedsiębiorstwa, takie jak wielkość firmy i rodzaj produktu, wpływają na poziom zgodności z wymogami bezpieczeństwa żywności. Wyniki potwierdziły również znaczenie potencjału regulacyjnego i praktyk interesariuszy w osiąganiu bezpieczeństwa żywności w przemyśle ekologicznym.

**Słowa kluczowe:** żywność ekologiczna, bezpieczeństwo żywności, ocena ryzyka, HACCP, zgodność, zrównoważony rozwój

### **The list of publications making up the doctoral thesis**

**P1** Murali AP, Trzaskowska M, Trafialek J. Microorganisms in Organic Food-Issues to Be Addressed. *Microorganisms*. 2023; 11(6):1557. <https://doi.org/10.3390/microorganisms11061557>

**Impact Factor: 4.1, Ministry Point: 40**

**P2** Murali AP, Trafialek J, Trzaskowska M, Mazurek-Kusiak AK, Kolanowski W. Food Safety Risk Assessment Based on HACCP Audit Results Using the FMEA Method in Indian Organic Food Processing Plants. *Current Nutrition & Food Science*. 21:1-15. doi:10.2174/0115734013415006250904112146

**Impact Factor: 0.8, Ministry Point: 20**

**P3** Murali AP, Trafialek J, Nair SS. HACCP compliance in organic food processing industries in India: A statistical study by product type and company size. *AIMS Agriculture and Food*, 2026, 11(1): 75-94. doi: 10.3934/agrfood.2026005

**Impact Factor: 1.9, Ministry Point: 40**

**P4** Murali AP, Kolożyn-Krajewska D, Mancinelli R, Muleo R, Nair SS, Trafialek J. Sustainability and Compliance in Organic Food Industries: A Comparative Study of India and Italy. *Sustainability*. 2026; 18(5):2302. <https://doi.org/10.3390/su18052302>

**Impact Factor: 3.3, Ministry Point: 100**

**Total Impact Factor: 10.1 , Total Ministry Points: 200**

## **Abbreviations**

HACCP - Hazard Analysis and Critical Control Points

FMEA - Failure Mode and Effect Analysis

CCP - Critical Control Points

ISO- International Organization for Standardization

SDGs- Sustainable Development Goals

EU - European Union

MSME - Micro, Small, and Medium Enterprises

PCA - Principal Component Analysis

RTE - Ready To Eat

S - Severity

O - Occurrence

D - Detectability

IN - India

IT - Italy

## 1. Introduction

The demand of organic food products in the world has been growing tremendously within the last 20 years due to increasing consumer concerns regarding health, sustainability of the environment, and healthy food production (1,2). Organic food systems are considered to be safer and healthier than conventionally produced foods because they are often associated with reduced use of synthetic pesticides, fertilisers, antibiotics and genetically modified organisms (3–5). It is due to this that the organic food market has experienced rapid growth in both developed and developing countries, as an important aspect of world agri-food trade (1,2).

Despite the positive perception of organic food, maintaining food safety in the organic industry is still a difficult and important task (3,4,6). Certain preventative and corrective techniques that are frequently used in conventional food production may not be able to be used in organic production systems due to technical and regulatory limitations (4,6,7). As a result, at different points in the food supply chain, such as primary production, processing, transport, and sale, organic foods may be subject to biological, chemical, and physical risks (4,6,8). Strong food safety management systems and efficient regulatory control are even more crucial given the growing size and globalisation of organic food supply chains (8,9).

Unlike conventional food systems, organic food production has a distinct set of food safety challenges. Limitations on the use of chemical disinfectants, antibacterial agents, and preservatives may lead to a greater reliance on less effective alternative control methods (3,4,7,10). Furthermore, organic farming methods frequently make use of manure, compost, and organic fertilizers, all of which can be sources of microbial contamination if not handled appropriately (4,11,12).

One of the biggest issues with organic food safety is still microbiological risks. Numerous organic food products, including fresh produce, dairy products, meat, and ready-to-eat foods, have been shown to include pathogenic microbes such as *Salmonella spp.*, *Listeria monocytogenes*, *Escherichia coli*, and *Campylobacter spp* (3,4,13). Several variables, including the production environment, hygienic procedures, processing conditions, and storage and transportation systems, may have an impact on how common these risks are (4,14,15).

Many countries require the use of food safety management systems, such as Hazard Analysis and Critical Control Points (HACCP), in organic food processing facilities (12,16,17). However, the degree of implementation, monitoring, and verification has a significant impact

on how effective these systems are (9). Food safety regulations may be applied inconsistently among organic food players due to differences in organisational culture, financial resources, infrastructure, and technical ability. Small and medium-sized businesses, which make up a sizable fraction of organic food growers and processors globally, are most affected by these issues (9).

To ensure compliance with organic standards and, in some cases, food safety standards, certification organisations are necessary (4,9,18). But often, organic certification is simply about manufacturing rather than rigorous risk management of food safety. That may result into a lack of connection between food safety assurance and organic compliance, unless certification audits and food safety audits are fully integrated (18,19). Food processors, distributors, and retailers have a duty to ensure food safety in the processing, storage, and distribution. They will conduct internal audits, implement HACCP procedures, and work with regulatory bodies, as well as external auditors. The creation of rules, inspection and enforcement, and managing food safety situations all fall under the responsibility of government organisations. And finally, consumers also indirectly influence food safety by their purchasing decisions, their quality expectations of products, and their belief in organic certification programs and labels.

The organic food industry functions in a very globalised environment. Because organic products are regularly sold internationally, they must adhere to a variety of legal requirements, certification programs, and food safety regulations. Countries may have different levels of assurance about food safety due to differences in institutional structures, enforcement capabilities, and national rules (7,20). The production of organic food has grown faster in many areas than the infrastructure for regulation and inspection. This discrepancy is especially noticeable in underdeveloped and rising nations, where organic food processing facilities may encounter difficulties with funding, training, and technological capability. Simultaneously, these areas are supplying more and more organic goods to global markets that have strict food safety regulations (9,21).

There is little empirical data on the efficacy of food safety management systems in organic food production and processing, despite the organic food industry's explosive growth and rising customer expectations about food safety (4,22). Comparative studies evaluating the effects of regulatory oversight, certification procedures, audit implementation, and enforcement mechanisms on food safety results in the organic industry across various national settings are particularly lacking. The actual application of HACCP systems in organic food processing facilities has not been thoroughly investigated using systematic risk assessment techniques,

despite the fact that these systems are widely acknowledged as a cornerstone of food safety management. In the context of organic food safety, there is still a lack of research on the integration of audit data with quantitative risk assessment techniques like Failure Mode and Effects Analysis (FMEA) (9).

## **2. Justification for Choosing the Topic**

### **2.1. Justification for choosing organic food as the research focus**

Over the past 20 years, the organic food industry has grown rapidly worldwide due to rising consumer demand for foods that are thought to be safer, healthier, and more ecologically friendly (21). Many people believe that organic foods are safer and of higher quality than conventional foods because they are produced under rigorous restrictions that limit the use of synthetic fertilisers, pesticides, antibiotics, and genetically modified organisms. Because of this, organic food items are now a significant part of both local and global food markets (3,4).

Organic production principles are not primarily intended as food safety systems, despite this favourable perception (7,8). While food safety assurance depends on distinct regulatory frameworks, hygiene laws, and food safety management systems like Hazard Analysis and Critical Control Points (HACCP), organic regulations primarily concentrate on production techniques, input limitations, and certification of organic integrity. As a result, operators of organic food operate in a dual regulatory framework, where adherence to organic standards does not guarantee efficient management of food safety risks (4,18).

The same microbial hazards that affect conventionally produced meals also affect organic foods, according to scientific research. Numerous organic food products have been shown to include pathogenic germs such as *Salmonella spp.*, *Listeria monocytogenes*, *Escherichia coli*, and *Campylobacter spp.* In this regard, Murali et al. (2023) (P1) offered a thorough analysis of microorganisms linked to organic foods, emphasising that biological risks continue to be a significant concern at every stage of the organic food chain, from primary production to processing and distribution. According to that study, if food safety systems are not strictly enforced, limitations on chemical control methods, the use of organic fertilisers, and limited processing techniques may increase susceptibility to contamination.

The inconsistency of the high level of trust in organic foods of consumers with the presence of microbial threats opens a significant research gap. Even though the fact of organic certification ensures that production rules are met, it does not strictly assess the effectiveness of food safety management processes. Thus, a study that would be focused on evaluating the reality of food safety among many participants has a very specific and reasonable environment in an organic food system. This argument is further supported by the fact that empirical studies combining audit-based assessment, regulatory practices, and microbiological risk assessment in the processing of organic foods are few (4,22).

## **2.2. Justification for choosing Italy and India as comparative country cases**

National regulatory frameworks, institutional capacity, and enforcement intensity all have a significant impact on how food safety is implemented in the organic sector. A comparative, cross-national approach offers insights into how regulatory context influences compliance behaviour and makes it possible to identify fundamental disparities in food safety governance. For this doctoral study, Italy and India were chosen because they are two different but complementary examples of the global organic food system (7,20).

Italy operates in a highly developed regulatory system defined by European Union food legislation and harmonised organic laws, making it one of Europe's top producers and exporters of organic food. Strict government regulations, established certification programs, and extensive use of quality and food safety management systems apply to Italian organic food manufacturers. Compliance with both public and commercial food safety regulations is further strengthened by the integration of organic production with export-oriented supply chains. Because of this, Italy is an example of a developed organic food system with standardised food safety procedures and comparatively high institutional control (7).

India, on the other hand, is a significant global producer of processed organic foods and organic raw materials, especially for export. The organic industry in India has grown quickly, yet it operates in a diverse regulatory environment with wide variations in technical resources, audit procedures, and enforcement capabilities. While small and medium-sized businesses encounter difficulties with infrastructure, training, and regulatory interpretation, large organic food processors frequently deploy globally recognised food safety procedures to satisfy export requirements. India is a prime example of a burgeoning organic food system with inconsistent food safety implementation because of its diversity (20,23).

The consistency and integration of food safety regulations, quality management systems, and sustainability practices varies significantly between the organic food processing industries in Italy and India, according to preliminary data from a submitted comparative manuscript. Indian businesses exhibit higher diversity, which is heavily impacted by company size and market orientation, whereas Italian businesses typically exhibit more uniform implementation backed by institutionalised enforcement. The choice of Italy and India as different case studies to investigate how regulatory maturity and enforcement impact food safety assurance in the organic industry is justified by these first empirical findings.

### **2.3. Food safety management systems, audits, and identified research gaps**

The main instruments for preventing and managing food safety risks in food processing, including the production of organic food, are food safety management systems, especially HACCP. A systematic, preventive framework for hazard identification, monitoring, and remedial action is offered by HACCP. However, rather than relying solely on formal adoption, its efficacy depends on the quality of implementation, audit rigour, and follow-up enforcement.

In organic food processing facilities, audit-based assessments are frequently used to evaluate compliance with HACCP and other precursor programs. The usefulness of utilising HACCP audit results as a foundation for organised food safety risk assessment in Indian organic food processing facilities was shown by Murali et al. (**P2**). That study demonstrated how audit data may be converted into a methodical tool for identifying crucial flaws and ranking food safety hazards by combining audit findings with Failure Mode and Effects Analysis (FMEA). The findings showed persistent non-compliance with hazard analysis, monitoring, and remedial actions, suggesting that documented HACCP systems and certification do not necessarily equate to efficient risk control.

**P3** and **P4** provide additional support for this research approach. Enterprise size has a major impact on food safety performance. While smaller businesses frequently struggle with documentation, verification processes, and systematic risk management, larger businesses regularly achieve higher levels of compliance. The implementation of food safety systems and their integration with quality and sustainability practices are significantly influenced by the legislative backdrop and enforcement intensity, according to **P4**.

### **3. Aim and research hypothesis of the doctoral thesis**

#### **3.1. Aim of the doctoral thesis**

The aim of the study was to assess the level of ensuring food safety among selected organic stakeholders. The specific objectives were:

1. To assess the food safety risk among organic stakeholders.
2. To assess the HACCP compliance in organic food processing industries by product type and company size.
3. To compare the sustainability and compliance with food safety in organic food industries among stakeholders.

#### **3.2. Research hypothesis**

Based on the research aim, the following hypotheses were formulated:

**H1:** The application of risk-based assessment methodologies helps to identify food safety issues in organic food systems.

**H2:** Food safety audits are an effective tool to verify whether food safety systems are properly implemented and functioning.

**H3:** Enterprise characteristics such as company size and product type affect the level of compliance with food safety.

**H4:** The level of sustainability practices and food safety compliance differs among stakeholders in the organic food industry.

## 4. Materials and methods

### 4.1. Materials

Research scheme: The research was conducted in the following phases (Table 1).

| Research Tasks and study tools                                                                                                                                          |                                                                                                                                                                                                                                   | Publication |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| <b>Phase I</b><br>Identification of microbiological hazards associated with organic foods.                                                                              | → Systematic literature analysis<br>→ Identification of microbiological hazards in organic foods                                                                                                                                  | <b>P1</b>   |
| <b>Phase II</b><br>Food safety risk assessment of HACCP audit results using FMEA method among Indian organic food enterprises.                                          | → Designing the HACCP audit checklist<br>→ HACCP audit evaluation<br>→ Compliance assessment based on Codex HACCP principles<br>→ Failure Mode and Effects Analysis (FMEA) for risk evaluation                                    | <b>P2</b>   |
| <b>Phase III</b><br>Evaluation of factors influencing HACCP compliance in organic food processing enterprises in India.                                                 | → External audit data analysis<br>→ Statistical analysis of compliance scores<br>→ Comparative analysis of enterprise characteristics and audit results                                                                           | <b>P3</b>   |
| <b>Phase IV</b><br>Comparative assessment of food safety rules, quality management and sustainability approaches among organic food stakeholders in different countries | → Designing the study tool<br>→ Cross-country comparative analysis<br>→ Evaluation of regulatory and organizational factors<br>→ Statistical analysis of food safety compliance, quality management and sustainability indicators | <b>P4</b>   |

Table 1. Overview of the research phases

#### 4.1.1. Research design

The study adopted four phases research design to assess food safety in the organic food sector. The research combined a systematic literature review, audit-based evaluation, and comparative statistical analysis to provide a comprehensive assessment of food safety risks and compliance among organic food stakeholders.

Phase I employed a systematic literature review to identify microbiological hazards associated with organic foods. Phase II involved a quantitative assessment of food safety risks using HACCP audit results combined with Failure Mode and Effects Analysis (FMEA). Phase III applied statistical methods to evaluate the HACCP compliance in organic food processing enterprises. Phase IV used a comparative cross-sectional design to assess food safety, quality management, and sustainability practices across different national contexts.

The cross-sectional approach enabled the evaluation of ensuring food safety implementation and compliance, while the multi-phase structure allowed for progressive analysis from hazard identification to system performance and comparative assessment.

#### **4.1.2. Research material**

The research was based on four scientific publications (**P1-P4**) and involved a total of 400 organic food stakeholders participating across different phases of the study. The empirical research included 100 organic food processing enterprises from which HACCP audit data were collected and analyzed (**P2, P3**), as well as 300 stakeholders involved in food safety, quality management, and sustainability practices in India and Italy (**P4**).

##### *Phase I: Identification of microbiological hazards associated with organic foods (P1)*

Data were collected through a structured literature review. Scientific publications were retrieved from databases such as Scopus, Web of Science, and PubMed using predefined search terms related to organic food, microbiological hazards, and food safety. Relevant studies were selected based on inclusion criteria, and qualitative analysis was conducted to identify key pathogens, contamination sources, and risk factors across the organic food supply chain.

##### *Phase II: Food safety risk assessment of HACCP audit results using FMEA method among Indian organic food enterprises (P2)*

A total of 100 organic food processing companies were selected to be diverse in terms of companies and product lines. The selection included small, medium, and large enterprises of organic food processing, covering product types: fruits & vegetables, meat, RTE, rice and dairy products. The companies were located in the state of Kerala in India. The research was done in certified organic food processing plants.

*Phase III: Evaluation of factors influencing HACCP compliance in organic food processing enterprises in India (P3)*

Phase III utilized HACCP audit data obtained from organic food processing enterprises in India. The same 100 organic food processing companies from Phase II were chosen to represent a varied range of companies and product categories. Statistical analyses were performed to evaluate the influence of enterprise characteristics, including company size and product type, on compliance levels.

*Phase IV: Comparative assessment of food safety rules, quality management and sustainability approaches among organic food stakeholders in different countries (P4)*

The research was conducted in India and Italy, representing different levels of regulatory bodies and systems within the organic food sector. India was selected as a rapidly developing country with a growing organic food industry and export-oriented production systems. Italy was selected as a representative of a developed European Union country with well-established food safety regulations and harmonized standards. A stratified purposive approach was used to make sure that the small, medium and large enterprises participated adequately. The company size was by annual turnover on-basis on EU & MSME(36) guidelines. The selection of these countries enabled a comparative analysis of food safety implementation under different regulatory frameworks, institutional conditions, and levels of industry development. This approach provided insights into the influence of governance structures on food safety compliance in the organic sector. There were 300 valid responses (150 by each country) collected. The sample was chosen in order to represent variations in organizational practices and the business environment in different countries.

## **4.2 Research Methods**

### **4.2.1. Phase I: Identification of microbiological hazards associated with organic foods**

Literature review was conducted in a systematic and organized manner based on the scientific publications that could be found in the major and bibliographic databases, including Scopus, Web of Science, and PubMed, using the pre-established search phrases associated with organic food, microbiological hazards, food safety, and contaminants.

Review of publications was based on inclusion and exclusion criteria that considered their applicability to organic food systems and microbiological approach. Redundant and duplicated

studies were eliminated. The chosen articles were analyzed qualitatively to assess the presence of the most significant pathogenic bacteria (*Salmonella spp.*, *Listeria monocytogenes*, *Escherichia coli*, and *Campylobacter spp.*), and possible routes of contamination.

#### **4.2.2. Phase II: Food safety risk assessment of HACCP audit results using the FMEA method among Indian organic food enterprises**

Audits are widely acknowledged as a fundamental verification method in the governance of food safety, fulfilling both certification and regulatory purposes. The audit process relied on a structured audit questionnaire proposed by Trafialek and Kolanowski (25) based on the criteria introduced in the Codex Alimentarius standards (17), ISO (International Organization for Standardization) 19011 guideline for auditing management systems (26).

The audit questionnaire was divided into two main parts (P2):

Part I: Implementation of HACCP,

Part II: Functioning of the Existing HACCP System.

Each segment included relevant questions designed to assess specific criteria, with the auditor required to score each question based on the degree of compliance observed. The auditor had extensive experience in food quality management, HACCP implementation and auditing, food hygiene research, and was regularly evaluated per ISO 19011 (26), maintaining competence through ongoing professional development and training. A grading scale was used for assessment: the highest score awarded was 5, which corresponded to all the requirements being met (100% compliance); a score of 4 reflected a slight deviation from complete fulfilment of all of the requirements (approximately 80% compliance); while a score of 3 meant that requirements were fulfilled to an inadequate extent (approximately 60% compliance); the lowest score was 2, which indicated that only a minority of the requirements were fulfilled (less than 40% compliance) (25,27).

This study used a modified Failure Mode and Effects Analysis (FMEA) method to assess risk in organic food enterprises, based on Trafialek and Kolanowski's approach (25). The technique was divided into three steps, each with a distinct level of risk rating based on HACCP audit data (P2).

The first step provided a general overview of risk across companies, categorized by type and size. This stage was intentionally simplified to allow benchmarking and trend identification among enterprises.

The FMEA had three key components: severity (S), occurrence (O), and detection (D). The formula used for calculating risk was:

$$\text{Risk (R)} = \text{Severity (S)} \times \text{Occurrence (O)} \times \text{Detectability (D)}$$

The second step was an in-depth risk assessment based on a detailed evaluation of risk factors specific to each company type. This assessment incorporated a range of critical factors in the HACCP system, including steps and principles. Unlike the overall assessments conducted in earlier phase I, this step provided actionable insights into the unique vulnerabilities of each company, ensuring that risk management interventions were both relevant and effective. The total scores obtained for each block of the questionnaire were analysed, and the risk was calculated for each block using the FMEA method (25). The S value was the parameter which represented the food safety requirements; each step of the HACCP has importance in the process, however, it is differentiated based on the impact as described in Table 2 (25).

Table 2. Severity (S) and occurrence (O) scoring criteria used for the evaluation of HACCP system implementation

| S value            |                     |                                                 | O value - Overall & In-depth assessment |            |
|--------------------|---------------------|-------------------------------------------------|-----------------------------------------|------------|
| Overall assessment | In-depth assessment | HACCP steps according to Code Alimentarius (24) | O value                                 | Mean score |
| 10                 | 1                   | Step 1                                          | 1                                       | 5          |
| 10                 | 2                   | Step 2                                          | 2                                       | 4.5-5      |
| 10                 | 3                   | Step 3                                          | 3                                       | 4-4.5      |
| 10                 | 4                   | Step 4                                          | 4                                       | 3.75-4     |
| 10                 | 5                   | Step 5                                          | 5                                       | 3.5-3.75   |
| 10                 | 6                   | Step 12, Principle VII                          | 6                                       | 3.25-3.5   |
| 10                 | 7                   | Steps 6, 7, 8, Principle I, II, III             | 7                                       | 3-3.25     |
| 10                 | 8                   | Steps 9, 10, Principle IV, V                    | 8                                       | 2.5-3      |
| 10                 | 9                   | Step 11, Principle VI                           | 9                                       | 2.25-2.5   |

|    |    |                              |    |   |
|----|----|------------------------------|----|---|
| 10 | 10 | Functioning of HACCP Part II | 10 | 2 |
|----|----|------------------------------|----|---|

Table source: developed based on **P2**

In the third step, the risk values calculated from the second step were evaluated using the FMEA model to prioritize failure modes. This helped in identifying the most critical areas in the HACCP implementation process, guiding risk mitigation and resource allocation efforts (**P2**).

Risk scores were then grouped into four categories: minor, moderate, high, and critical (Figure 1) (25,28,29). These standardised values facilitate a broad understanding of risk trends without delving into the nuances of each company's specific risk factors. In contrast, the specific risk assessment was conducted with a more detailed approach, incorporating calculations based on actual data specific to each company and size. This method (25) allowed for more accurate and actionable risk evaluation (**P2**).



Figure 1. Risk classification matrix based on risk score ranges used for the categorization of food safety hazards. Figure source: developed based on **P2**

#### 4.2.3. Phase III: Evaluation of factors influencing HACCP compliance in organic food processing enterprises in India

The audit questionnaire for data collection was developed in alignment with the Codex Alimentarius Commission's General Principles of Food Hygiene and HACCP System Guidelines (31,32). The questionnaire contained both documentation (Part I: 110 questions) and practical functioning aspects (Part II: 36 questions) of the HACCP system (Table. 3). Each company underwent a single audit visit, during which data were collected using direct observation. Each component was scored using a 4 - point ordinal scale, where: 2 - non-compliance, 3 - partial compliance, 4 - substantial compliance, 5 - full compliance. In Part I, the total score ranges from a minimum of 220 to a maximum of 550, while in Part II, the score

ranges from a minimum of 72 to a maximum of 180. Scores from individual sections were aggregated and normalized to produce an overall compliance score for each company. This structured scoring approach provided a quantitative basis for statistical analysis of HACCP performance according to company size and product category. The data was then converted into a compliance score and further statistical analysis. The audit was conducted by an experienced professional specializing in food quality management, HACCP system implementation, food hygiene research, and auditing. The auditor's competence was regularly reviewed in accordance with ISO 19011 guidelines (33) and maintained through continuous professional development and training. A four-point grading scale was used to evaluate compliance: a score of 5 indicated full compliance (100%), 4 reflected minor deviations (approximately 80%), 3 represented partial compliance (approximately 60%), and 2 indicated minimal compliance (less than 40%) (27,34). The scale was intentionally non-centralized, allowing the auditor to exercise professional judgment in assigning scores (P3).

Table 3. Structure of the HACCP audit questionnaire developed in accordance with Codex Alimentarius guidelines

| Questions                                                      | 2 | 3 | 4 | 5 |
|----------------------------------------------------------------|---|---|---|---|
| <b>PART I</b>                                                  |   |   |   |   |
| Step 1. Assemble HACCP team                                    |   |   |   |   |
| Step 2. Describe product                                       |   |   |   |   |
| Step 3. Identify intended use                                  |   |   |   |   |
| Step 4. Construct flow diagram                                 |   |   |   |   |
| Step 5. On site confirmation of flow diagram                   |   |   |   |   |
| Step 6. Principle I. Identify and analyze hazards              |   |   |   |   |
| Step 7. Principle II. Determine Critical Control points (CCPs) |   |   |   |   |
| Step 8. Principle III. Establish critical limits for each CCP  |   |   |   |   |
| Step 9. Principle IV. Monitoring of CCPs                       |   |   |   |   |
| Step 10. Principle IV. Monitoring of CCPs                      |   |   |   |   |
| Step 11. Principle VI. Verification procedures                 |   |   |   |   |
| Step 12. Principle VII. Recordkeeping and documentation        |   |   |   |   |
| <b>PART II</b>                                                 |   |   |   |   |
| Step 7. Principle II. Determine Critical Control Points (CCPs) |   |   |   |   |
| Step 8. Principle III. Establish critical limits for each CCP  |   |   |   |   |

|                                                         |  |  |  |  |
|---------------------------------------------------------|--|--|--|--|
| Step 9. Principle IV. Monitoring of CCPs                |  |  |  |  |
| Step 10. Principle V. Establish corrective action       |  |  |  |  |
| Step 11. Principle VI. Verification procedures          |  |  |  |  |
| Step 12. Principle VII. Recordkeeping and documentation |  |  |  |  |

Table source: developed based on P3

#### **4.2.4. Phase IV: Comparative assessment of food safety rules, quality management and sustainability approaches among organic food stakeholders in different countries**

The research was done in organic foods industries which had been certified by internationally or nationally perceived certification bodies. These two territories were chosen to represent opposite forms of governance - one which was a developing state with organic framework (India) (20,35) and another with a mature and EU aligned regulatory framework (Italy) (7). A total of 300 valid responses (150 from each country) were collected. The sample size was determined using standard statistical power estimation. Respondents were quality managers, food safety officers or production leads who are directly involved in compliance and certification management.

A structured questionnaire was designed as the tool for primary data collection which was divided in 3 sections: food safety rules, quality management and sustainability practices with suitable questions in accordance with country and international guidelines. A thorough evaluation across all three domains was made possible by the structured questionnaire's 31 items, which included 14 questions on food safety rules, 8 questions on quality management, and 9 questions on sustainable practices. Each question used a 3 point ordinal scale; Yes = 1, Maybe = 0.5, No = 0. Composite scores were calculated for each sections for overall compliance.

Data collection was conducted between the period of May 2024 - May 2025. In India, data were gathered through online forms and direct visits. In Italy, the questionnaire was translated by a native speaker and the responses were collected through online forms via industry associations and research collaborations. Completed questionnaires were anonymised and coded for statistical analysis.

#### **4.3. Statistical analysis**

To assess the level of adoption of food safety management system, determine the factors that affect HACCP compliance, explore the relationships between organisational and regulatory

factors, and conduct cross-national comparisons of organic food processing firms, statistical studies were conducted. Analysis of variables, ordinal nature of the data, and analysis objectives of the individual studies that constituted the PhD thesis also contributed to the selection of the statistical methods.

The following statistical methods were applied:

- Descriptive statistics: The arithmetic mean, median, standard deviation, minimum and maximum values were used to summarise HACCP audit scores, compliance levels and composite indices of the food safety practices, quality management practices and sustainability practices. Descriptive analyses were applied to all the published study.
- The Shapiro–Wilk test was used to assess the normality of the distribution of quantitative variables prior to the application of parametric statistical tests
- The following relationships were examined using the Spearman rank correlation coefficient ( $\rho$ ):
  - HACCP compliance ratings and business attributes like product category and firm size.
  - compliance with food safety regulations, quality control, and sustainability metrics,
  - Failure Mode and Effects Analysis (FMEA) derived food safety risk indicators and audit-based compliance outcomes
- The Student's t-test was used to compare mean values between two independent groups when the assumption of normal distribution was met, including:
  - comparisons of HACCP compliance levels between selected enterprise groups
  - comparisons of food safety, quality management, and sustainability scores between organic food processing enterprises operating in Italy and India.
- The Mann–Whitney U test was applied as a non-parametric alternative to the t-test when the assumption of normality was not satisfied. This test was used to compare:
  - differences in food safety and management practice indicators between countries,
  - differences in compliance levels between enterprise size categories where data distributions were non-normal

- Analysis of variance (ANOVA) was employed to determine whether statistically significant differences existed between mean compliance scores across more than two groups, including: enterprise size categories (small, medium, and large) and organic product categories.
- Post hoc tests were conducted following ANOVA where statistically significant differences were identified, in order to determine specific group-level differences.
- Multidimensional cluster analysis was applied to classify organic food processing enterprises according to similarity in HACCP compliance profiles and to identify groups representing different levels of food safety management system maturity.
- Principal Component Analysis (PCA) was used in the cross-country comparative study to reduce the dimensionality of food safety, quality management, and sustainability indicators and to examine interrelationships among these domains.

## **5. Results and discussion**

### **5.1 Phase I: Identification of microbiological hazards associated with organic foods**

Literature analysis has confirmed that microbiological hazards are a major food safety issue in organic food production. Organic food production and microbial contamination is a health issue of concern to consumers because it leads to foodborne infections like bacterial infections, outbreaks of viruses and fungi, etc. Poorly immune individuals such as pregnant women, the elderly, and others may be particularly susceptible to these threats (37).

The microbiological safety of fresh food is affected by a number of factors, growing circumstances being of particular importance. Manure and other animal droppings are widely used in both organic and conventional farming. The possibility of contamination of products with microbiological organisms (especially *Escherichia coli* O157) is a concern when manure is applied as fertiliser in conventional or organic farming(38).

To prevent or reduce microbiological contamination of organic food when processing, organic food processors are required to adhere to the high standards of food safety, such as frequent monitoring, testing, pest control and training of the workers (22).

These results offer a conceptual basis to **H1**: The application of risk-based assessment methodologies helps to identify food safety issues in organic food systems. It demonstrates that the identification of microbiological hazards is a fundamental component of risk-based assessment in organic food systems.

### **5.2. Phase II: Food safety risk assessment of HACCP audit results using the FMEA method among Indian organic food enterprises**

The assessment of the outcome of the HACCP audits indicated that all of the inspected organic food processing plants had implemented a food safety management system that complied with regulatory requirements. But there was different implementation of individual system elements.

The greatest compliance rates were observed on requirements related to documentation, including the preparation of the HACCP plan, identification of hazards, and documentation. On the contrary, there was less implementation on the operational elements like continuous monitoring, verification, validation of control measures and efficacy of corrective actions. These differences indicate that formal adherence may not be represented by the actual operational performance of the food safety system.

Using FMEA in the HACCP system has determined the risks related to the principles and steps of the system. The choice of enterprises of organic food industries that had already adopted the HACCP system showed that this system is not applicable to all types of products and also to the size of the company. The overall risk assessment of several organic food industries in India showed significant disparity in sectors (Table 4). The risks that were identified were not critical or high. A higher risk score of 180 units was found in fruit and vegetables, RTE, and dairy plants. The meat industry scored lowly at 120 meaning that its risk levels were relatively moderate. It is worth noting that rice sector scored the highest risk of 240.

Table 4. Overall risk assessment based on the type of organic enterprises.

| Type of company                | Mean score | % conformity | of FMEA (Risk = S×O×D) |   |   |      |
|--------------------------------|------------|--------------|------------------------|---|---|------|
|                                |            |              | S                      | O | D | Risk |
| <b>Fruits &amp; vegetables</b> | 4.09       | 81.8         | 10                     | 3 | 6 | 180  |
| <b>Meat</b>                    | 4.86       | 97.2         | 10                     | 2 | 6 | 120  |
| <b>RTE</b>                     | 4.13       | 82.6         | 10                     | 3 | 6 | 180  |
| <b>Dairy</b>                   | 4.20       | 84.0         | 10                     | 3 | 6 | 180  |
| <b>Rice</b>                    | 3.91       | 78.2         | 10                     | 4 | 6 | 240  |

Table source: developed based on **P2**

Results of FMEA indicated the presence of different levels of risks depending on the types and sizes of Indian organic food companies. The larger companies in all types of products always have low (minor) risk level, and the scores usually are within 50 and 150 (Table 5). Even medium size businesses tend to handle minor risks, but at times this goes into the moderate risk category, especially with things like dairy and fresh produce whose risk scores can sometimes go up to 200. Risks to the smaller companies in certain product categories were moderate to high, with increased incidence and decreased detectability. To illustrate, small companies in dairy and fruit and vegetables industries had moderate risk scores (around 350) and fresh produce and rice exhibited increasing risks with slightly higher as well as near high risk scores of around 400.

Table 5. Overall risk assessment based on type and size of the enterprise

| Type of company     | Company size | % of conformity | FMEA (Risk = S×O×D) |   |   |      |
|---------------------|--------------|-----------------|---------------------|---|---|------|
|                     |              |                 | S                   | O | D | Risk |
| Fruits & vegetables | Small        | 68              | 10                  | 6 | 6 | 360  |
|                     | Medium       | 85              | 10                  | 3 | 6 | 180  |
|                     | Big          | 92.8            | 10                  | 2 | 6 | 120  |
| Meat                | Small        | 93.4            | 10                  | 2 | 6 | 120  |
|                     | Medim        | 99.2            | 10                  | 2 | 6 | 120  |
|                     | Big          | 99.2            | 10                  | 2 | 6 | 120  |
| RTE                 | Small        | 63.6            | 10                  | 7 | 6 | 420  |
|                     | Medim        | 84.4            | 10                  | 3 | 6 | 180  |
|                     | Big          | 100             | 10                  | 1 | 6 | 60   |
| Dairy               | Small        | 68.2            | 10                  | 6 | 6 | 360  |
|                     | Medim        | 84.2            | 10                  | 3 | 6 | 180  |
|                     | Big          | 99.6            | 10                  | 2 | 6 | 120  |
| Rice                | Small        | 63              | 10                  | 7 | 6 | 420  |
|                     | Medim        | 80              | 10                  | 4 | 6 | 240  |
|                     | Big          | 92.2            | 10                  | 2 | 6 | 120  |

Table source: developed based on P2

FMEA results indicated the lack of critical risks, which is a positive outcome of the system safety. The assessment however had high and moderate risks in some key actions like hazard analysis, identification and monitoring of critical control points (CCPs), corrective measures, verification processes and recordkeeping. Other authors also found such nonconformities that could cause the same risk (25,28). In this method, the failures were probable and their likelihood of occurrence was determined and their effects on the system were evaluated (30). These findings indicate that there should be special development in these areas to achieve robust risk management and food safety processes. The findings of the audit indicated that there was a higher conformity and reduced risks in meat industries compared to other businesses in addition to the findings of the study indicating that non-conformance problems in meat industries were emphasized particularly in small- and medium-sized plants in the study by Kang and Hong (39). Other authors (40–42) also made similar observations assessed in meat slaughterhouses

The findings support **H1** and **H2** and confirm the relevance of extensive and risk-based audit strategies. The results show that the application of risk-based assessment methodologies helps to identify food safety issues in organic food systems. (**H1**) and food safety audits are an effective tool to verify whether food safety systems are properly implemented and functioning. (**H2**). Thus, the two hypotheses, **H1** and **H2** were confirmed.

### **5.3. Phase III: Enterprise-level HACCP compliance assessment in Indian organic food sector**

The second study (**P3**) focused on identifying organizational factors affecting the level of HACCP implementation. The statistical analysis revealed significant differences in compliance levels depending on enterprise characteristics.

The two-way ANOVA was used to examine the effects of product type, company size, and product type and company size on the HACCP compliance score among certified organic food processing businesses in Kerala, India. These scores were HACCP implementation (Part I), HACCP functioning (Part II) and general HACCP scores. They include f-values, equal p-values, mean squares, and sums of squares. HACCP compliance depends on the type of product, the size of the company, as well as on their interaction based on statistically significant effect sizes ( $p < 0.05$ ) (Table 6). The ANOVA 2 way analysis showed a statistically significant impact of the type of product, the size of the company and their combination on HACCP implementation (Part I) as well as HACCP functioning (Part II) and total HACCP compliance scores.

Table 6. The results of two-way ANOVA assessing the effects of product type, company size, and their interaction on HACCP implementation (Part I), HACCP functioning (Part II), and total HACCP compliance scores.

| <b>Part I (HACCP Implementation score)</b> |         |
|--------------------------------------------|---------|
| Groups                                     | P-value |
| Type of products                           | <0.001  |
| Company size                               | <0.001  |
| Type × Size interaction                    | <0.001  |
| <b>Part II (HACCP Functioning score)</b>   |         |
| Groups                                     | P-value |

|                          |         |
|--------------------------|---------|
| Type of products         | 0.007   |
| Company size             | <0.001  |
| Type × Size interaction  | <0.001  |
| <b>Total HACCP score</b> |         |
| Groups                   | P-value |
| Type of products         | 0.004   |
| Company size             | <0.001  |
| Type × Size interaction  | <0.001  |

Table source: developed based on **P3**

To assess the effect of the product type and size of the company on the HACCP compliance, two-way ANOVA tests were conducted consecutively on each of the scores categories and the difference value between the average scores of the two groups under comparison was taken. The asterisk (\*) in the mean values signifies that there is statistical significance between the two group means. In part I (Documentation), statistically significant effects were observed on the product type ( $F = 3.75$ ,  $p < 0.001$ ), company size ( $F = 55.91$ ,  $p < 0.001$ ), and a significant interaction effect ( $F = 7.34$ ,  $p < 0.001$ ) existed where the effects of company size were different based on the type of product. The same was true of Part II (functioning) with all product types ( $F = 2.60$ ,  $p = 0.007$ ), company size ( $F = 38.67$ ,  $p < 0.001$ ) and all interactions ( $F = 5.29$ ,  $p < 0.001$ ) being significant. Regarding the total HACCP score, all the fundamental effects and interactions were significant (product type:  $p = 0.004$ ; company size:  $p < 0.001$ ; interaction:  $p < 0.001$ ).

There were higher scores in HACCP compliance in companies that processed meat and ready-to-eat (RTE) foods. By comparison, the rice-based and dairy processing units scored low. Intermediate performance was seen in fruit and vegetable processors. Companies with high HACCP compliance were large companies followed by medium-sized companies and finally, the small enterprises recorded the lowest levels of HACCP compliance in all the areas evaluated.

Hierarchical cluster analysis was used to create three distinct groups of the high, moderate, and low level of HACCP compliance. Meat and ready-to-eat item processing businesses were predominant in the high-compliance category (0). The largest proportion of the moderate-compliance cluster consisted of medium-sized companies that represent different product lines (1). The major group in the low-compliance cluster (2) was composed of small-scale processors

(primarily in rice-based and dairy products), which indicates that structural limitations to HACCP processing persist.

These results were further supported by the cluster analysis where companies were grouped into high, moderate and low compliance clusters which closely reflected the disparity in company size and product type. Clusters that performed well consisted of large companies or companies that dealt with export sensitive goods and those that did not do so and were dominated by small companies.

The hierarchical cluster analysis of products categories according to HACCP audit score produced a dendrogram which entailed grouping of the five products types into three major clusters (Figure 2). Ready-to-Eat (RTE) and Dairy products were the two that were close to each other, meaning that they were almost identical in terms of HACCP compliance scores. Fruits and Rice represented another sub-cluster that was moderate. Meat products were placed as an independent cluster that is further away than the other groups signifying a lesser reliance of similarity in HACCP scores that when compared to others. The clustering was founded on patterns of scores on the HACCP documentation and operating components.

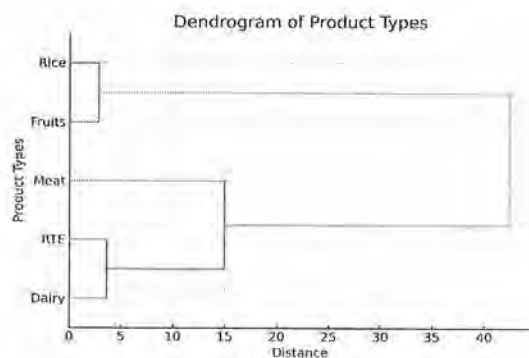


Figure 2. Hierarchical cluster dendrogram of organic food processing enterprises based on HACCP documentation, functioning, and total compliance scores, identifying three distinct compliance clusters.

Figure source (P3).

The PCA correlation diagram diagrams demonstrate how variables that affect HACCP compliance relate among them such as the company size, product type and audit score components. PC1 and PC2 include the first two major components (PC1 and PC2), respectively, which represent 55.0 and 30.0 percent of the total variation, respectively, and cumulatively 85 percent of the variation in the data.

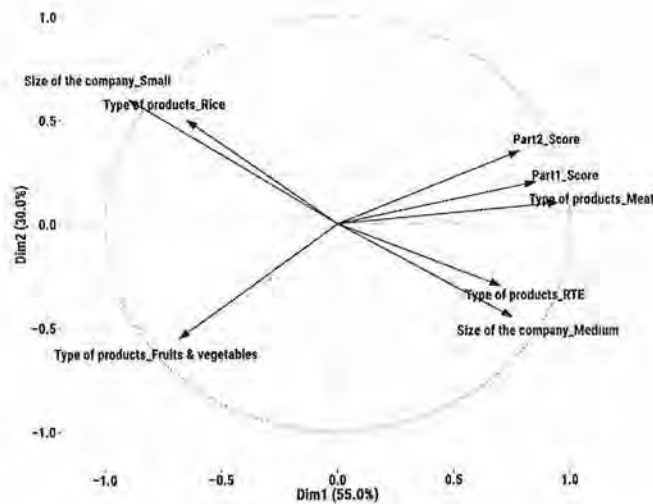


Figure 3. PCA biplot illustrating associations between HACCP compliance scores, company size, and product categories among certified organic food processors.

Figure source (P3)

As the diagram (Figure 3) shows, Part I score and Part II score vectors are close to each other, which means that these two variables show a strong positive correlation. The nature of the product, meat and the RTE vector are found within the positive quadrant of the documentation and functioning scores meaning that these processors also have an effective implementation of the HACCP system. The Rice vector is in the negative Dim1 and positive Dim2 sphere, and thus this position opposes the functions and documentation scores. This means that it is negatively correlated. The fruits and vegetables vector points in a medium negative direction on both scales indicating that performance amongst these processors is ambivalent. Small companies are a pointer in the strong negative direction in Dim1, almost the antithesis of the documentation and functioning vectors. This indicates that small businesses always rank below in HACCP compliance. Medium-sized company vector is in the positive Dim1 and negative Dim2 quadrant, which is near the origin. This shows a moderate positive correlation with HACCP documentation and functioning.

Interestingly, the research revealed a significant interaction effect between company size and type of products and this revealed that the size does not have a similar effect on the performance of HACCP on the products of different types (43). This implies that the risk profile of the item

can increase the structural constraints of smaller businesses and make them even less able to comply with regulations in higher-risk groups (44). According to the researchers (4,22,45), there were considerable gaps in the knowledge of the operators of organic food companies in the chosen EU countries regarding the principles and implementation of HACCP systems, in particular, documentation and hazard analysis. Though improvement of HACCP implementation in underdeveloped nations is challenged with significant challenges, including poor regulatory systems, lack of technical expertise, and poor understanding of hygiene, this challenge also comes with a huge opportunity (46,47). The trend of organic food demand in the world is increasing (48–51). With this popularity, developing countries will not only be able to improve food safety and the health of people, but also establish themselves competitively in expanding worldwide organic markets.

These results support **H2** and **H3**. The results show that food safety audits are an effective tool to verify whether food safety systems are properly implemented and functioning (**H2**). Enterprise characteristics such as company size and product type affect the level of compliance with food safety (**H3**). Hence both **H2** and **H3** are validated. Meanwhile, the results indicate that regulatory pressure might not be enough, especially in relation to small and medium-sized enterprises. These companies probably need extra technical and organizational assistance.

#### **5.4. Phase IV: Comparative assessment of food safety rules, quality management and sustainability approaches among organic food stakeholders in different countries**

This study examined differences in food safety practices between organic food processing enterprises operating in different national contexts. The comparative analysis revealed statistically significant differences in overall HACCP compliance between India and Italy.

The results of the questionnaire revealed clear trends in all three areas. Food safety rules were the most inconsistent, and quality management was shown to be the strongest area. Particularly among smaller enterprises, sustainability procedures were the weakest and least consistent, suggesting a lack of capability or a lack of emphasis on environmental measures. These trends illustrate that different areas have varying levels of maturity, with food safety rules and sustainability exhibiting more firm-to-firm variation and quality management being rather well-established.

The Mann-Whitney U test findings showed that there was no statistically significant difference in the level of quality management in India and Italy ( $p = 0.94$ ), which showed that the level of performance was similar in the two countries. Owing to this, both sustainability ( $p < 0.001$ ) and

food safety rules ( $p < 0.001$ ) differed significantly. It indicates that there are the same quality management mean scores in both countries, implying that there are the same levels of quality system implementation. Instead, Italy has superior mean ratings than India on sustainable practices and food safety regulation, which implies better and more consistent compliance in said aspects (Table 7).

Table 7. Quality, sustainability, and food safety compliance in India and Italy.

| Variables                | Country | Std. Deviation | p Value |
|--------------------------|---------|----------------|---------|
| Quality management       | India   | 0.27           | 0.94    |
|                          | Italy   | 0.22           |         |
| Sustainability practices | India   | 0.27           | <0.001  |
|                          | Italy   | 0.14           |         |
| Food safety rules        | India   | 0.31           | <0.001  |
|                          | Italy   | 0.22           |         |

Table source: developed based on P4

Table 8 uses statistical measures of mean, standard deviation, median and Mann-Whitney U test to provide a size wise score of quality management, food safety rules and sustainability practices between the organic food business in Italy and India. Although the scores related to sustainability are not hugely different across countries, there is a distinct difference in the small business in Italy, which scores higher in the quality management and food safety regulations. No statistically significant differences are found in any of the three dimensions of medium-sized businesses, which implies that compliance behaviour is consistent. However, compliance with food safety rules is statistically the same, large Indian companies have achieved higher quality management and sustainability than the Italian companies. In general, the table demonstrates that the trend of cross-country compliance is highly dependent on the size of firms.

8. Quality management, food safety rules, and sustainability practices between India and Italy across different company sizes.

| Size  | Variables          | p Value |
|-------|--------------------|---------|
| Small | Quality management | 0.004   |
|       | Food safety rules  | <0.001  |
|       | Sustainability     | 0.084   |

|        |                    |        |
|--------|--------------------|--------|
| Medium | Quality management | 0.354  |
|        | Food safety rules  | 0.501  |
|        | Sustainability     | 0.496  |
| Large  | Quality management | <0.001 |
|        | Food safety rules  | 0.897  |
|        | Sustainability     | 0.002  |

Table source: developed based on **P4**

Italy has always done more successfully compared to India in terms of sustainability and general food safety regulations, as more mean scores and fewer deviations in these parameters were noticed. A small number of authors investigated the consumer perception concerning organic foods in Italy (52,53). This tendency is likely to be explained by the strict and uniform regulatory frameworks introduced to the agri-food industry by the European Union(7), which demand a systematic adoption of HACCP by the industry, its traceability, hygiene management, and monitoring of its environmental performance. The Italian organic companies belong to the well-established ecosystem, where sustainability, quality management, and certification become the part of everyday business and are enhanced by frequent audits, networking of businesses and high demands of customers towards transparency (54,55).

India however, had more variation in sustainability and food safety. Despite the high availability of various businesses with strong internal quality management systems, the larger deviation of ratings indicates inconsistency of the environmental management use, documentation processes, and hygiene standards (58,59). Such differences may be explained by technical capacity differences, lack of infrastructure, and the different levels of development of the Indian organic business. Moreover, there is still a lack of standardisation of compliance culture in businesses as the organic industry is relatively new in areas such as Kerala (56,60).

The findings confirm the importance of regulatory capacity and stakeholder practices in the attainment of food safety in the organic industry. The results show that the level of sustainability practices and food safety compliance differs among stakeholders in the organic food industry (**H4**). Thus, **H4** is confirmed.

## 6. Conclusion

The study offers an in-depth evaluation of food safety assurance in the organic food market through the combination of hazard identification, evaluation through audit, compliance statistical analysis, and cross-country comparison. The results show that even though the common belief holds that organic food is naturally safer, food safety in the organic sector represents risks associated with production practices and the implementation of food safety ensuring system.

The analysis of the HACCP implementation showed that, in spite of the fact that the formal compliance with food safety results is usually obtained, there remain serious gaps in the areas of operational activities, including monitoring, verification, and corrective measures. This means that certification and documentation are not enough to affect adequate management of the risk of food safety. Failure Mode and Effects Analysis (FMEA) was applied to illustrate that risk-based strategies promote more effective assessment of HACCP implementation and performance and, thus, more effective food safety evaluation.

1. Food safety ensuring among organic stakeholders should be supported by risk management due to the possibility of serious gaps in the areas of operational activities, including monitoring, verification, and corrective measures.
2. The food safety audits can be conducted as an effective tool supporting risk-based thinking and verification of the proper implementation and functioning of food safety systems.
3. Small enterprises demonstrate lower and more variable performance in food safety assessments, which is associated with differences in HACCP compliance.
4. The level of sustainability practices and food safety compliance differs significantly among selected organic stakeholders and is associated with the regulatory frameworks and company size. Higher and more consistent compliance was observed in the country with stronger regulatory frameworks, underscoring the importance of effective governance and regulatory oversight.

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**8. Copies of the articles making up the doctoral thesis and statements of co-authors**



Warsaw, 10/03/2026

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**Co-authorship statement**

I hereby represent that in the thesis, Murali AP, Trzaskowska M, Trafialek J. Microorganisms in Organic Food-Issues to Be Addressed. Microorganisms. 2023; 11(6):1557.<https://doi.org/10.3390/microorganisms11061557>, my individual contribution in the development thereof involved methodology, investigation, data curation, writing—original draft preparation, writing—review and editing, visualization.



**Signature**



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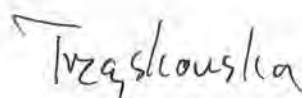
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**Signature**

A handwritten signature in black ink, appearing to read 'Trzaskowska', with a stylized flourish at the end.



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**Signature**



Review

# Microorganisms in Organic Food-Issues to Be Addressed

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**Abstract:** The review aimed to analyse the latest data on microorganisms present in organic food, both beneficial and unwanted. In conclusion, organic food's microbial quality is generally similar to that of conventionally produced food. However, some studies suggest that organic food may contain fewer pathogens, such as antibiotic-resistant strains, due to the absence of antibiotic use in organic farming practices. However, there is little discussion and data regarding the importance of some methods used in organic farming and the risk of food pathogens presence. Concerning data gaps, it is necessary to plan and perform detailed studies of the microbiological safety of organic food, including foodborne viruses and parasites and factors related to this method of cultivation and specific processing requirements. Such knowledge is essential for more effective management of the safety of this food. The use of beneficial bacteria in organic food production has not yet been widely addressed in the scientific literature. This is particularly desirable due to the properties of the separately researched probiotics and the organic food matrix. The microbiological quality of organic food and its potential impact on human health is worth further research to confirm its safety and to assess the beneficial properties resulting from the addition of probiotics.

**Keywords:** organic food; food safety; microorganisms; pathogen; probiotic



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## 1. Introduction

Organic agriculture is one of the fastest-growing agricultural sectors [1] and is different from conventional agriculture in its approach to farming practices, with organic agriculture prioritizing natural methods and minimizing synthetic inputs, while conventional farming relies heavily on synthetic chemicals as well as genetically modified organisms to achieve high yields [2–4]. Generally, organic foods are products derived from organic agriculture, and as a consequence, these products lack Genetically Modified Organisms (GMOs), artificial colours, preservatives, and flavour enhancers. Organic cultivation avoids or prohibits the utilization of artificial feed additives, pesticides, herbicides, growth hormones, and similar substances [5–9]. Furthermore, one of the fastest-expanding sectors presently is the worldwide organic food market, experiencing a growth rate of several per cent annually [7,10]. This can be attributed to the overall progress of the organic farming industry and the societal focus of national policies. There is a shift towards promoting sustainable development in rural areas through the adoption of resource-conserving technologies [10].

Consumers buy organic foods because they associate this kind of food with a healthy and sustainable diet and lifestyle [10–13]. Global sales of organic products have increased significantly in the 21st century. For instance, according to a survey conducted in 2016, the majority of Americans (68%) indicated that they had bought organic food at least once during the previous month [7]. Between 2014 and 2018, organic retail market in the European Union (EU) and across Europe has seen strong progress. Every year in that period, the EU market grew by 3.4 to 3.5 billion Euros [14]. Between 2016 and 2020, the organic food market in the Asia-Pacific region experienced a compound annual growth rate (CAGR) of 11.4%, resulting in total revenues of \$16.4 billion in 2020 [15].

The notion that organic food might be healthier has some support [16,17]. While there seems to be minimal variation in terms of macronutrient content (such as protein, fat, carbohydrate, and dietary fibre) between organic and conventional food products, additional differences in composition have been observed. These contain higher antioxidant concentrations (particularly polyphenols) in organic crops [16,18], increased levels of omega-3 fatty acids in organic dairy products [11,16] and better fatty acid profiles in organic meat products [3,16]. When contrasting organic goods with alternatives made using conventional methods, consumers of organic food take several non-monetary factors into account [19]. Food safety, nutritional, and sensory features are these non-monetary factors that influence consumers' preferences between organic and conventionally grown produce [19,20]. Product flavour, shelf-life, and freshness are other attributes that contribute to purchasing decisions of organic shoppers [19,21,22]. Several studies revealed that organically grown foods have lower nitrate content and higher mineral and dry matter contents than non-organically grown foods [19,23,24]. Total daily nitrates intake in vegetables from organic farming was equal to  $1.91 \text{ mg NO}_3 \text{ kg}^{-1} \text{ bw day}^{-1}$  (28.5% ADI) [25]. In most cases, the majority of the time, the nitrate content of organic veggies was lower than that of conventional vegetables. However, production procedures, seasonal variations, and the size of those variations can all affect the nitrate level [26]. Regarding the impact on human health, a higher frequency of organic food consumption was linked with a reduced risk of cancer [27].

For centuries, different microorganisms are used in the production of food and food ingredients mainly in the processing of wine, beer, bakery, and dairy products as well as vegetables and cereals [28].

Among valuable microbes are probiotics, i.e., "live microorganisms that, when administered in adequate amounts, confer a health benefit on the host". Probiotics can have different means of administration, for example as drugs, with common and medicinal foods, non-oral probiotics, animal feed, defined microbial consortia, dietary supplements, or infant formula [29]. Probiotics have various health benefits, including intestinal and non-intestinal effects. Among others, the prevention of diarrhoea and gastrointestinal cancers, the alleviation of lactose intolerance, and a decrease in *Helicobacter pylori* infections. The impact of using probiotics on immunological conditions, including asthma, and atopic disorders is unconfirmed in humans. However, they may have an advantageous effect by reducing symptom severity and medication usage [30–32].

The other group of microorganisms present in food are spoilage and pathogenic microorganisms, which are considered as one of the main causes of food loss [33]. Moreover, foodborne illnesses due to the consumption of foods contaminated with foodborne pathogens pose a significant public health problem [34]. Like conventional food, organic food must by law fulfil the food safety requirements, and it must be produced according to specific regulations [35–38]. The microbial quality of organic food can vary depending on a variety of factors, including production practices, handling, processing, and storage conditions [39].

In 2017, Garcia and Teixeira conducted an in-depth literature review and discussion of the safety of organic food [35]. Regarding pathogens, food samples contained harmful microorganisms more often than those from conventional systems. The authors suggested further food safety studies comparing organic and conventional production with more samples analysed and over a longer period.

Therefore, the purpose of the review was to analyse the latest data on microorganisms present in organic food, not only undesirable but also beneficial. Comprehensive knowledge of the microbiological quality of organic food is essential to fully understand the factors that shape its unique value. Determining data gaps allows for proper planning of further research and, consequently, ensuring the highest microbiological quality and safety of organic food.

## 2. Materials and Methods

A comprehensive search of relevant reports from academic databases, such as PubMed, Scopus, and Science Direct, was conducted. The search was related to the keywords, such as organic food, organic food standards, microorganisms, microbial quality, food safety, pathogens, probiotics, etc.

The timeline for the literature sources was set from 2017 to 2023. The article titles and abstracts were reviewed and duplicates were eliminated. Only studies on organic food quality and safety and microorganisms were considered for inclusion. Selected sources of evidence included research and review articles, short communications, peer-reviewed conference materials, book chapters, and to a minimum extent, websites of recognized institutions.

## 3. Results

### 3.1. Standards for Organic Food

Some standards are referring to the set of guidelines and regulations that define what qualifies as organic food. Furthermore, they ensure that organic food is produced in a way that minimizes harm to the environment and promotes sustainable agriculture. In this context, various regulatory bodies around the world have developed their organic food standards, which are designed to meet the unique needs of their respective countries and regions. Whenever doubts exist relating to the usage of synthetic chemicals, the relevant law should be consulted.

The USDA (United States Department of Agriculture) [36,37,40,41] and the EU (European Union) [38,42] have established stringent standards for organic foods, ensuring the integrity and quality of these products. In Asia, the standards for organic foods vary among countries. While some Asian countries have developed their organic certification systems, there is no unified standard across the region. A regional standard for organic production in East, Southeast, and South Asia is called the Asia Regional Organic Standard (AROS). The procedure that led to AROS was intended to harmonize regional organic standards and promote new ones [43,44].

Legal requirements do not define any additional precautions for food products regarding microbiological quality. However, care must be taken with plant and animal components to preserve or improve soil organic matter in a way that avoids the transmission of pathogenic organisms into crops, soil, or water [45].

Microbial quality is an essential parameter that determines the safety and shelf-life of food products [45,46]. Organic food should not be treated with chemical preservatives, which can increase the risk of bacterial growth during storage and transportation. However, there are allowed natural substances and processes that are used along the organic food chain to ensure food safety. Moreover, consumers need to handle and prepare organic food safely to minimize the risk of microbial contamination [47]. The presence of harmful microorganisms, such as pathogenic bacteria, viruses, and parasites, in food can cause foodborne illnesses, leading to severe health consequences [48–50]. Therefore, ensuring the microbial safety of organic food is very important.

In the EU, from a legal point of view, Commission Regulation (EC) No. 2073/2005 of 15 November 2005 and Commission Regulation (EC) No. 1441/2007 of 5 December 2007 on microbiological criteria for food products lay down microbiological criteria for certain microorganisms and the implementing regulations to be met by food stakeholders. The regulation sets limits on the levels of microorganisms that are considered acceptable in organic food products based on the potential health risks associated with their consumption. These limits are based on scientific evidence and are designed to ensure that organic food products are safe for consumers to eat. In addition to setting limits on microbial contamination, the regulation also requires organic food producers to implement good hygiene practices and monitor and test their products for microbial contamination. This helps to further ensure that organic food products meet the microbial quality standards established by the EU [51,52].

### 3.2. Microorganisms in Organic Food

Microbial contamination in organic food production can pose health risks to consumers as it may lead to foodborne illnesses, such as bacterial infections, viral outbreaks, and fungal infections. Vulnerable populations, such as pregnant women, elderly individuals, and those with weakened immune systems, may be particularly susceptible to these risks [53].

Microorganisms can be present in any type of food, including organic food. Microbes are found all over the globe with a few exceptions, for example, sterilized surfaces [54]. Microorganisms such as *Salmonella* spp., *Escherichia coli* O157:H7, and *Listeria* spp. are commonly associated with plant foods. *Salmonella* spp. is frequently found in cut fruits, pre-cut melons, fresh papayas, cucumbers, and other fresh produce [55–57]. *Escherichia coli* O157:H7 is frequently associated with sprouts, lettuce, spinach, and other leafy greens [56,58–60]. *Listeria* spp. are often found in cantaloupes, mushrooms, apples, stone fruits, and other fresh produce [56,61–63]. *Salmonella* Typhimurium is a type of bacteria commonly found in animal foods such as poultry, beef, pork, and seafood [64–66]. *Campylobacter jejuni* and *Campylobacter coli* are two species of bacteria widely found in animal foods such as poultry, cattle, pigs, and even domestic pets [64,67]. Shiga-toxin-producing *E. coli* (STEC) is another type of bacteria that can be found in animal foods such as beef, sheep, goats, and other ruminants [64,68]. *Listeria monocytogenes* is a microorganism that can be found in animal foods of cattle, sheep, goats, and poultry origin [64,69,70]. These microorganisms can cause foodborne illnesses and pose a risk to public health. To reduce the risk of foodborne illness, it is crucial to follow proper food safety practices when growing, processing, and preparing food.

Beneficial microorganisms that benefit human health and food production consist of another kind of microorganisms found in food. Numerous clinical studies have demonstrated the efficacy of probiotics in the treatment of conditions, such as type 2 diabetes, obesity, non-alcoholic fatty liver disease, and insulin resistance syndrome. Probiotics' beneficial benefits on human health have also been demonstrated by raising immunity (immunomodulation) [71]. For example, *Bifidobacterium breve* is commonly found in European fermented milk [72,73]. *Enterococcus faecium* is present in soybean, dairy, meat, and vegetables, and is used in probiotic foods to support gut health. *Lactobacillus acidophilus* is found in fermented milk and vegetables. Moreover, *Lactobacillus delbrueckii* is commonly found in yoghurt, fermented milk, and mozzarella cheese, and can improve digestion and promote overall health [72]. *Lactobacillus kefir* is found in fermented milk and can reduce the bitter taste in citrus juice [72,74,75]. *Pediococcus acidilactici* is used in meat fermentation and biopreservation of meat as well as in cheese starters [72,76]. *Lactococcus lactis* is used as a dairy starter and can produce nisin that plays a role of a protective culture that helps to prevent the growth of harmful bacteria in food [72].

Given the high interest in organic food, little data on its microbiological quality has been found in the available literature as of 2017. The newest and most available data are listed in Table 1.

The study of Urkek et al. (2017) aimed to investigate the effects of production methods and milk collection periods on the somatic cell count and some microbiological properties in Turkey. Comparing organic milk to conventional milk, the general means of the total aerobic mesophilic bacteria, coliform, yeast, and mould counts were significantly lower, but the general means of the somatic cell count and the coagulase-positive *S. aureus* count was significantly higher [77].

Malissiova et al. (2017) studied the differences in the microbial profile and antimicrobial resistance of bacteria isolated from milk from organic and conventional sheep and goat farms. The study involved 25 organic and 25 conventional sheep and goat farms. It was found that milk from organic farms has a better microbiological profile compared to milk from conventional farms [78].

Another research regarding the dairy product was conducted by Selah et al. (2023). The goal of this study was to assess the microbiological quality of organic and conventional Minas Frescal cheese samples as well as the antimicrobial susceptibility of isolated cultures

of *Escherichia coli* and coagulase-positive staphylococci to various antimicrobial agents. *Listeria* spp. and *Salmonella* spp. were not detected in any of the analysed samples. For coagulase-positive staphylococci, 43.4% conventional and 26.6% organic samples had a higher count than recommended by Brazilian regulations but with no significant difference between the systems. In determining the most likely *E. coli* count, a significant difference was observed between the systems, with a higher rate of contamination in cheeses from the organic system. Given the similarity of the acquired results, it is required to investigate other criteria, such as the production system, herd health, and appropriate production methods, to thoroughly compare the two systems [79].

Regarding plant organic foods, Szczech et al. [80] have found that the numbers of mesophilic bacteria, yeasts and moulds, coliforms, and Enterobacteriaceae for radishes and carrots were similar in organic and conventional farming systems. Organic lettuce contained significantly more bacteria than conventional lettuce. Organic beetroot contained higher amounts of yeasts and moulds and Enterobacteriaceae than conventional. Vegetables from organic farms were characterized by a significantly higher load of *E. coli* than vegetables from conventional farms. Furthermore, a farmer survey was conducted to gather information on farm management practices. An index (from 0—no risk to 4—high risk) of potential contamination of the product with human pathogens was developed related to the fertilization system. Its value increased with the increased share of manure and other animal waste used for fertilization. Organic products, therefore, had a higher contamination risk index (2–4) than conventional vegetables (1–2). High rates were associated with a higher amount of *E. coli*. It was discovered that the organic farm's fertilizer strategy may degrade the hygienic quality of the products. [80].

Kuan et al. [81] compared the microbiological status of organic vs. conventional fresh produce at the retail level in Malaysia. The findings revealed that mesophilic aerobic bacteria, yeasts and moulds, and all coliforms were present in comparable amounts in most types of conventional and organic vegetables. None of the samples examined for this investigation included *E. coli* O157:H7 or *S. Typhimurium*. Vegetables cultivated either organically or conventionally did not generally provide a higher microbial risk. [81].

In terms of research on the presence or development of organic foods with the addition of beneficial microorganisms (defined as probiotics), no studies were found. The only example in this field is the study by Rzepkowska et al. [82] on the isolation of strains with potential probiotic properties. Thus, spontaneously fermented organic foods can be a source of beneficial microorganisms. This direction of research is supported by the results of Wassermann et al. [83] who compared the apple microbiota to find tissue-specific variations and the effects of organic vs. conventional management. Organic and conventional apples contained a similar quantity of microbiota. However, organically managed apples harbour a significantly more diverse, more even, and distinct microbiota compared to conventional ones.

In light of numerous studies on the positive impact of microorganisms on health, including gut microbiota, it is important to address this issue in organic food research. Many factors influence the composition of the gut microbiota and its functioning, but one of the main triggers is diet [84]. Therefore, one can expect additional benefits that may result from combining in one product the proven properties of organic food, e.g., antioxidants, dietary fibre content, and others [16,18,19], with the proven impact of food ingredients on the condition of the microbiota [85–87].

**Table 1.** Examples of pathogens and beneficial organisms found in organic foods since 2017.

| Pathogen                                                             | Animal Foods       | Count [log10 cfu g/mL <sup>-1</sup> ] or Prevalence [%] | Reference |
|----------------------------------------------------------------------|--------------------|---------------------------------------------------------|-----------|
| <i>Campylobacter</i>                                                 | Raw chicken meat   | 25%                                                     | [88]      |
| <i>Salmonella</i>                                                    | Pigs               | 8.3%                                                    | [88,89]   |
|                                                                      | Eggs               | 2.6%                                                    |           |
|                                                                      | Dairy farms        | 20%                                                     |           |
|                                                                      | Poultry farms      | 2.9%                                                    |           |
| Shiga toxin-producing <i>Escherichia coli</i>                        | Beef               | 14.8%                                                   | [88,89]   |
| <i>Listeria monocytogenes</i>                                        | Chicken meat       | 25%                                                     | [88]      |
|                                                                      | Eggs               | 1.8%                                                    |           |
| <i>Staphylococcus aureus</i>                                         | Chicken farms      | 1.3%                                                    | [79,88]   |
|                                                                      | Meat               | 16.7%                                                   |           |
|                                                                      | Poultry farms      | 27.4%                                                   |           |
|                                                                      | Dairy products     | 31%                                                     | [77]      |
|                                                                      | Milk               | 0.28–0.91                                               |           |
| Coliforms                                                            | Milk               | 2.72–4.46                                               | [77]      |
| Yeasts and moulds                                                    | Milk               | 2.46–3.70                                               | [77]      |
| Pathogen                                                             | Plant Foods        |                                                         |           |
| Mesophilic bacteria                                                  | Organic vegetables | 6.6–7.2                                                 | [80,81]   |
| <i>Enterobacteriaceae</i>                                            | Lettuce            | 2.5 0                                                   | [80,81]   |
|                                                                      | High-protein bar   | 2.81–3.32                                               |           |
| Coliforms                                                            | Lettuce            | 1.80                                                    | [80,81]   |
| <i>Escherichia coli</i>                                              | Organic vegetables | 1.00                                                    | [80,81]   |
| Yeasts and moulds                                                    | Organic vegetables | 5.10                                                    | [80,81]   |
| Beneficial Bacteria                                                  | Food Product       |                                                         |           |
| <i>Lactic acid bacteria with high potential for food application</i> | Organic Whey       | -                                                       | [82]      |

### 3.3. Factors Affecting the Microbial Quality of Organic Food

The main sources of microbial contamination and strategies for improving the microbial quality of organic food are summarized in Table 2.

The microbial safety of fresh produce is influenced significantly by various factors, with the conditions present at the growing site being particularly crucial. Both organic and conventional agriculture make substantial use of manure and other animal wastes. Concerns regarding the possibility of products being contaminated with microbiological organisms, particularly *Escherichia coli* O157, occur when manure is used as fertilizer in either conventional or organic agriculture [90]. Soil fertilized by animal manure is more likely to be contaminated with enteric pathogens because of their ability to survive in soil for months or years [91]. The content of *E. coli* and *Salmonella* spp. is between 10<sup>2</sup> and 10<sup>5</sup> CFU/g and between 10<sup>2</sup> and 10<sup>7</sup> CFU/g, respectively, in animal faeces. The manure of ruminants (cattle and sheep) and sewage are reputed to be the main sources of *Salmonella* spp. and *E. coli* O157:H7. Furthermore, *C. jejuni* is a typical member of the gastrointestinal microbiota of poultry, pigs, and cattle. Fresh produce's microbiological safety is influenced by the quality of the irrigation water and the system type. The safety of fresh produce's microbiology is influenced by harvesting and processing. These processes that can both contaminate products with hazardous microorganisms and encourage bacterial development include human and mechanical touch, immersion in water, and cutting or slicing [92].

Concerning manure usage in organic farming, the research conducted by Nazareth et al. [89] is quite interesting and relevant. The researchers examined models of integrated organic crop and livestock systems established in three US states. Organically reared cattle and their feed, faeces, skin, and meat were tested for two pathogens, *Escherichia coli* O157:H7 and *Salmonella* spp. The results confirmed that *E. coli* O157:H7 was not isolated from any skin or meat sample. Across all locations, the prevalence of *E. coli* O157:H7 in feed and faeces was 9.43 and 7.26%, respectively. *Salmonella* spp. were isolated from 1.89, 3.33, and 18.6% of feed, faeces, and skin samples, respectively. *Salmonella* spp. was not detected in any meat sample. From June to August, the feed was more likely to test positive for *E. coli* O157:H7, highlighting the necessity of stringent sanitation procedures to avoid feed contamination. These findings demonstrate the potential for reducing the risk of microbiological contamination in integrated agricultural and livestock systems through rigorous adherence to food safety management measures [89].

The effectiveness of composting chicken manure was demonstrated in the experiment of Begum et al. [93]. The study investigated the current situation of small poultry farms and their waste management practices in selected areas of Bangladesh, and the presence of *Escherichia coli* and *Salmonella* in vegetables from farms using unprocessed poultry manure as fertilizer. *E. coli* or *Salmonella* or both have been confirmed in vegetables, soil and, pond water but only in untreated poultry waste used for fertilization.

#### 3.4. Strategies for Improving Microbial Quality of Organic Food and Data Gaps

One of the essential components for sustaining life on Earth is soil. Almost half of the Sustainable Development Goals (SDGs) are linked to soil [94]. Numerous goals can be achieved by adopting sustainable land utilization and enhancing the quality of the soil. These objectives can be defined as the ability of soil to serve as an essential living system, supporting biological productivity, safeguarding environmental integrity, and preserving the well-being of plants, animals, and humans [94,95]. Pathogenic microorganisms originate from the environment in which plants grow as well as post-harvest movements, processing, and transport movements. One of the most important post-harvest practices for preventing food-borne illnesses and preserving the excellent quality of raw fruits and vegetables is post-harvest microbial control, for instance, utilizing suitable disinfection procedures [96].

Organic food processors need to implement rigorous food safety practices, including regular monitoring, testing, pest control, and training of personnel, to prevent or minimize microbial contamination during processing [97].

A range of food safety issues have been raised concerning organic primary production and processing, including mycotoxins, enteric pathogens, and heavy metal and agro-chemical residues [98,99]. In the regulation on microbiological criteria of food products (No. 2073/2005), it is stated that food business operators at each step of food production, processing, and distribution, including retail, must implement precautions to assure that food safety and process hygiene criteria are met as part of their procedures based on Hazard Analysis and Critical Control Point (HACCP) principles along with the implementation of good hygiene practices (GHP). Therefore, the HACCP plans for organic production are elaborated and brochures for consumers, retailers, and producers on the safety and contamination of organic food are written [97]. Documentation for apples, grapes, cereals, cabbage, and tomatoes as well as milk and egg production are included. These provide practical advice to improve the quality and safety of organic products [100].

Microbial contamination can be a major concern when it comes to the packaging of organic food. The packaging stage of the food production process is essential because it maintains the quality of the finished goods for use in storage, transit, and consumption. [101]. With packaging methods, the industry has designed modified atmosphere packaging (MAP), edible-film coating, and active packaging. Packaging methods need minimal human intervention over the properties of the food product, giving consumers a sense of an “unprocessed” and “natural” product [102–104].

The consumer of processed organic food expects a specific nutritional and sensory value. Particularly, processing techniques that do not significantly alter the nutritional and sensory qualities of food could provide goods that look appealing and fresh. Given that they are required to maintain the nutritional value of food, health-conscious consumers should prefer “minimally” processed food [102,105,106]. It is proved that even with restricted usage of chemical substances, simple combinations of water heated to 60 °C, acetic acid (0.2–5%), and H<sub>2</sub>O<sub>2</sub> (3–4%) can reduce the count of all three species of bacterial pathogens on mung bean [107]. Therefore, a re-examination of known methods using permitted chemicals seems to be the right direction in the development of research on the safety of organic food.

To mitigate microbial contamination during wholesale storage of organic food, proper handling, storage, and transportation practices should be followed. This includes maintaining appropriate temperature and humidity levels, regular cleaning and sanitizing of equipment and facilities, avoiding cross-contamination between different food products, and implementing strict hygiene protocols for food handlers [108,109].

Comparing organic products to conventional foods on the same level, organic products appear to be more sensitive to microbial infection [110,111]. Therefore, additional research is required to assess the product’s safety and determine the appropriate storage times [110]. Proper storage of organic food can help prevent the growth of harmful bacteria. This can include refrigeration, proper packaging, and controlling the temperature and humidity. Food products’ moisture content can fluctuate even slightly due to changes in atmospheric humidity. The increase in air humidity caused the product under test to absorb moisture from air and also caused a change in the product’s mass. At 80% relative air humidity and 25 °C, the maximum mass gain and mass growth rate were noted [112]. All strategies for improving the microbial quality of organic food should be based on the requirements of the hygiene of foodstuffs and should contain rules and programs referring to Good Manufacturing Practices, Good Hygiene Practices, and Hazard Analysis and Critical Control Point (HACCP) principles [113]. They are mandatory both for conventional and organic food producers and processors alike. The examples of the strategies for improving and managing the microbial quality of organic food at different stages are presented in Table 2.

**Table 2.** Microbial contamination sources and main strategies for improving microbial quality of organic food production.

| Production Stage/Sources                                                                                                                                                                      | Strategies for Improving Microbial Quality                                                                                                                                                                                                                                                                                                                                                                                     | Reference           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <b>Farming</b>                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |
| Soil, faeces, irrigation water, reconstituted fungicides and insecticides, dust, insects, inadequately composted manure, wild or domestic animals, and human handling.                        | Good agricultural and handling practices relating to soil, faeces, manure, pests, and cleaning. Training of workers.<br>Post-harvest microbial control.                                                                                                                                                                                                                                                                        | [53,92,108,114,115] |
| <b>Harvesting</b>                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |
| Harvesting equipment, transport containers, insects, dust, and human handling.                                                                                                                | Establishing rules of conduct for harvesting.<br>Training of workers and using good agricultural and handling practices. Post-harvest microbial control.                                                                                                                                                                                                                                                                       | [53,92,108,116]     |
| <b>Processing</b>                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |
| Rinse water, ice, transport vehicles, and human handling. Improper temperature control, cross-contamination with contaminated surfaces or equipment, and lack of proper packaging or sealing. | Implementing effective washing and disinfection program refers to transporting vehicles, equipment, and production utensils to avoid cross-contamination with contaminated surfaces or equipment. Pest control. Applying proper personnel hygiene rules and training of personnel.<br>Establishment of the right conditions for storage of raw materials and final product, daily temperature control, and processing methods. | [108,113,117,118]   |

Table 2. Cont.

| Production Stage/Sources                                                              | Strategies for Improving Microbial Quality                                                                                                                                                                                                                                                                              | Reference         |
|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Wholesale storage                                                                     |                                                                                                                                                                                                                                                                                                                         |                   |
| Storage temperature, containers, dust, insects, human handling, storage duration etc. | Establishment of proper handling, storage, and transportation practices to maintain appropriate temperature and humidity levels. Regular cleaning and sanitizing of equipment and facilities to avoid cross-contamination between different food products, and implementing strict hygiene protocols for food handlers. | [108,113,117,118] |

#### 4. Conclusions

In conclusion, the microbial quality of organic food is generally considered to be similar to that of conventionally produced food. However, some studies suggest that organic food may contain lower numbers of harmful bacteria, such as antibiotic-resistant strains, due to the absence of antibiotic use in organic farming practices. Therefore, it is important to note that while organic farming practices may reduce the risk of certain bacterial infections; however, they do not eliminate all potential risks associated with foodborne illness.

On the other hand, there is still little discussion and data regarding the importance of some methods used in organic farming and the risk of food pathogens presence. From the scientific point of view, additional studies are needed to fully assess the risk of using manure and free-range breeding and its influence on the transmission of foodborne pathogens along the food chain.

The application of proper food safety measures, such as appropriate cooking and handling techniques, should always be followed regardless of whether the food is organic or conventionally grown.

Concerning data gaps, it is necessary to plan and perform detailed studies of the microbiological safety of organic food, including factors related to this method of cultivation and specific food processing requirements. Among the missing data are those on the prevalence of foodborne viruses and parasites. Such knowledge is essential for more effective management of the safety of this food.

Bearing in mind that not all microorganisms are harmful, the use of beneficial ones in organic food production has not yet been widely addressed in the scientific literature. This is particularly desirable due to the properties of the separately researched probiotics and the organic food matrix. The expected mutually reinforcing effect must be supported by research results.

In conclusion, the microbiological quality of organic food and its potential impact on human health is worth further research. Both to confirm its safety and to assess the beneficial properties resulting from the addition of probiotics.

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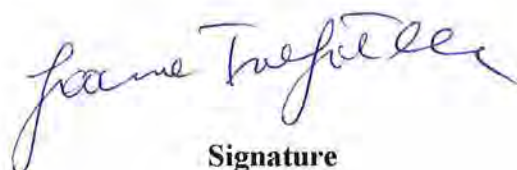
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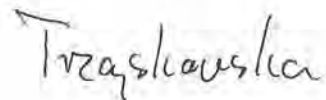
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A handwritten signature in black ink, appearing to read 'Trzaskowska', is written over a light gray rectangular background.



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A handwritten signature in dark ink, reading 'Wojciech Kolanowski', written in a cursive style.

**Signature**



## RESEARCH ARTICLE

# Food Safety Risk Assessment Based on HACCP Audit Results Using the Fmea Method in Indian Organic Food Processing Plants

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## ARTICLE HISTORY

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**Abstract: Introduction:** The safety of organic food is increasingly recognized as a critical factor for both environmental sustainability and consumer health in India. However, there is a lack of structured methodologies to assess risks specific to organic food enterprises, especially regarding Hazard Analysis and Critical Control Points (HACCP) implementation.

**Methods:** An audit was conducted across 100 organic food enterprises in Kerala, India. The selected enterprises represented five product categories: fruits and vegetables (n=28), dairy products (n=19), ready-to-eat foods (n=14), meat products (n=14), and rice (n=15). A structured audit questionnaire was used, and the collected data were analyzed using the FMEA method.

**Results:** Larger companies consistently demonstrated low risk levels across all product categories. Medium-sized enterprises generally managed minor risks, although some instances of moderate risk were observed. Smaller enterprises in certain categories exhibited moderate to high risk levels.

**Discussion:** There is evidence of both successful applications and persistent obstacles in the global adoption of HACCP, which varies by country and industry. Recent data from Iraq show quantifiable hygiene benefits in food service through HACCP implementation, whereas studies emphasize challenges in UK small and medium enterprises, structured adoption in Oman's seafood sector, and various approaches in other countries.

**Conclusion:** The proposed FMEA-based method accurately detected weaknesses in organic food processing in India. It provides a scalable strategy to improve HACCP implementation, with potential for large-scale application in enhancing food safety in organic sectors worldwide.

**Keywords:** Audits, food safety, HACCP, organic food, risk assessment, health concerns.

## 1. INTRODUCTION

Food safety is a fundamental public health concern globally, with direct implications for consumer well-being, economic stability, and social welfare [1]. Risk assessment is a systematic approach that is essential in the food industry to ensure consumer health, comply with regulations, and maintain food quality [2]. Beyond simply satisfying customers, risk assessment in the food industry is crucial as it directly impacts public health, social welfare, and economic stability [3-5]. It supports compliance with regulatory requirements and promotes consumer confidence by maintaining product quality and safety standards [6-9].

The organic food business in India is rapidly growing, reflecting rising consumer acceptance [10-12]. Its popularity stems from health concerns and increasing awareness of the environmental and health issues associated with conventional farming, such as pesticide residues and chemical fertilizers [13-19]. Although there is no conclusive evidence that organic products are nutritionally superior, consumer preferences have shifted toward perceived safety. A strong regulatory framework that ensures quality and safety is essential for maintaining trust and supporting the growth of organic agriculture in India [20-22].

In India, there are three main categories of regulations regarding the safety of organic food: general regulations that apply to all foods, regulations specific to organic foods, and certification schemes. In 2011, the Food Safety and Standards Act of India, Schedule IV, mandated efforts for the im-

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plementation of Hazard Analysis and Critical Control Points (HACCP); however, HACCP remains a voluntary system in India [23, 24].

HACCP is a globally recognised preventive approach for food safety management. It prioritises hazard prevention over end-product testing by identifying and reducing biological, chemical, and physical risks at all stages of food processing and handling [25-27]. HACCP has been applied with varying degrees of success in different countries. Research has shown that it can be difficult to implement in small and medium-sized food businesses in the UK [28], can be adopted in a structured manner in the fish industry of Oman [29], there are various global approaches to HACCP application [30, 31], and it can improve hygiene in restaurants in the Basrah Governorate of Iraq [32]. Effective HACCP implementation greatly minimises the risk of foodborne diseases and contamination, contributing to improved public health outcomes [33-36]. Implementing the HACCP system significantly enhances food safety by providing a systematic approach to identifying and managing potential hazards [37-39].

This study used an audit-based approach to perform risk assessment based on HACCP system audit results, enabling an accurate evaluation of food safety levels in organic food processing enterprises in India. Organic food firms were selected due to their rapid growth in India and the lack of data on food safety risk management in this emerging sector. Since no existing methodology for risk assessment in the Indian organic food sector was available, we developed a risk assessment methodology based on Failure Mode and Effects Analysis (FMEA). It was hypothesized that this risk assessment would provide more in-depth insights into food safety risk factors within individual companies. Despite the increasing adoption of HACCP in the organic food sector, research on risk assessment based on HACCP audits in organic food enterprises, particularly in India, remains limited. The aim of this study was to develop and practically validate a methodology for risk assessment in Indian organic food enterprises using FMEA based on HACCP audits. The results address this gap by examining risks in both HACCP implementation and its operational effectiveness within this growing food industry sector.

## 2. MATERIALS AND METHODS

### 2.1. Selection of Enterprises

The audit was conducted in 100 organic food enterprises in Kerala, India. The selection process was carried out with the support and collaboration of a private organic food certification agency in India. All 100 enterprises had already implemented the HACCP system in their processes.

The selected enterprises included different types of products such as fruits & vegetables ( $n=28$ ), dairy products ( $n=19$ ), ready-to-eat ( $n=14$ ), meat products ( $n=14$ ), and rice ( $n=15$ ). 90% of the selected enterprises were local producers ( $n=90$ ), and only 10 % ( $n=10$ ) were exporters. The selected enterprises, except the exporters, were subdivided into 3 groups according to the company size: big, medium, and

small. Company size was determined based on annual turnover, using thresholds aligned with Indian food industry standards: Small: turnover less than INR (Indian rupee) 100 crore, medium: turnover between INR 250 crore and INR 500 crore, large: turnover above INR 500 crore [40]. The study and audit were carried out in the year 2023.

### 2.2. Audit Process

The audit process relied on a structured audit questionnaire proposed by Trafialek and Kolanowski [41] based on the criteria introduced in the Codex Alimentarius standards [42], ISO (International Organization for Standardization) 19011 guideline for auditing management systems [43].

The audit questionnaire was divided into two main parts:

Part I: Implementation of HACCP system - This section focused on assessing how well the HACCP system had been implemented within the industry. It contained 12 blocks addressing different steps of the HACCP application, such as hazard identification, critical control points (CCPs), monitoring procedures, and corrective actions [41].

Part II: Functioning of the Existing HACCP System - This section focused on evaluating the ongoing effectiveness and efficiency of the HACCP system. It consisted of 6 blocks and contained HACCP principles from II to VII functioning in practice [41].

Each segment included relevant questions designed to assess specific criteria, with the auditor required to score each question based on the degree of compliance observed. The auditor had extensive experience in food quality management, HACCP implementation and auditing, food hygiene research, and was regularly evaluated per ISO 19011 [43], maintaining competence through ongoing professional development and training. A grading scale was used for assessment: the highest score awarded was 5, which corresponded to all the requirements being met (100% compliance); a score of 4 reflected a slight deviation from complete fulfilment of all of the requirements (approximately 80% compliance); while a score of 3 meant that requirements were fulfilled to an inadequate extent (approximately 60% compliance); the lowest score was 2, which indicated that only a minority of the requirements were fulfilled (less than 40% compliance) [41, 44]. The scale did not have a clearly defined center, which allowed the auditor some flexibility to exercise judgment when assigning final scores. Scores of 4 and 5 indicated a pass, while scores of 2 and 3 indicated a fail for both documentation and functioning.

### 2.3. Application of FMEA for Risk Assessment

This study used a modified Failure Mode and Effects Analysis (FMEA) method to assess risk in organic food enterprises, based on Trafialek and Kolanowski's approach [41]. The technique was divided into three phases, each with a distinct level of risk rating based on HACCP audit data (Fig. 1). The goal was to create and verify a viable risk assessment tool specific to the organic food business in India.

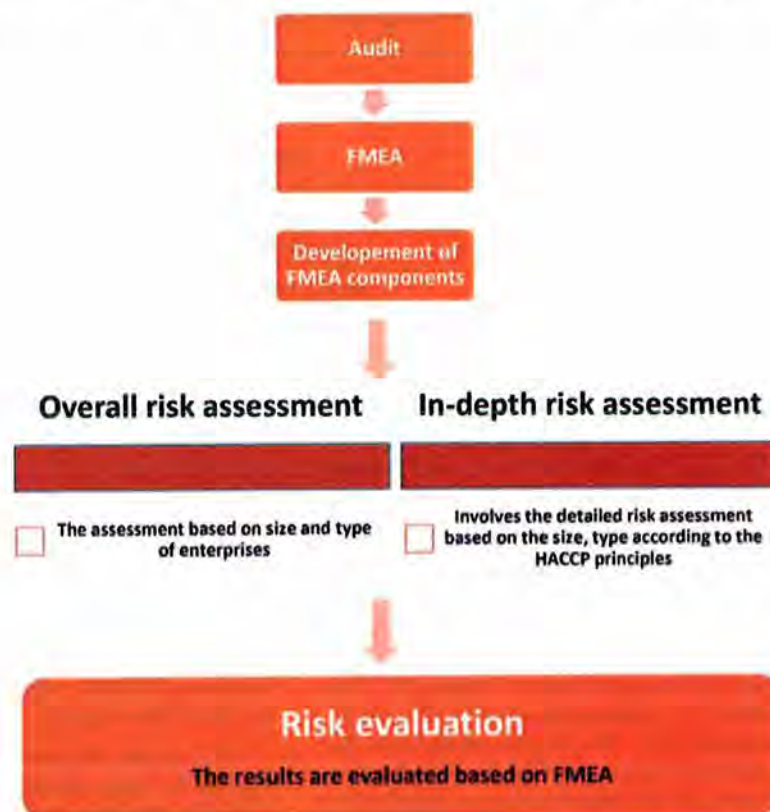


Fig. (1). Schematic diagram: stepwise process of risk assessment in organic food enterprises. (A higher resolution / colour version of this figure is available in the electronic copy of the article).

### 2.3.1. Phase I: Overall Risk Assessment

The first phase provided a general overview of risk across companies, categorized by type and size. This stage was intentionally simplified to allow benchmarking and trend identification among enterprises.

The formula used for calculating risk was:

Risk (R) = Severity (S) × Occurrence (O) × Detectability (D)

- Severity (S) was fixed at 10, reflecting the high potential impact on food safety.
- Detectability (D) was fixed at 6, indicating average detection ability.
- Occurrence (O) was determined from the HACCP audit scores.

Risk scores were then grouped into four categories: minor, moderate, high, and critical (Fig. 2) [41, 45, 46]. These standardised values facilitate a broad understanding of risk trends without delving into the nuances of each company's specific risk factors. In contrast, the specific risk assessment was conducted with a more detailed approach, incorporating calculations based on actual data specific to each company and size. This method [41] allowed for more accurate and actionable risk evaluation.

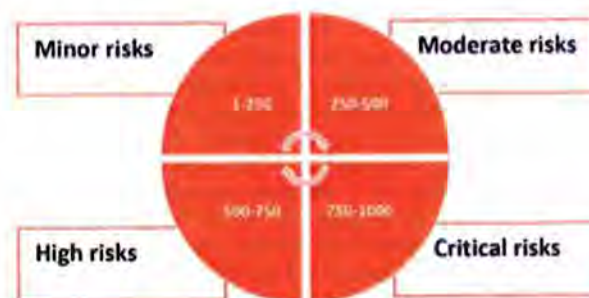


Fig. (2). Risk matrix displaying scores based on severity across risk categories, and adopted risk units. (A higher resolution / colour version of this figure is available in the electronic copy of the article).

### 2.3.2. Phase II in-depth Assessment

The assessment was based on a detailed evaluation of risk factors specific to each company type. It incorporated a range of critical elements in the HACCP system, including steps and principles. Unlike the overall assessments conducted in the earlier Phase I, this step provided actionable insights into the unique vulnerabilities of each company, ensuring that risk management interventions were both relevant and effective. The total scores obtained for each section of the questionnaire were analysed, and the risk for each section was calculated using the FMEA method [41]. This approach identified probable failures, assessed their likelihood of oc-

**Table 1.** The scale and scores for calculating s (severity) value & o (occurrence) values.

| S value            |                     | HACCP Steps                                                                                                                      | O value - Overall & In-depth Assessment |            |
|--------------------|---------------------|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------|
| Overall Assessment | In-depth Assessment |                                                                                                                                  | O Value                                 | Mean Score |
| 10                 | 1                   | Establish HACCP team (step 1)                                                                                                    | 1                                       | 5          |
| 10                 | 2                   | Describe product (step 2)                                                                                                        | 2                                       | 4.5-5      |
| 10                 | 3                   | Identify intended use (step 3)                                                                                                   | 3                                       | 4-4.5      |
| 10                 | 4                   | Construct flow diagram (Step 4)                                                                                                  | 4                                       | 3.75-4     |
| 10                 | 5                   | Onsite confirmation of flow diagram (step 5)                                                                                     | 5                                       | 3.5-3.75   |
| 10                 | 6                   | Establish documentation and recordkeeping (step 12, Principle VII)                                                               | 6                                       | 3.25-3.5   |
| 10                 | 7                   | Identify and analyse hazards, determine critical control limits, establish critical limits (steps 6, 7, 8, Principle I, II, III) | 7                                       | 3-3.25     |
| 10                 | 8                   | Establish monitoring systems for CCPs, establish corrective actions (steps 9, 10, Principle IV, V)                               | 8                                       | 2.5-3      |
| 10                 | 9                   | Establish verification procedures (step 11, Principle VI)                                                                        | 9                                       | 2.25-2.5   |
| 10                 | 10                  | Functioning of HACCP Part II                                                                                                     | 10                                      | 2          |

currence, and evaluated their impact on the system [47]. The FMEA included three key components: severity (S), occurrence (O), and detection (D). The S value represented the food safety requirements; each step of the HACCP has importance in the process, but its impact varies, as described in Table 1 [41]. The O value was calculated based on the mean score obtained for each section of the questionnaire.

If the mean score is high, the occurrence is low, and vice versa. The O values corresponding to each mean score are given in Table 1. The D value (detectability) indicates how easily a nonconformity can be identified without an audit and reflects the likelihood of detecting a potential hazard or failure within a process. It ranges from 1 to 10, with lower values indicating easier detection. A D value of 1 represents very easy detectability, where issues are highly visible, while a D value of 3 indicates average detectability, requiring standard monitoring. As values increase (4-6), detection becomes progressively harder, requiring more focused inspection. Values between 7 and 8 represent very hard detectability, often requiring specialised attention, and values of 9 or 10 indicate that detection is highly unlikely.

### 2.3.3. Phase III: FMEA-based Evaluation

In the final phase, the risk values calculated in Phase II were evaluated using the FMEA model to prioritize failure modes. This process helped identify the most critical areas in HACCP implementation, guiding risk mitigation and the allocation of resources.

## 3. RESULTS

### 3.1. Overall Risk Assessment Based on the Type of Enterprise

Applying FMEA to the HACCP system identified the risks associated with its principles and steps. The selection of enterprises from organic food industries that had already implemented the HACCP system showed that the system

functions differently depending on the type of product and the size of the company.

The overall risk assessment of various organic food industries in India revealed notable variation across sectors (Table 2). The identified risks were not high or critical. Fruit and vegetable, RTE, and dairy plants each showed a risk score of 180 units. The meat and exporting industries had a lower risk score of 120, suggesting relatively moderate risk levels in their operations. Notably, the rice sector exhibited the highest risk score of 240.

### 3.2. Overall Assessment of Risk Based on the Size and Type of the Enterprise

The FMEA results revealed varying risk levels based on company size and type of organic food in India. Larger companies across all product categories consistently maintained low (minor) risk levels, with scores generally between 50 and 150 (Table 3). Medium-sized companies generally managed minor risks; however, in some cases, this reached the moderate risk range, particularly in industries such as dairy and fresh produce, where risk scores sometimes reached up to 200. Smaller companies in certain product categories faced moderate to high risks due to higher occurrence rates and lower detectability. For example, in the dairy and fruit & vegetable industries, small companies had moderate risk scores (around 350), while fresh produce and rice showed slightly higher risks with scores around 400, approaching high risk.

### 3.3. In-depth Assessment of the Risk

#### 3.3.1. Overview

The assessment revealed notable differences in the risk levels associated with HACCP implementation and functioning. Larger companies showed lower risk scores,

Table 2. Overall risk assessment based on the type of organic enterprises.

| Type of Company     | Mean Score | % of Conformity | FMEA (Risk = S×O×D) |   |   |      |
|---------------------|------------|-----------------|---------------------|---|---|------|
|                     |            |                 | S                   | O | D | Risk |
| Fruits & vegetables | 4.09       | 81.8            | 10                  | 3 | 6 | 180  |
| Meat                | 4.86       | 97.2            | 10                  | 2 | 6 | 120  |
| RTE                 | 4.13       | 82.6            | 10                  | 3 | 6 | 180  |
| Dairy               | 4.20       | 84.0            | 10                  | 3 | 6 | 180  |
| Rice                | 3.91       | 78.2            | 10                  | 4 | 6 | 240  |

Abbreviations: S - severity; O - occurrence; D - detectability.

Table 3. Overall risk assessment based on type and size of the enterprise.

| Type of Company     | Company Size | Mean Score | % of Conformity | FMEA (Risk = S×O×D) |   |   |      |
|---------------------|--------------|------------|-----------------|---------------------|---|---|------|
|                     |              |            |                 | S                   | O | D | Risk |
| Fruits & vegetables | Small        | 3.4        | 68              | 10                  | 6 | 6 | 360  |
|                     | Medium       | 4.25       | 85              | 10                  | 3 | 6 | 180  |
|                     | Big          | 4.64       | 92.8            | 10                  | 2 | 6 | 120  |
| Meat                | Small        | 4.67       | 93.4            | 10                  | 2 | 6 | 120  |
|                     | Medim        | 4.96       | 99.2            | 10                  | 2 | 6 | 120  |
|                     | Big          | 4.96       | 99.2            | 10                  | 2 | 6 | 120  |
| RTE                 | Small        | 3.18       | 63.6            | 10                  | 7 | 6 | 420  |
|                     | Medim        | 4.22       | 84.4            | 10                  | 3 | 6 | 180  |
|                     | Big          | 5          | 100             | 10                  | 1 | 6 | 60   |
| Dairy               | Small        | 3.41       | 68.2            | 10                  | 6 | 6 | 360  |
|                     | Medim        | 4.21       | 84.2            | 10                  | 3 | 6 | 180  |
|                     | Big          | 4.98       | 99.6            | 10                  | 2 | 6 | 120  |
| Rice                | Small        | 3.15       | 63              | 10                  | 7 | 6 | 420  |
|                     | Medim        | 4          | 80              | 10                  | 4 | 6 | 240  |
|                     | Big          | 4.61       | 92.2            | 10                  | 2 | 6 | 120  |

Abbreviations: S - severity; O - occurrence; D - detectability.

medium-sized companies encountered moderate risks, and small-sized enterprises faced the highest risks (Fig. 3).

The results revealed distinct differences between the risk levels in Part I (HACCP implementation) and Part II (HACCP functioning), irrespective of product type. HACCP functioning showed higher risks compared to HACCP implementation (Fig. 4).

In HACCP implementation, no critical risks were identified, but verification procedures emerged. Moderate risks were associated with steps such as hazard analysis, identifying critical control points (CCPs), establishing monitoring systems, implementing corrective actions, and maintaining recordkeeping. In the HACCP functioning system, critical

risks also remained absent, but high risks were observed in corrective actions, verification procedures, and recordkeeping. Moderate risks were associated with the identification of CCPs and the establishment of monitoring systems (Fig. 5).

### 3.3.2. Comprehensive Assessment

The in-depth assessment involved a detailed risk evaluation based on the company's type and size according to the HACCP procedures, with the results shown in Tables 4-8. In small fruit and vegetable plants, the risk scores ranged widely, from 10 to 600, with the highest values occurring in later HACCP principles, notably verification procedures (600) and corrective actions (540). Medium plants exhibited a more controlled risk profile, with maximum scores of 360

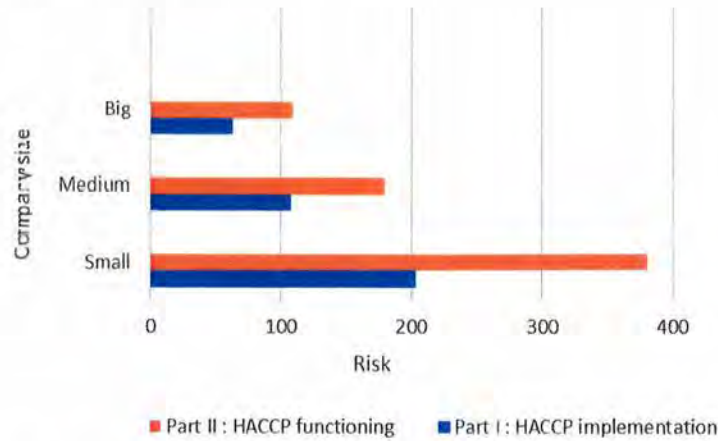


**Fig. (3).** Comparative assessment of risks in HACCP implementation and functioning across company sizes, and adopted risk units. (A higher resolution / colour version of this figure is available in the electronic copy of the article).

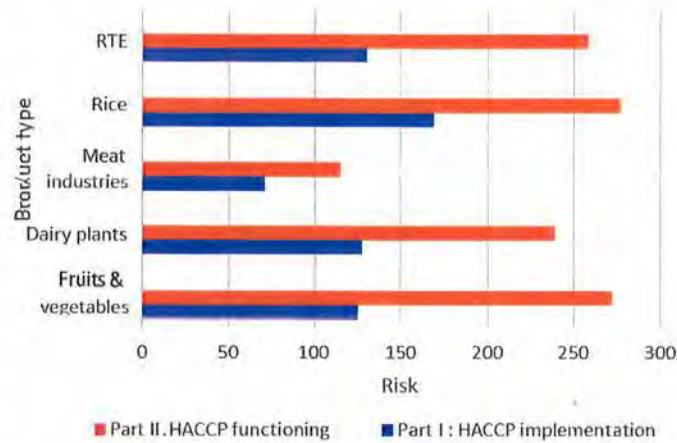


**Fig. (4).** Risk dynamics in HACCP processes based on company type, and adopted risk units. (A higher resolution / colour version of this figure is available in the electronic copy of the article).

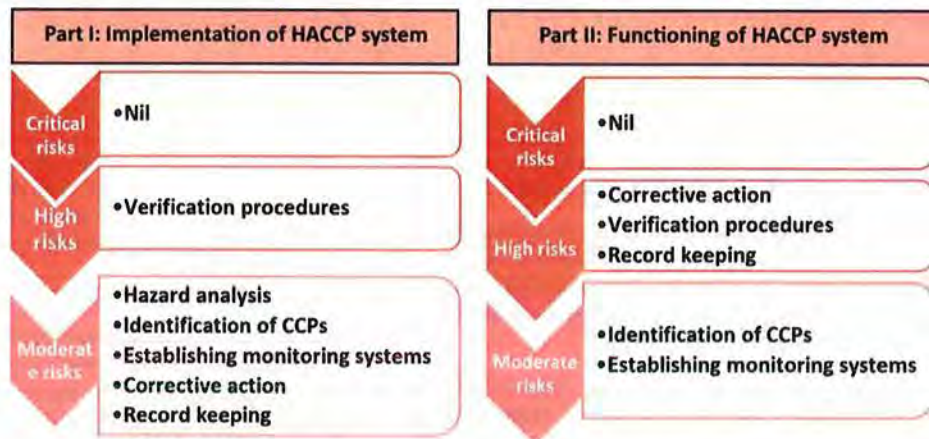


**Fig. (5).** Risk intensity across steps in HACCP implementation and functioning. (A higher resolution / colour version of this figure is available in the electronic copy of the article).

Table 4. In-depth risk assessment of organic fruits &amp; vegetables enterprises.

| Fruits & Vegetables                                                       | Small Plants |      |    |   |    |      | Medium Plants |      |    |   |    |      | Big Plants |      |    |   |    |      |
|---------------------------------------------------------------------------|--------------|------|----|---|----|------|---------------|------|----|---|----|------|------------|------|----|---|----|------|
|                                                                           | Mean Score   | %    | S  | O | D  | Risk | Mean Score    | %    | S  | O | D  | Risk | Mean Score | %    | S  | O | D  | Risk |
| <b>Part I</b>                                                             |              |      |    |   |    |      |               |      |    |   |    |      |            |      |    |   |    |      |
| Step 1. Establishing HACCP team                                           | 3.44         | 68.8 | 1  | 6 | 5  | 30   | 4.47          | 89.4 | 1  | 3 | 5  | 15   | 4.77       | 95.4 | 1  | 2 | 5  | 10   |
| Step 2. Description of products                                           | 3.39         | 67.8 | 2  | 6 | 5  | 60   | 4.24          | 84.8 | 2  | 3 | 5  | 30   | 4.56       | 91.2 | 2  | 2 | 5  | 20   |
| Step 3. Identification of intended use                                    | 3.18         | 63.6 | 3  | 7 | 5  | 105  | 4.16          | 83.2 | 3  | 3 | 5  | 45   | 4.49       | 89.8 | 3  | 3 | 5  | 45   |
| Step 4. Construction of flow diagram                                      | 3.25         | 65   | 4  | 7 | 4  | 112  | 4.24          | 84.8 | 4  | 3 | 4  | 48   | 4.52       | 90.4 | 4  | 2 | 4  | 32   |
| Step 5. On-site confirmation of flow diagram                              | 3.57         | 71.4 | 5  | 5 | 4  | 100  | 4.08          | 81.6 | 5  | 3 | 4  | 60   | 4.52       | 90.4 | 5  | 2 | 4  | 40   |
| Step 6. Principle I. Conducting hazard analysis                           | 4.77         | 95.4 | 7  | 6 | 10 | 140  | 4.16          | 83.2 | 7  | 3 | 10 | 210  | 4.59       | 91.8 | 7  | 2 | 10 | 140  |
| Step 7. Principle II. Identification of critical control points           | 3.53         | 70.6 | 7  | 5 | 10 | 350  | 4.31          | 86.2 | 7  | 3 | 10 | 210  | 4.77       | 95.4 | 7  | 2 | 10 | 140  |
| Step 8. Principle III. Establishment of critical limits                   | 3.33         | 66.6 | 7  | 6 | 4  | 168  | 4.16          | 83.2 | 7  | 3 | 4  | 84   | 4.83       | 96.6 | 7  | 2 | 4  | 56   |
| Step 9. Principle IV. Establishing monitoring systems for each CCP        | 3.48         | 69.6 | 8  | 6 | 5  | 240  | 4.36          | 87.2 | 8  | 3 | 5  | 120  | 4.79       | 95.8 | 8  | 2 | 5  | 80   |
| Step 10. Principle V. Establishment of corrective action                  | 3.45         | 69   | 8  | 6 | 6  | 288  | 4.36          | 87.2 | 8  | 3 | 6  | 144  | 4.74       | 94.8 | 8  | 2 | 6  | 96   |
| Step 11. Principle VI. Establishment of verification procedures           | 3.32         | 66.4 | 9  | 6 | 9  | 486  | 4.2           | 84   | 9  | 3 | 9  | 243  | 4.65       | 93   | 9  | 2 | 9  | 162  |
| Step 12. Principle VII. Establishment of documentation and record-keeping | 3.41         | 68.2 | 6  | 6 | 9  | 324  | 4.27          | 85.4 | 6  | 3 | 9  | 162  | 4.7        | 94   | 6  | 2 | 9  | 108  |
| <b>Part II</b>                                                            |              |      |    |   |    |      |               |      |    |   |    |      |            |      |    |   |    |      |
| Principle II. Identification of critical control points(CCPs)             | 3.1          | 62   | 10 | 7 | 5  | 350  | 4.5           | 90   | 10 | 3 | 5  | 150  | 4.97       | 99.4 | 10 | 2 | 5  | 100  |
| Principle III. Establishment of critical limits                           | 3.71         | 74.2 | 10 | 5 | 2  | 100  | 4.43          | 88.6 | 10 | 3 | 2  | 60   | 4.83       | 96.6 | 10 | 2 | 2  | 40   |
| Principle IV. Monitoring of CCPs                                          | 3.38         | 67.6 | 10 | 6 | 7  | 420  | 4.22          | 84.4 | 10 | 3 | 7  | 210  | 4.55       | 91   | 10 | 2 | 7  | 140  |
| Principle V. Establishment of corrective action                           | 3.47         | 69.4 | 10 | 6 | 9  | 540  | 4.22          | 84.4 | 10 | 3 | 9  | 270  | 4.55       | 91   | 10 | 2 | 9  | 180  |
| Principle VI. Verification procedures                                     | 3.39         | 67.8 | 10 | 6 | 10 | 600  | 4.23          | 84.6 | 10 | 3 | 10 | 300  | 4.63       | 92.6 | 10 | 2 | 10 | 200  |
| Principle VII. Record-keeping and documentation                           | 3.4          | 68   | 10 | 6 | 9  | 540  | 3.92          | 78.4 | 10 | 4 | 9  | 360  | 4.26       | 85.2 | 10 | 3 | 9  | 270  |

observed in documentation and recordkeeping, keeping them within the minor risk level. For large plants, the FMEA revealed lower risk levels, with maximum scores of 270 in corrective actions and recordkeeping, all within the minor risk category (Table 4).

The risk assessment in organic dairy plants revealed variations according to plant size. In small plants, the risk scores were higher compared to medium- and large-sized plants. The highest risks (600, 540) were found in HACCP principle VI, verification procedures, and principle VII, recordkeeping

Table 5. In-depth risk assessment of organic dairy plants.

| Dairy Plants                                                             | Small Plants |      |    |   |    |      | Medium Plants |      |    |   |    |      | Big Plants |     |    |   |    |      |
|--------------------------------------------------------------------------|--------------|------|----|---|----|------|---------------|------|----|---|----|------|------------|-----|----|---|----|------|
|                                                                          | Mean Score   | %    | S  | O | D  | Risk | Mean Score    | %    | S  | O | D  | Risk | Mean Score | %   | S  | O | D  | Risk |
| <b>Part I</b>                                                            |              |      |    |   |    |      |               |      |    |   |    |      |            |     |    |   |    |      |
| Step 1. Establishing HACCP team                                          | 3.26         | 65.2 | 1  | 6 | 5  | 30   | 4.38          | 87.6 | 1  | 3 | 5  | 15   | 5          | 100 | 1  | 1 | 5  | 5    |
| Step 2. Description of products                                          | 3.36         | 67.2 | 2  | 6 | 5  | 60   | 4.39          | 87.8 | 2  | 3 | 5  | 30   | 5          | 100 | 2  | 1 | 5  | 10   |
| Step 3. Identification of intended use                                   | 3.35         | 67   | 3  | 6 | 5  | 90   | 4.24          | 84.8 | 3  | 3 | 5  | 45   | 5          | 100 | 3  | 1 | 5  | 15   |
| Step 4. Construction of flow diagram                                     | 3.43         | 68.6 | 4  | 6 | 4  | 96   | 4.21          | 84.2 | 4  | 3 | 4  | 48   | 5          | 100 | 4  | 1 | 4  | 16   |
| Step 5. On-site confirmation of flow diagram                             | 3.5          | 70   | 5  | 5 | 4  | 100  | 4.09          | 81.8 | 5  | 3 | 4  | 60   | 5          | 100 | 5  | 1 | 4  | 20   |
| Step 6. Principle I. Conducting hazard analysis                          | 3.45         | 69   | 7  | 6 | 10 | 420  | 4.12          | 82.4 | 7  | 3 | 10 | 210  | 5          | 100 | 7  | 1 | 10 | 70   |
| Step 7. Principle II. Identification of critical control points          | 3.5          | 70   | 7  | 5 | 10 | 350  | 4.19          | 83.8 | 7  | 3 | 10 | 210  | 5          | 100 | 7  | 1 | 10 | 70   |
| Step 8. Principle III. Establishment of critical limits                  | 3.44         | 68.8 | 7  | 6 | 4  | 168  | 4.22          | 84.4 | 7  | 3 | 4  | 84   | 5          | 100 | 7  | 1 | 4  | 28   |
| Step 9. Principle IV. Establishing monitoring systems for each CCP       | 3.42         | 68.4 | 8  | 6 | 5  | 240  | 4.23          | 84.6 | 8  | 3 | 5  | 120  | 5          | 100 | 8  | 1 | 5  | 40   |
| Step 10. Principle V. Establishment of corrective action                 | 3.41         | 68.2 | 8  | 6 | 9  | 288  | 4.34          | 86.8 | 8  | 3 | 9  | 144  | 5          | 100 | 8  | 1 | 9  | 48   |
| Step 11. Principle VI. Establishment of verification procedures          | 3.48         | 69.6 | 9  | 6 | 9  | 486  | 4.17          | 83.4 | 9  | 3 | 9  | 243  | 5          | 100 | 9  | 1 | 9  | 81   |
| Step 12. Principle VII. Establishment of documentation and recordkeeping | 3.37         | 67.4 | 6  | 6 | 9  | 324  | 4.28          | 85.6 | 6  | 3 | 9  | 162  | 5          | 100 | 6  | 1 | 9  | 54   |
| <b>Part II</b>                                                           |              |      |    |   |    |      |               |      |    |   |    |      |            |     |    |   |    |      |
| Principle II. Identification of critical control points (CCPs)           | 3.37         | 67.4 | 10 | 6 | 5  | 300  | 4.34          | 86.8 | 10 | 3 | 5  | 150  | 5          | 100 | 10 | 1 | 5  | 50   |
| Principle III. Establishment of critical limits                          | 3.41         | 68.2 | 10 | 6 | 2  | 120  | 4.36          | 87.2 | 10 | 3 | 2  | 60   | 5          | 100 | 10 | 1 | 2  | 20   |
| Principle IV. Monitoring of CCPs                                         | 3.52         | 70.4 | 10 | 5 | 7  | 350  | 4.25          | 85   | 10 | 3 | 9  | 210  | 4.85       | 97  | 10 | 1 | 9  | 140  |
| Principle V. Establishment of corrective action                          | 3.36         | 67.2 | 10 | 5 | 9  | 450  | 4.04          | 80.8 | 10 | 3 | 10 | 270  | 5          | 100 | 10 | 1 | 10 | 90   |
| Principle VI. Verification procedures                                    | 3.37         | 67.4 | 10 | 6 | 10 | 600  | 4.12          | 82.4 | 10 | 4 | 9  | 300  | 5          | 100 | 10 | 1 | 9  | 100  |
| Principle VII. Recordkeeping and documentation                           | 3.42         | 68.4 | 10 | 6 | 9  | 540  | 3.94          | 78.8 | 10 | 3 | 7  | 360  | 5          | 100 | 10 | 2 | 7  | 90   |

and documentation. Moderate risks were observed in hazard analysis, CCP identification, CCP monitoring, and corrective actions (Table 5).

The risk assessment in meat industries showed relatively favorable results compared to other product types. In small

plants, verification procedures scored a maximum risk of 200, which is still a minor risk, though close to moderate. In medium- and large-sized industries, the risk levels remained under the minor risk threshold (Table 6).

Table 6. In-depth risk assessment of organic meat industries.

| Meat Industries                                                           | Small Plants |      |    |   |    |      | Medium Plants |     |    |   |    |      | Big Plants |      |    |   |    |      |
|---------------------------------------------------------------------------|--------------|------|----|---|----|------|---------------|-----|----|---|----|------|------------|------|----|---|----|------|
|                                                                           | Mean Score   | %    | S  | O | D  | Risk | Mean Score    | %   | S  | O | D  | Risk | Mean Score | %    | S  | O | D  | Risk |
| Part I                                                                    |              |      |    |   |    |      |               |     |    |   |    |      |            |      |    |   |    |      |
| Step 1. Establishing HACCP team                                           | 4.71         | 94.2 | 1  | 2 | 5  | 10   | 4.85          | 97  | 1  | 2 | 5  | 10   | 4.92       | 98.4 | 1  | 2 | 5  | 10   |
| Step 2. Description of products                                           | 4.75         | 95   | 2  | 2 | 5  | 20   | 5             | 100 | 2  | 1 | 5  | 10   | 5          | 100  | 2  | 1 | 5  | 10   |
| Step 3. Identification of intended use                                    | 4.71         | 94.2 | 3  | 2 | 5  | 30   | 5             | 100 | 3  | 1 | 5  | 15   | 4.94       | 98.8 | 3  | 2 | 5  | 30   |
| Step 4. Construction of flow diagram                                      | 4.84         | 96.8 | 4  | 2 | 4  | 32   | 5             | 100 | 4  | 1 | 4  | 16   | 5          | 100  | 4  | 1 | 4  | 16   |
| Step 5. On-site confirmation of flow diagram                              | 4.75         | 95   | 5  | 2 | 5  | 40   | 4.5           | 90  | 5  | 2 | 4  | 40   | 5          | 100  | 5  | 1 | 4  | 20   |
| Step 6. Principle I. Conducting hazard analysis                           | 4.8          | 96   | 7  | 2 | 10 | 140  | 4.8           | 96  | 7  | 2 | 10 | 140  | 5          | 100  | 7  | 1 | 10 | 70   |
| Step 7. Principle II. Identification of critical control points           | 4.5          | 90   | 7  | 2 | 10 | 140  | 5             | 100 | 7  | 1 | 10 | 70   | 4.96       | 99.2 | 7  | 2 | 10 | 140  |
| Step 8. Principle III. Establishment of critical limits                   | 4.66         | 93.2 | 7  | 2 | 4  | 56   | 5             | 100 | 7  | 1 | 4  | 28   | 5          | 100  | 7  | 1 | 4  | 28   |
| Step 9. Principle IV. Establishing monitoring systems for each CCP        | 4.54         | 90.8 | 8  | 2 | 5  | 80   | 5             | 100 | 8  | 1 | 5  | 40   | 5          | 100  | 8  | 1 | 5  | 40   |
| Step 10. Principle V. Establishment of corrective action                  | 4.5          | 90   | 8  | 2 | 6  | 96   | 5             | 100 | 8  | 1 | 6  | 48   | 4.89       | 97.8 | 8  | 2 | 6  | 96   |
| Step 11. Principle VI. Establishment of verification procedures           | 4.6          | 92   | 9  | 2 | 9  | 162  | 4.9           | 98  | 9  | 2 | 9  | 162  | 4.92       | 98.4 | 9  | 2 | 9  | 162  |
| Step 12. Principle VII. Establishment of documentation and record-keeping | 4.87         | 97.4 | 6  | 2 | 9  | 108  | 5             | 100 | 6  | 1 | 9  | 54   | 4.92       | 98.4 | 6  | 2 | 9  | 108  |
| Part II                                                                   |              |      |    |   |    |      |               |     |    |   |    |      |            |      |    |   |    |      |
| Principle II. Identification of critical control points (CCPs)            | 4.75         | 95   | 10 | 2 | 5  | 100  | 5             | 100 | 10 | 1 | 5  | 50   | 5          | 100  | 10 | 1 | 5  | 50   |
| Principle III. Establishment of critical limits                           | 4.75         | 95   | 10 | 2 | 2  | 40   | 5             | 100 | 10 | 1 | 2  | 20   | 4.96       | 99.2 | 10 | 2 | 2  | 40   |
| Principle IV. Monitoring of CCPs                                          | 4.57         | 91.4 | 10 | 2 | 7  | 140  | 5             | 100 | 10 | 1 | 7  | 70   | 4.98       | 99.6 | 10 | 2 | 7  | 140  |
| Principle V. Establishment of corrective action                           | 4.66         | 93.2 | 10 | 2 | 9  | 180  | 5             | 100 | 10 | 1 | 9  | 90   | 4.97       | 99.4 | 10 | 2 | 9  | 180  |
| Principle VI. Verification procedures                                     | 4.75         | 95   | 10 | 2 | 10 | 200  | 5             | 100 | 10 | 1 | 10 | 100  | 5          | 100  | 10 | 1 | 10 | 100  |
| Principle VII. Record-keeping and documentation                           | 4.57         | 91.4 | 10 | 2 | 9  | 180  | 5             | 100 | 10 | 1 | 9  | 90   | 4.85       | 97   | 10 | 2 | 9  | 180  |

Table 7. In-depth risk assessment of organic rice companies.

| Rice                                                                     | Small Plants |      |    |   |    |      | Medium Plants |      |    |   |    |      | Big Plants |      |    |   |    |      |
|--------------------------------------------------------------------------|--------------|------|----|---|----|------|---------------|------|----|---|----|------|------------|------|----|---|----|------|
|                                                                          | Mean Score   | %    | S  | O | D  | Risk | Mean Score    | %    | S  | O | D  | Risk | Mean Score | %    | S  | O | D  | Risk |
| Part I                                                                   |              |      |    |   |    |      |               |      |    |   |    |      |            |      |    |   |    |      |
| Step 1. Establishing HACCP team                                          | 3.05         | 61   | 1  | 7 | 5  | 35   | 4.52          | 90.4 | 1  | 2 | 5  | 10   | 4.8        | 96   | 1  | 2 | 5  | 10   |
| Step 2. Description of products                                          | 3.3          | 66   | 2  | 6 | 5  | 60   | 4.22          | 84.4 | 2  | 3 | 5  | 30   | 4.62       | 92.4 | 2  | 2 | 5  | 20   |
| Step 3. Identification of intended use                                   | 3.17         | 63.4 | 3  | 7 | 5  | 105  | 4.19          | 83.8 | 3  | 3 | 5  | 45   | 4.42       | 88.4 | 3  | 3 | 5  | 45   |
| Step 4. Construction of flow diagram                                     | 3.15         | 63   | 4  | 7 | 4  | 112  | 4.05          | 81   | 4  | 3 | 4  | 48   | 4.48       | 89.6 | 4  | 3 | 4  | 48   |
| Step 5. On-site confirmation of flow diagram                             | 3.4          | 68   | 5  | 6 | 4  | 120  | 3.66          | 73.2 | 5  | 5 | 4  | 100  | 4          | 80   | 5  | 3 | 4  | 60   |
| Step 6. Principle I. Conducting hazard analysis                          | 3.21         | 64.2 | 7  | 7 | 10 | 490  | 3.77          | 75.4 | 7  | 4 | 10 | 280  | 4.37       | 87.4 | 7  | 3 | 10 | 210  |
| Step 7. Principle II. Identification of critical control points          | 3.37         | 67.4 | 7  | 6 | 10 | 420  | 3.83          | 76.6 | 7  | 4 | 10 | 280  | 4.25       | 85   | 7  | 3 | 10 | 210  |
| Step 8. Principle III. Establishment of critical limits                  | 3.1          | 62   | 7  | 7 | 4  | 196  | 3.88          | 77.6 | 7  | 4 | 4  | 112  | 4.11       | 82.2 | 7  | 3 | 4  | 84   |
| Step 9. Principle IV. Establishing monitoring systems for each CCP       | 3.07         | 61.4 | 8  | 7 | 5  | 280  | 4             | 80   | 8  | 3 | 5  | 120  | 4.39       | 87.8 | 8  | 3 | 5  | 120  |
| Step 10. Principle V. Establishment of corrective action                 | 3            | 60   | 8  | 8 | 6  | 384  | 4.05          | 81   | 8  | 3 | 6  | 144  | 4.11       | 82.2 | 8  | 3 | 6  | 144  |
| Step 11. Principle VI. Establishment of verification procedures          | 2.98         | 59.6 | 9  | 8 | 9  | 648  | 3.66          | 73.2 | 9  | 5 | 9  | 405  | 4.7        | 94   | 9  | 2 | 9  | 162  |
| Step 12. Principle VII. Establishment of documentation and recordkeeping | 3            | 60   | 6  | 7 | 9  | 378  | 4.04          | 80.8 | 6  | 3 | 9  | 162  | 4.75       | 95   | 6  | 2 | 9  | 108  |
| Part II                                                                  |              |      |    |   |    |      |               |      |    |   |    |      |            |      |    |   |    |      |
| Principle II. Identification of critical control points (CCPs)           | 3            | 60   | 10 | 5 | 5  | 350  | 4.16          | 83.2 | 10 | 3 | 5  | 150  | 4.75       | 95   | 10 | 2 | 5  | 100  |
| Principle III. Establishment of critical limits                          | 3.3          | 66   | 10 | 6 | 2  | 120  | 4.08          | 81.6 | 10 | 3 | 2  | 60   | 4.83       | 96.6 | 10 | 2 | 2  | 40   |
| Principle IV. Monitoring of CCPs                                         | 3.22         | 64.4 | 10 | 7 | 7  | 490  | 4             | 80   | 10 | 3 | 7  | 210  | 4.71       | 94.2 | 10 | 2 | 7  | 140  |
| Principle V. Establishment of corrective action                          | 3.16         | 63.2 | 10 | 7 | 9  | 630  | 3.94          | 78.8 | 10 | 4 | 9  | 360  | 4.66       | 93.2 | 10 | 2 | 9  | 180  |
| Principle VI. Verification procedures                                    | 3.5          | 70   | 10 | 5 | 10 | 500  | 4             | 80   | 10 | 3 | 10 | 300  | 5          | 100  | 10 | 1 | 10 | 100  |
| Principle VII. Recordkeeping and documentation                           | 3.05         | 61   | 10 | 7 | 9  | 630  | 3.9           | 78   | 10 | 4 | 9  | 360  | 4.8        | 96   | 10 | 2 | 9  | 180  |

The risk assessment in rice industries showed greater risks compared to other product types. Small-sized plants exhibited higher risks compared to medium- and large-sized companies (Table 7). The HACCP principles in the high-risk range in rice industries were principle VI, verification procedures; principle V, corrective actions; and principle VII, recordkeeping and documentation. Moderate risks were observed in hazard analysis, CCP identification, CCP monitoring, and related areas.

In ready-to-eat companies, principle V, corrective actions; principle VI, verification procedures; and principle VII, recordkeeping and documentation showed higher risks, while moderate risks were observed in hazard analysis, CCP identification, and CCP monitoring (Table 8).

#### 4. DISCUSSION

This study analyzed the risks associated with the implementation (Part I) and functioning (Part II) of the HACCP

Table 8. In-depth risk assessment of organic ready to eat products enterprises.

| RTE                                                                       | Small Plants |      |    |   |    |      | Medium Plants |      |    |   |    |      | Big Plants |     |    |   |    |      |
|---------------------------------------------------------------------------|--------------|------|----|---|----|------|---------------|------|----|---|----|------|------------|-----|----|---|----|------|
|                                                                           | Mean Score   | %    | S  | O | D  | Risk | Mean Score    | %    | S  | O | D  | Risk | Mean Score | %   | S  | O | D  | Risk |
| Part I                                                                    |              |      |    |   |    |      |               |      |    |   |    |      |            |     |    |   |    |      |
| Step 1. Establishing HACCP team                                           | 3.23         | 64.6 | 1  | 7 | 5  | 35   | 4.14          | 82.8 | 1  | 3 | 5  | 15   | 5          | 100 | 1  | 1 | 5  | 5    |
| Step 2. Description of products                                           | 3.45         | 69   | 2  | 6 | 5  | 60   | 4.23          | 84.6 | 2  | 3 | 5  | 30   | 5          | 100 | 2  | 1 | 5  | 10   |
| Step 3. Identification of intended use                                    | 3.23         | 64.6 | 3  | 7 | 5  | 105  | 4.28          | 85.6 | 3  | 3 | 5  | 45   | 5          | 100 | 3  | 1 | 5  | 15   |
| Step 4. Construction of flow diagram                                      | 3.17         | 63.4 | 4  | 7 | 4  | 112  | 4.21          | 84.2 | 4  | 3 | 4  | 48   | 5          | 100 | 4  | 1 | 4  | 16   |
| Step 5. On-site confirmation of flow diagram                              | 3.16         | 63.2 | 5  | 7 | 4  | 140  | 4.2           | 84   | 5  | 3 | 4  | 60   | 5          | 100 | 5  | 1 | 4  | 20   |
| Step 6. Principle I. Conducting hazard analysis                           | 3.26         | 65.2 | 7  | 6 | 10 | 420  | 4.25          | 85   | 7  | 3 | 10 | 210  | 5          | 100 | 7  | 1 | 10 | 70   |
| Step 7. Principle II. Identification of critical control points           | 3.29         | 65.8 | 7  | 6 | 10 | 420  | 4.3           | 86   | 7  | 3 | 10 | 210  | 5          | 100 | 7  | 1 | 10 | 70   |
| Step 8. Principle III. Establishment of critical limits                   | 3.33         | 66.6 | 7  | 6 | 4  | 168  | 4.3           | 86   | 7  | 3 | 4  | 84   | 5          | 100 | 7  | 1 | 4  | 28   |
| Step 9. Principle IV. Establishing monitoring systems for each CCP        | 3.15         | 63   | 8  | 7 | 5  | 280  | 4.2           | 84   | 8  | 3 | 5  | 120  | 5          | 100 | 8  | 1 | 5  | 40   |
| Step 10. Principle V. Establishment of corrective action                  | 3.22         | 64.4 | 8  | 7 | 6  | 336  | 4.23          | 84.6 | 8  | 3 | 6  | 144  | 5          | 100 | 8  | 1 | 6  | 48   |
| Step 11. Principle VI. Establishment of verification procedures           | 3.13         | 62.6 | 9  | 7 | 9  | 567  | 4.26          | 85.2 | 9  | 3 | 9  | 243  | 5          | 100 | 9  | 1 | 9  | 81   |
| Step 12. Principle VII. Establishment of documentation and record-keeping | 3.12         | 62.4 | 6  | 7 | 9  | 378  | 4.22          | 84.4 | 6  | 3 | 9  | 162  | 5          | 100 | 6  | 1 | 9  | 54   |
| Part II                                                                   |              |      |    |   |    |      |               |      |    |   |    |      |            |     |    |   |    |      |
| Principle II. Identification of critical control points (CCPs)            | 3.08         | 61.6 | 10 | 7 | 5  | 350  | 4.15          | 83   | 10 | 3 | 5  | 150  | 5          | 100 | 10 | 1 | 5  | 50   |
| Principle III. Establishment of critical limits                           | 3.16         | 63.2 | 10 | 7 | 2  | 140  | 4.25          | 85   | 10 | 3 | 2  | 60   | 5          | 100 | 10 | 1 | 2  | 20   |
| Principle IV. Monitoring of CCPs                                          | 3.09         | 61.8 | 10 | 7 | 7  | 490  | 4.22          | 84.4 | 10 | 3 | 7  | 210  | 5          | 100 | 10 | 1 | 7  | 70   |
| Principle V. Establishment of corrective action                           | 3.16         | 63.2 | 10 | 7 | 9  | 630  | 4.13          | 82.6 | 10 | 3 | 9  | 270  | 5          | 100 | 10 | 1 | 9  | 90   |
| Principle VI. Verification procedures                                     | 3.16         | 63.2 | 10 | 7 | 10 | 700  | 4.12          | 82.4 | 10 | 3 | 10 | 300  | 5          | 100 | 10 | 1 | 10 | 100  |
| Principle VII. Record-keeping and documentation                           | 3.19         | 63.8 | 10 | 7 | 9  | 630  | 4.37          | 87.4 | 10 | 3 | 9  | 270  | 5          | 100 | 10 | 1 | 9  | 90   |

system across organic food enterprises of varying sizes and types in India, using a modified audit method [41] and ISO and Codex guidelines [42, 43]. While researchers worldwide have conducted studies on food safety concerns in the organic food sector [48, 49], to the best of our knowledge, this is the first study to systematically analyze risk assessment in the HACCP system using an audit method in Indian organic food enterprises. This gap in the literature underscores the importance of the current study in addressing the specific challenges faced by organic food enterprises in India.

Various strengths and weaknesses were identified in the risk assessment. In general, HACCP system implementation showed greater compliance than actual HACCP system functioning, as also reported by other authors [50]. Rochman *et al.* [51] suggested that regular internal audits and updates of HACCP plans are essential to maintain compliance.

The identified risks from the study indicated that small enterprises showed lower food safety compliance than medium-sized firms, as observed by numerous authors [45, 52]. Large enterprises demonstrated relatively high compliance. Research in similar areas reported comparable results. In small companies, food safety risks were higher due to limited resources and knowledge [53-55]. Management commitment is also crucial for the proper functioning of food safety management systems [53]. Although medium-sized enterprises have more resources than small plants, they still face challenges in ensuring proper functioning of food safety management systems [56]. Stevens and Hood [57] reported that large enterprises usually have established FSMS frameworks, which enhance regulatory compliance, and the presence of dedicated teams and resources ensures continuous improvement.

The FMEA results revealed the absence of critical risks, indicating a positive outcome for the system's overall safety. However, within some crucial steps, such as hazard analysis, the identification and monitoring of critical control points (CCPs), corrective measures, verification processes, and recordkeeping, the assessment found high and moderate risks. Similar nonconformities were also reported by other authors [41, 45]. These results highlight the necessity of focused improvements in these areas to ensure robust risk management and food safety procedures. A lack of staff education can lead to insufficient hazard identification and ineffective control measures. Effective risk identification and evaluation often rely heavily on employee experience and knowledge, which makes the process challenging. Many businesses may struggle to allocate the necessary time, personnel, and technological resources for proper CCP monitoring. Additionally, corrective actions must be clearly defined and implemented immediately when hazards are identified, as failure to do so can escalate risks.

The audit results showed greater conformity and lower risk in meat industries than in other enterprises, whereas the study by Kang and Hong [58] highlighted non-compliance issues in meat industries, especially in small- and medium-sized plants. Similar observations in meat slaughterhouses were reported by other authors [59-61]. Many dairy plants

struggle with insufficient staff training on HACCP principles, leading to inconsistent application of safety measures [62-65]. Food safety risks in the fruit and vegetable industries have also been discussed by numerous authors [58, 66-68]. Some studies have mentioned risks related to food safety nonconformity in ready-to-eat industries [69-72]. In the present study, nonconformity was most often identified in organic rice industries; however, there is currently a lack of literature on food safety risks in rice industries.

To maintain compliance and efficacy, staff members must receive ongoing training on HACCP principles [73]. For accountability and traceability, it is essential to keep thorough records of HACCP planning and monitoring operations [74]. Regular audits of the HACCP system ensure adherence to established procedures and aid in identifying areas for improvement [50].

While this study contains useful information, it is vital to recognize its limitations. The data were taken from a small sample of Indian businesses; thus, they may not fully reflect the conditions of industries in other regions or global markets. Future studies should include longitudinal assessments to examine changes in risk profiles over time, as well as a broader scope that incorporates companies from diverse geographical regions. Furthermore, investigating the influence of external factors, such as global market dynamics and regulatory frameworks, may help provide a more comprehensive understanding of HACCP-related hazards.

## CONCLUSIONS

The elaborated methodology identified the risks associated with organic food processing in India. The FMEA risk assessment results revealed varying risk levels based on company sizes and types within the organic food industries. Larger companies across all product categories consistently maintained low risk levels. Medium-sized companies generally managed minor risks; however, in some cases, these risks reached the moderate range. Smaller companies in certain product categories faced moderate to high risks. The results also showed greater conformity and lower risk in meat enterprises compared to other industries. The food safety risk assessment methodology used in this study was validated among organic food producers in India. The findings and conclusions of the research may have broad applicability due to the increasing number of organic food establishments worldwide and the global trend toward sustainable development, emphasizing the production of organic food that is both healthy for society and minimally burdensome to the natural environment.

The implementation and functioning of HACCP in Indian establishments may pose risks to food safety in several areas. These include lack of infrastructure, inadequate training, and limited government support, which should also be considered in organic food establishments in other countries. The results of the risk assessment can be used to guide the planning of internal audits in organic food establishments worldwide, particularly in developing countries, to improve food safety systems. The identified risk areas may negatively

affect the assurance of food safety in organic products, potentially undermining the perception that organic products are safer or more recommended than conventional products. Therefore, greater efforts are required from organic food producers to enhance risk management and food safety assurance.

By focusing on the organic food sector, this research fills a significant gap in the literature, providing insights into the unique challenges and risks faced by this growing industry in India. The adoption of FMEA for HACCP risk assessment in this context enhances food safety and lays a foundation for future research and practices in organic food safety management. Furthermore, the established methodology can serve as an adaptable model for large-scale industrial applications, enabling food firms worldwide to proactively identify critical risk points, optimize HACCP implementation, and strengthen food safety systems in line with international standards.

### AUTHOR'S CONTRIBUTIONS

The authors confirm their contribution to the paper as follows: Conceptualization: APM and JT; Methodology: APM; Validation: JT; Formal analysis: APM; Investigation: APM; Data curation: APM, AKMK; Writing - original draft preparation: APM; Writing - review and editing: JT, MT, WK; Visualization: APM; Supervision: JT. All authors have read and agreed to the published version of the manuscript.

### LIST OF ABBREVIATIONS

|       |   |                                                |
|-------|---|------------------------------------------------|
| CCPs  | = | Critical control points                        |
| FMEA  | = | Failure mode and effects analysis              |
| HACCP | = | Hazard analysis and critical control point     |
| ISO   | = | International Organization for Standardization |
| RTE   | = | Ready to eat                                   |

### ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

### HUMAN AND ANIMAL RIGHTS

Not applicable.

### CONSENT FOR PUBLICATION

Not applicable.

### AVAILABILITY OF DATA AND MATERIALS

The data and supportive information are available within the article.

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### CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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**Signature**



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*Research article*

## **HACCP compliance in organic food processing industries in India: A statistical study by product type and company size.**

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**Abstract:** Organic food is gaining global popularity due to its perceived health benefits and compatibility with sustainability goals. However, the application of hazard analysis and critical control point (HACCP) in organic food processing, particularly in developing countries, is barely discussed. In this study, we examined the level of HACCP compliance in certified organic food processing units in Kerala, India, with an emphasis on the impact of product type and company size. In 2023-2024, a structured audit based on Codex criteria was carried out, with a standardized scoring system used to evaluate the paperwork and operational performance. Significant trends and interactions were identified using statistical methods, including two-way ANOVA, Tukey's HSD post hoc test, principal component analysis (PCA), and cluster analysis. Across product categories, there were notable variations in HACCP compliance, with meat and ready-to-eat food processors showing higher levels of compliance than dairy and rice-based processors. Company size was also an important determinant, with larger enterprises demonstrating superior system implementation. Significant interaction effects demonstrated that performance patterns were not consistent across categories. Significant interaction effects between product type and company size indicated that compliance patterns vary depending on the combination of these factors. These findings underline the importance of targeted training, regulatory support, and the incorporation of HACCP into organic certification frameworks to enhance food safety standards in the organic industry, particularly among small-scale and high-risk processors in developing countries.

**Keywords:** HACCP; food safety; organic food; audit; HACCP compliance; organic food processing

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## 1. Introduction

The increasing demand for safe, high-quality, and sustainably produced food contribute to the popularity of the organic food industry worldwide, including India [1]. Consumers connect organic products with minimum chemical use and natural processing, so ensuring food safety compliance in this industry is critical, not only to satisfy regulatory standards but also to maintain customer trust [1,2].

The Hazard Analysis and Critical Control Points (HACCP) method has emerged as a globally recognized framework for ensuring food safety by identifying and addressing possible hazards throughout the food production process [3]. While HACCP has been extensively studied and implemented in conventional food industries, its application in the organic food processing sector is mostly unexplored, particularly in developing economies such as India, where organic certification systems are maturing and enterprise diversity is widespread. The Food Safety and Standards Authority of India (FSSAI) advises and mandates Food Safety Management Systems (FSMS) based on HACCP for food businesses in specified product categories. HACCP is mandatory for enterprises that export food, particularly in sectors like seafood and meat [4,5]. India is one of the biggest producers of organic food in terms of volume and area [6]. The organic food industry in India is governed by two major regulatory regimes, with varying roles depending on whether the product is for domestic sale or export: The Participatory Guarantee System (PGS-India) and National Programme for Organic Production (NPOP). HACCP is not mandatory under NPOP or PGS, but it is increasingly adopted by export-focused or high-risk product companies [5–7]. The Ministry of Commerce and Industry of the Government of India manages the Agricultural and Processed Food Products Export Development Authority (APEDA), a statutory body tasked with promoting, certifying, and facilitating the export of agricultural and processed food products, including organic products [6].

The literature on HACCP has focused on conventional food processing industries or general food safety challenges [8–12]. However, organic food processing presents distinct structural and operational challenges. In contrast to the highly regulated conventional food industry, many organic food processing businesses in India are small or medium-sized, with little administrative and technical infrastructure. The degree and uniformity of HACCP system implementation among organic processors vary significantly as a result of this structural variance [13–17]. Small-scale producers often lack the technical capacity to implement systems like HACCP. To date, there is a notable lack of published literature addressing the HACCP systems within the organic food processing sector [18–20]. Effective implementation of food safety management systems like HACCP is difficult in many developing nations, despite the promotion of organic food production as a sustainable alternative to conventional agriculture [1]. Organic processors' ability to develop, implement, and maintain reliable HACCP systems is directly impacted by limitations on expertise, structured training, and regulatory guidelines, especially in small businesses [21,22].

Thus, through a systematic audit-based assessment and multiple statistical analyses, we intend to measure HACCP compliance among certified organic food processors in Kerala, India, and investigate how compliance levels vary according to company size and product type. This can help regulatory agencies and certification bodies develop targeted interventions that address the needs of underperforming groups [15,23]. Moreover, this provides insight into how food safety capacity is distributed across types of processors, which is vital for building resilient and equitable food supply chains. Finally, such analysis supports the development of more tailored training, policy, and resource allocation strategies to strengthen food safety in the organic sector.

We respond to these gaps by focusing on HACCP compliance among organic food processors in Kerala, India. Additionally, we seek to examine the relationship between company characteristics, particularly company size and product category, and their food safety performance, as measured through structured HACCP audits.

## 2. Materials and methods

### 2.1. Study design and data collection

This study is an audit-based investigation conducted to evaluate the level of HACCP compliance in organic food processing industries in Kerala, India. Our aim was to assess the impact of company size and product type on HACCP functioning and adherence within these facilities. The study was carried out from 2023 to 2024. A total of 100 organic food processing companies were selected to ensure representation across product categories and company sizes. The convenience-based sampling method was used. The selection process was executed with the help and collaboration of a private organic food certification agency in India. To enable comparative investigation of HACCP compliance patterns, classification by product category and company size was used. To guarantee uniformity and comparability of audited units, eligibility criteria were established before sampling. Businesses that met the following criteria were included: (1) They were certified organic food processing firms operating under recognized certification schemes (NPOP or PGS-India); (2) they were based in Kerala; and (3) they consented to take part in a HACCP compliance audit.

Enterprises were excluded if they: (1) Lacked appropriate organic certification at the time of assessment; (2) were not operational during the audit window; or (3) denied or were unable to provide access to documents, facilities, or relevant individuals required for the audit. The final sample of 100 audited corporations comprised only businesses that satisfied all inclusion criteria and none of the exclusion criteria.

Kerala was selected as the research region because it is one of the leading Indian states in the development and promotion of organic agriculture and organic food processing. The state has a comparatively large number of certified organic food processing businesses working under NPOP and PGS-India systems, and it has adopted several government-sponsored organic cultivation and certification initiatives. This offered a sizable and varied sampling frame that covered a wide range of product categories and business sizes.

**Table 1.** Structured audit questionnaire based on Codex HACCP principles [24].

| Questions                                                                                                                              | 2 | 3 | 4 | 5 |
|----------------------------------------------------------------------------------------------------------------------------------------|---|---|---|---|
| <b>PART I</b>                                                                                                                          |   |   |   |   |
| Block 1 Step 1. Assemble the HACCP team                                                                                                |   |   |   |   |
| 1. Was the HACCP team assembled in the enterprise?                                                                                     |   |   |   |   |
| 2. Was it a multidisciplinary team?                                                                                                    |   |   |   |   |
| 3. Were all team members trained in HACCP?                                                                                             |   |   |   |   |
| 4. Was the HACCP plan developed?                                                                                                       |   |   |   |   |
| 5. Did the team consist of people with an understanding of particular biological, chemical, and physical hazards and associated risks? |   |   |   |   |

*Continued on the next page*

| Questions                                                                                              | 2 | 3 | 4 | 5 |
|--------------------------------------------------------------------------------------------------------|---|---|---|---|
| 6. Did the team consist of people involved in the production process?                                  |   |   |   |   |
| 7. Did the team consist of people with knowledge in microbiology, hygiene, and food technology?        |   |   |   |   |
| Block 2 Step 2. Describe product                                                                       |   |   |   |   |
| 1. Were products described?                                                                            |   |   |   |   |
| 2. Where all range of products described?                                                              |   |   |   |   |
| 3. Was the description of the products made properly?                                                  |   |   |   |   |
| 4. Was the composition of products described, including all raw materials, ingredients, and additives? |   |   |   |   |
| 5. Was the composition of products complete?                                                           |   |   |   |   |
| 6. Was the type of product processing specified?                                                       |   |   |   |   |
| 7. Was it specified how the product should be packaged?                                                |   |   |   |   |
| 8. Were the microbiological parameters of the product specified?                                       |   |   |   |   |
| 9. Were the chemical parameters of the product specified?                                              |   |   |   |   |
| 10. Were the sensory parameters of the product specified?                                              |   |   |   |   |
| 11. Were the physical parameters of the product specified?                                             |   |   |   |   |
| 12. Was it specified how the product should be stored?                                                 |   |   |   |   |
| 13. Was it specified how the product should be transported and distributed?                            |   |   |   |   |
| 14. Was the durability term of the product specified?                                                  |   |   |   |   |
| 15. Is the labeling information appropriate?                                                           |   |   |   |   |
| Block 3 Step 3. Identify intended use                                                                  |   |   |   |   |
| 1. Was the intended use of all products specified?                                                     |   |   |   |   |
| 2. Was the nature of the target group for the product specified?                                       |   |   |   |   |
| 3. Did the target group include infants?                                                               |   |   |   |   |
| 4. Was the target group elderly people?                                                                |   |   |   |   |
| 5. Was the target group adults?                                                                        |   |   |   |   |
| 6. Was the target group included, allergic or malnourished people?                                     |   |   |   |   |
| 7. Was the intended use of products defined?                                                           |   |   |   |   |
| Block 4 Step 4. Construct a flow diagram                                                               |   |   |   |   |
| 1. Were detailed flow diagrams drawn up?                                                               |   |   |   |   |
| 2. Did the flow diagrams include all raw materials, ingredients, and additives?                        |   |   |   |   |
| 3. Did the flow diagrams include packaging?                                                            |   |   |   |   |
| 4. Was the sequence of all production steps established?                                               |   |   |   |   |
| 5. Did the flow diagrams include technical parameters of raw materials?                                |   |   |   |   |
| 6. Did the flow diagrams include technical parameters of byproducts?                                   |   |   |   |   |
| 7. Did the flow diagrams include technical parameters of final products?                               |   |   |   |   |
| 8. Did the flow diagrams include breaks between production steps?                                      |   |   |   |   |
| 9. Did flow diagrams exclude the risk of cross-contamination?                                          |   |   |   |   |
| 10. Were procedures for cleaning and disinfection established?                                         |   |   |   |   |
| 11. Was the hygienic environment of the production process provided?                                   |   |   |   |   |
| 12. Did employees maintain hygiene during the production process?                                      |   |   |   |   |
| 13. Were adequate conditions of storage and distribution of products ensured?                          |   |   |   |   |

*Continued on the next page*

| Questions                                                                                                             | 2 | 3 | 4 | 5 |
|-----------------------------------------------------------------------------------------------------------------------|---|---|---|---|
| <b>Block 5 Step 5. On-site confirmation of flow diagram</b>                                                           |   |   |   |   |
| 1. Was on site conformation of the flow diagram made?                                                                 |   |   |   |   |
| 2. Was flow diagram confirmation made during the production process?                                                  |   |   |   |   |
| 3. Was there evidence of performed confirmation?                                                                      |   |   |   |   |
| 4. Was on site conformation made by the HACCP team?                                                                   |   |   |   |   |
| <b>Block 6 Step 6. Principle I. Identify and analyze hazards</b>                                                      |   |   |   |   |
| 1. Was a list of possible hazards made?                                                                               |   |   |   |   |
| 2. Was a list made for all steps in accordance with the developed product flow diagrams?                              |   |   |   |   |
| 3. Did the list include physical hazards?                                                                             |   |   |   |   |
| 4. Did the list include chemical hazards?                                                                             |   |   |   |   |
| 5. Did the list include microbiological hazards?                                                                      |   |   |   |   |
| 6. Did the list include biological hazards?                                                                           |   |   |   |   |
| 7. Were causes of possible hazards specified?                                                                         |   |   |   |   |
| 8. Were preventive actions that eliminate or reduce hazards established?                                              |   |   |   |   |
| 9. Were the undesirable health influences of the mentioned hazards specified?                                         |   |   |   |   |
| 10. Were survival and multiplication of pathogenic microorganisms considered?                                         |   |   |   |   |
| 11. Were the formation of chemicals in products and the production environment considered?                            |   |   |   |   |
| 12. Were allergens in products considered?                                                                            |   |   |   |   |
| 13. Was the possibility of secondary pollution between raw materials, intermediate, and finished products considered? |   |   |   |   |
| 14. Were control measures for specific hazards specified?                                                             |   |   |   |   |
| 15. Were all control measures assigned to existing procedures and specifications?                                     |   |   |   |   |
| <b>Block 7 Step 7. Principle II. Determine Critical Control Points (CCPs)</b>                                         |   |   |   |   |
| 1. Were CCPs established?                                                                                             |   |   |   |   |
| 2. Were methods leading to the determination of CCPs specified?                                                       |   |   |   |   |
| 3. Was a decision tree used to determine CCPs?                                                                        |   |   |   |   |
| 4. Was a decision tree used in accordance with flow diagrams at each production step?                                 |   |   |   |   |
| 5. Was a decision tree applied for each hazard at each production step?                                               |   |   |   |   |
| 6. Did the HACCP team members receive training on the use of the decision tree, and was it evidenced?                 |   |   |   |   |
| 7. Were CCPs identified properly?                                                                                     |   |   |   |   |
| 8. Whether any step, for which CCP should be determined, was omitted?                                                 |   |   |   |   |
| <b>Block 8 Step 8. Principle III. Establish critical limits for each CCP</b>                                          |   |   |   |   |
| 1. Were parameters and critical limits established for each CCP?                                                      |   |   |   |   |
| 2. Were parameters and critical limits acknowledged in the documentation?                                             |   |   |   |   |
| 3. Do critical limits correspond to the acceptable border values about product safety?                                |   |   |   |   |
| 4. Were critical limits set for observable or measurable parameters that could show that CCP is under control?        |   |   |   |   |
| 5. Were limits based on reasonable assumptions?                                                                       |   |   |   |   |
| 6. Were critical limits properly chosen in each CCP?                                                                  |   |   |   |   |

*Continued on the next page*

| Questions                                                                                                                   | 2 | 3 | 4 | 5 |
|-----------------------------------------------------------------------------------------------------------------------------|---|---|---|---|
| Block 9 Step 9. Principle IV. Monitoring of CCPs                                                                            |   |   |   |   |
| 1. Were monitoring systems for all CCPs established?                                                                        |   |   |   |   |
| 2. Were monitoring procedures for each CCP elaborated?                                                                      |   |   |   |   |
| 3. Was the frequency of monitoring established?                                                                             |   |   |   |   |
| 4. Was the frequency of monitoring established properly?                                                                    |   |   |   |   |
| 5. Were there monitoring methods established?                                                                               |   |   |   |   |
| 6. Were monitoring methods adequate?                                                                                        |   |   |   |   |
| 7. Were employees responsible for monitoring the designated?                                                                |   |   |   |   |
| 8. Were there CCPs monitoring devices used?                                                                                 |   |   |   |   |
| 9. Were monitoring devices showing reliable measurements?                                                                   |   |   |   |   |
| 10. Were there available control cards to record the results of monitoring for each CCP?                                    |   |   |   |   |
| 11. Did control cards allowed keeping of records of all monitored parameters in CCPs?                                       |   |   |   |   |
| Block 10 Step 10. Principle IV. Establishing corrective action                                                              |   |   |   |   |
| 1. Were there corrective actions for each CCP established, in the case when monitoring results indicated a loss of control? |   |   |   |   |
| 2. Were corrective actions fully ensured a return to the assumed parameters?                                                |   |   |   |   |
| 3. Were there corrective actions procedures for each CCP established?                                                       |   |   |   |   |
| 4. Were there designated employees responsible for corrective actions for each CCP?                                         |   |   |   |   |
| 5. Were there control cards to document the corrective action taken at all established CCPs?                                |   |   |   |   |
| 6. Was there instruction of specified use of products obtained during the period when CCP was out of control?               |   |   |   |   |
| Block 11 Step 11. Principle VI. Verification procedures                                                                     |   |   |   |   |
| 1. Were methods of HACCP verification established?                                                                          |   |   |   |   |
| 2. Was the frequency of HACCP verification established?                                                                     |   |   |   |   |
| 3. Were established verification methods appropriate?                                                                       |   |   |   |   |
| 4. Was established frequency of HACCP verification adequate?                                                                |   |   |   |   |
| 5. Were verification procedures established to confirm that the HACCP system was effective and consistent with the plan?    |   |   |   |   |
| 6. Was an employee responsible for analyze of verification results designated?                                              |   |   |   |   |
| 7. Did verification included the accuracy of records?                                                                       |   |   |   |   |
| 8. Did verification included also asking questions of employees, especially ,CCP monitors?                                  |   |   |   |   |
| 9. Did verification included observation of operations at CCPs?                                                             |   |   |   |   |
| 10. Did verification included calibration of monitoring devices?                                                            |   |   |   |   |
| Block 12 Step 12. Principle VII. Recordkeeping and documentation                                                            |   |   |   |   |
| 1. Was there any documentation of the HACCP system available?                                                               |   |   |   |   |
| 2. Was there any documentation available documentation on the implementation steps of the HACCP system?                     |   |   |   |   |
| 3. Was there way of documenting supervision established?                                                                    |   |   |   |   |
| 4. Was the way of archiving system documentation established?                                                               |   |   |   |   |
| 5. Was a time archiving documents specified?                                                                                |   |   |   |   |

*Continued on the next page*

| Questions                                                                                                                                             | 2 | 3 | 4 | 5 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|---|---|---|---|
| 6. Was there a way to make amendments in the control cards specified if the employee made a mistake?                                                  |   |   |   |   |
| 7. Were all documents properly marked, and was it possible their unambiguous identification?                                                          |   |   |   |   |
| 8. Was a method of exchanging outdated document to the current version established?                                                                   |   |   |   |   |
| PART II                                                                                                                                               |   |   |   |   |
| Block 1 Step 7. Principle II. Determine Critical Control Points (CCPs)                                                                                |   |   |   |   |
| 1. Did employees working in the CCP area knew that in this step CCP was established?                                                                  |   |   |   |   |
| 2. Did employees working in the CCP area knew what the CCP established for?                                                                           |   |   |   |   |
| 3. Could supervisor of HACCP system listed all CCPs?                                                                                                  |   |   |   |   |
| 4. Could manager of evaluated enterprise listed all CCPs?                                                                                             |   |   |   |   |
| Block 2 Step 8. Principle III. Establish critical limits for each CCP                                                                                 |   |   |   |   |
| 1. Did employees working in the CCP area knew parameters of critical limits at this CCP?                                                              |   |   |   |   |
| 2. Did employees working in the CCP area knew values of critical limits parameters at this CCP?                                                       |   |   |   |   |
| 3. Did employees responsible for monitoring of CCPs know the Parameters and critical limits at CCPs for which they are responsible?                   |   |   |   |   |
| 4. Did supervisor of HACCP system knew parameters and critical limits for all established CCPs?                                                       |   |   |   |   |
| Block 3 Step 9. Principle IV. Monitoring of CCPs                                                                                                      |   |   |   |   |
| 1. Did the CCP monitoring procedures were available to employees responsible for each CCP?                                                            |   |   |   |   |
| 2. Did employees knew the monitoring procedure at the CCP for which they are responsible?                                                             |   |   |   |   |
| 3. Whether employees responsible for monitoring at the CCP were aware of their responsibility for food safety?                                        |   |   |   |   |
| 4. Were results of CCPs monitoring recorded regularly?                                                                                                |   |   |   |   |
| 5. Were entries in CCPs control cards completed?                                                                                                      |   |   |   |   |
| 6. Were results of CCPs monitoring regularly evaluated by supervisor or competent person?                                                             |   |   |   |   |
| 7. Were control cards located at easily accessible place which allowed records keeping?                                                               |   |   |   |   |
| Block 4 Step 10. Principle V. Establish corrective action                                                                                             |   |   |   |   |
| 1. Did employees working in the CCP area knew procedures of corrective action at the CCP for which they are responsible?                              |   |   |   |   |
| 2. Could employees responsible for the CCP explain the way of action in case of exceeding the critical limit at the CCP?                              |   |   |   |   |
| 3. Whether employees responsible for corrective actions at the CCP for which they are responsible were aware of their responsibility for food safety? |   |   |   |   |
| 4. Were corrective actions always took when control was lost in all the CCP?                                                                          |   |   |   |   |
| 5. Were control cards located at easily accessible place which allowed records keeping?                                                               |   |   |   |   |
| 6. Were records of actions taken in line with the procedures of corrective actions?                                                                   |   |   |   |   |

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| Questions                                                                                                                     | 2 | 3 | 4 | 5 |
|-------------------------------------------------------------------------------------------------------------------------------|---|---|---|---|
| Block 5 Step 11. Principle VI. Verification procedures                                                                        |   |   |   |   |
| 1. Were the verification of HACCP system made at established frequency?                                                       |   |   |   |   |
| 2. Were the verification of HACCP system made in accordance to established verification methods?                              |   |   |   |   |
| 3. Were the verification results analyzed by competent person?                                                                |   |   |   |   |
| 4. Did the verification results influenced the frequency of verifications?                                                    |   |   |   |   |
| 5. Did the verification results lead to improvement of HACCP system?                                                          |   |   |   |   |
| 6. Did persons designated to verification had a relevant authority e.g. auditor's training, proven expertise in HACCP system? |   |   |   |   |
| 7. Were preventive and corrective actions taken after verification of HACCP system?                                           |   |   |   |   |
| 8. Were developed documentation of HACCP system verified periodically?                                                        |   |   |   |   |
| Block 6 Step 12. Principle VII. Recordkeeping and documentation                                                               |   |   |   |   |
| 1. Was the system documentation available to relevant employees?                                                              |   |   |   |   |
| 2. Whether the operating documentation was completed by designated employees?                                                 |   |   |   |   |
| 3. Was the system documentation under appropriate supervision?                                                                |   |   |   |   |
| 4. Were all amendments in control cards authorized and signed by responsible employees?                                       |   |   |   |   |
| 5. Was all system documentation up to date?                                                                                   |   |   |   |   |
| 6. Were outdated documents replaced to date in due course?                                                                    |   |   |   |   |
| 7. Did operating records legible and clearly understood?                                                                      |   |   |   |   |

The audit questionnaire for data collection was developed in alignment with the Codex Alimentarius Commission's General Principles of Food Hygiene and HACCP System Guidelines [25,26]. The questionnaire contained documentation (Part I: 110 questions) and practical functioning aspects (Part II: 36 questions) of the HACCP system (Table 1). Each company underwent a single audit visit, during which data were collected using direct observation. Each component was scored using a 4-point ordinal scale, where: 2 - non-compliance, 3 - partial compliance, 4 - substantial compliance, and 5 - full compliance. In Part I, the total score ranged from a minimum of 220 to a maximum of 550, while in Part II, the score ranged from a minimum of 72 to a maximum of 180. Scores from individual sections were aggregated and normalized to produce an overall compliance score for each company. This structured scoring approach provided a quantitative basis for statistical analysis of HACCP performance according to company size and product category. The data was then converted into a compliance score and further statistical analysis. The audit was conducted by an experienced professional specializing in food quality management, HACCP system implementation, food hygiene research, and auditing. The auditor's competence was regularly reviewed in accordance with ISO 19011 guidelines [27] and maintained through continuous professional development and training. A four-point grading scale was used to evaluate compliance: A score of 5 indicated full compliance (100%), 4 reflected minor deviations (approximately 80%), 3 represented partial compliance (approximately 60%), and 2 indicated minimal compliance (less than 40%) [24,28]. The scale was intentionally non-centralized, enabling the auditor to exercise professional judgment in assigning scores. Scores of 4 and 5 were considered a pass, while scores of 2 and 3 were classified as non-compliant for documentation and functional aspects. All data collected were anonymized to ensure confidentiality and were used strictly for academic and policy research purposes.

## 2.2. Classification of variables and HACCP compliance scoring

To study the factors influencing HACCP compliance, audited companies were classified according to two key variables: Type of organic product processed and company size, with compliance evaluated using a standard scoring framework. Each company was classified according to its primary organic food product into one of the following five categories: fruits and vegetables, meat and meat products, dairy and dairy products, rice and rice-based products, and ready-to-eat (RTE) Foods. Company size was determined based on annual turnover using thresholds aligned with Indian food industry standards: Small: Turnover less than INR (Indian rupee) 100 crore, medium: Turnover between INR 100–500 crore, and large: Turnover above INR 500 crore [29].

## 2.3. Statistical analysis

All data were analyzed using MS excel R Studio. Descriptive statistics were used to summarize mean scores across groups. To examine how product type and company size jointly influence HACCP compliance, a two-way analysis of variance (ANOVA) was applied separately to Part I (HACCP documentation), Part II (HACCP functioning), and total HACCP scores. This method enabled the identification of major effects as well as any significant interaction effects between the two factors, indicating whether the influence of one variable depends on the level of the other. The Shapiro-Wilk test and Levene's test were used to assess the assumptions of normality and homogeneity of variance before doing ANOVA, and it was discovered that these conditions were sufficiently met for all dependent variables.

Tukey's Honest Significant Difference (HSD) test was employed to test which groups differed significantly in their total HACCP Scores. In addition, cluster analysis was applied to identify natural groupings among companies based on HACCP performance. Finally, Principal Component Analysis (PCA) was used to reduce data dimensionality and identify underlying patterns [30,31]. For the analysis, we focused on understanding how the type of products and the size of the company influence the implementation and functioning of the HACCP system.

## 3. Results

### 3.1. Overview of HACCP performance by company size

Table 2. Findings from a two-way analysis of variance (ANOVA) that looked at how product type, company size, and their combination affected HACCP compliance scores among certified organic food processing businesses in Kerala, India. These scores included HACCP implementation (Part I), HACCP functioning (Part II), and overall HACCP scores. F-values, matching p-values, mean squares, sums of squares, and degrees of freedom (DF) are presented. HACCP compliance varied by product category, company size, and their interaction, according to statistically significant effects ( $p < 0.05$ ) (Table 2). Two-way ANOVA revealed statistically significant effects of product type, company size, and their interaction on HACCP implementation (Part I), HACCP functioning (Part II), and total HACCP compliance scores (Table 2).

**Table 2.** The results of two-way ANOVA assessing the effects of product type, company size, and their interaction on HACCP implementation (Part I), HACCP functioning (Part II), and total HACCP compliance scores.

| Part I (HACCP implementation score) |    |                |             |        |         |
|-------------------------------------|----|----------------|-------------|--------|---------|
| Groups                              | DF | Sum of squares | Mean square | F      | P-value |
| Type of products                    | 11 | 12220.223      | 1110.929    | 3.746  | <0.001  |
| Company size                        | 2  | 33165.596      | 16582.798   | 55.914 | <0.001  |
| Type × size interaction             | 22 | 47919.975      | 2178.181    | 7.344  | <0.001  |
| Part II (HACCP functioning score)   |    |                |             |        |         |
| Groups                              | DF | Sum of squares | Mean square | F      | P-value |
| Type of products                    | 11 | 16845.325      | 1531.393    | 2.6    | 0.007   |
| Company size                        | 2  | 45553.402      | 22776.701   | 38.669 | <0.001  |
| Type × size interaction             | 22 | 68538.852      | 3115.402    | 5.289  | <0.001  |
| Total HACCP score                   |    |                |             |        |         |
| Groups                              | DF | Sum of squares | Mean square | F      | P-value |
| Type of products                    | 11 | 123184.709     | 11198.61    | 2.841  | 0.004   |
| Company size                        | 2  | 346409.321     | 173204.66   | 43.94  | <0.001  |
| Type × size interaction             | 22 | 512998.888     | 23318.131   | 5.915  | <0.001  |

A descriptive analysis of HACCP audit scores revealed a clear gradient in compliance based on company size. As shown in Table 3, large enterprises had the highest average scores across all three components of the audit, Part I (HACCP implementation), Part II (HACCP functioning), and the total score, while small enterprises showed the lowest compliance levels.

**Table 3.** Mean and standard deviation of HACCP implementation (Part I), HACCP functioning (Part II), and total scores by company size (big, medium, small).

| Company size | n  | Part I<br>(mean ± SD) | Part II<br>(mean ± SD) | Total<br>(mean ± SD) | % of conformity |
|--------------|----|-----------------------|------------------------|----------------------|-----------------|
| Big          | 27 | 473.7 ± 16.4          | 148.7 ± 10.3           | 622.4 ± 19.4         | 85.30%          |
| Medium       | 44 | 396.2 ± 32.4          | 137.2 ± 21.8           | 533.2 ± 39.1         | 73.00%          |
| Small        | 29 | 325.4 ± 32.0          | 133.7 ± 26.6           | 459.1 ± 41.6         | 62.9%           |

Subsequent post-hoc pairwise comparison of company sizes (using Tukey's HSD test) confirmed that larger companies outperformed medium and small enterprises in all aspects of HACCP compliance (Table 4). The most significant discrepancies were observed in Part I (documentation), where small businesses struggled to achieve even basic standards like structured hazard analysis and crucial control point identification. These differences suggest that smaller processors' ability to maintain fully functional HACCP systems is limited.

**Table 4.** Tukey's HSD post hoc comparisons of HACCP scores by company size.  
\*Significant at  $p < 0.05$ .

| Comparison      | Part I score mean difference (p-value) | Part II score mean difference (p-value) | Total score mean difference (p-value) |
|-----------------|----------------------------------------|-----------------------------------------|---------------------------------------|
| Large vs Medium | -43.64* (<0.05)                        | -58.28* (<0.001)                        | -156.67* (<0.001)                     |
| Large vs Small  | 40.09* (<0.001)                        | 41.68* (<0.001)                         | 120.66* (<0.001)                      |
| Medium vs Small | 83.73* (<0.01)                         | 99.96* (0.02)                           | 277.33* (0.03)                        |

### 3.2. Impact of product type and company size on HACCP scores

To evaluate the impact of product type and company size on HACCP compliance, a series of two-way ANOVA tests was conducted for each score category, and the mean difference value between the average scores of the two groups was compared. The asterisk (\*) in the mean values indicates that the difference between the two groups means is statistically significant. For Part I (Documentation), there were statistically significant effects of product type ( $F = 3.75$ ,  $p < 0.001$ ), company size ( $F = 55.91$ ,  $p < 0.001$ ), and a significant interaction effect ( $F = 7.34$ ,  $p < 0.001$ ), indicating that the effect of company size varied depending on the product category. Similar patterns were observed for Part II (functioning), where product type ( $F = 2.60$ ,  $p = 0.007$ ), company size ( $F = 38.67$ ,  $p < 0.001$ ), and interaction ( $F = 5.29$ ,  $p < 0.001$ ) were all significant. For the total HACCP score, all major effects and interactions were significant (product type:  $p = 0.004$ ; company size:  $p < 0.001$ ; interaction:  $p < 0.001$ ).

Companies processing meat and RTE foods recorded higher HACCP compliance scores. In contrast, rice-based and dairy processing units had lower scores. Fruit and vegetable processors showed intermediate performance. Large companies demonstrated the highest levels of HACCP compliance, followed by medium-sized companies, while small enterprises showed the lowest compliance across all assessed areas.

### 3.3. Cluster-based grouping of organic food companies by HACCP performance

Three separate groups representing high, moderate, and low HACCP compliance levels were formed using hierarchical cluster analysis. Large businesses, especially those that processed meat and ready-to-eat goods, dominated the high-compliance cluster (0). Medium-sized businesses from a variety of product categories made up most of the moderate-compliance cluster (1). Small-scale processors, mostly engaged in rice-based and dairy products, made up most of the low-compliance cluster (2), suggesting ongoing structural constraints in HACCP implementation.

The cluster analysis further reinforced these findings by grouping companies into high, moderate, and low compliance clusters, which closely mirrored differences in company size and product type. High-performing clusters were dominated by large enterprises or those handling export-sensitive commodities, while low-performing clusters were primarily composed of small firms dealing with less regulated products (Table 5).

**Table 5.** Cluster analysis summary.

| Cluster | Mean<br>( Part I Score) | Mean<br>(Part II score) | Mean<br>(Total score) |
|---------|-------------------------|-------------------------|-----------------------|
| 0       | 208.8                   | 249.9                   | 687.9                 |
| 1       | 165.2                   | 191.6                   | 531.3                 |
| 2       | 125.1                   | 149.9                   | 410.6                 |

The hierarchical cluster analysis of product categories based on HACCP audit scores resulted in a dendrogram that grouped the five product types into three major clusters (Figure 1). RTE and Dairy products were closely clustered, indicating high similarity in their HACCP compliance scores. Rice and Fruits formed a separate sub-cluster with moderate similarity. Meat products were positioned as a separate cluster at a higher distance from the other groups, indicating lower similarity in HACCP scores compared to the rest. The clustering was based on score patterns from HACCP documentation and functioning components.

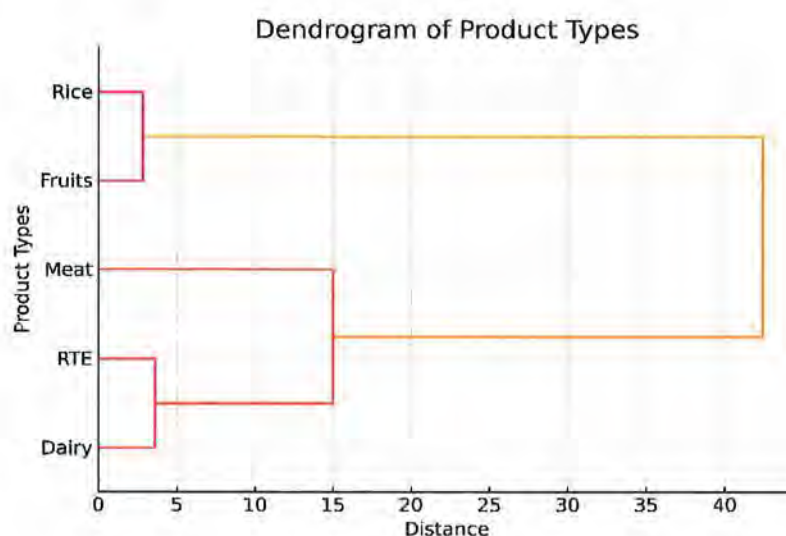


**Figure 1.** Hierarchical cluster dendrogram of organic food processing enterprises based on HACCP documentation, functioning, and total compliance scores, identifying three distinct compliance clusters.

### 3.4. Principal component analysis of HACCP compliance scores

The PCA correlation diagram illustrates the relationships among variables influencing HACCP compliance, including company size, product type, and audit score components. The first two principal components (PC1 and PC2) explained 55.0% and 30.0% of the total variance, respectively, accounting for a combined 85% of the variation in the dataset.

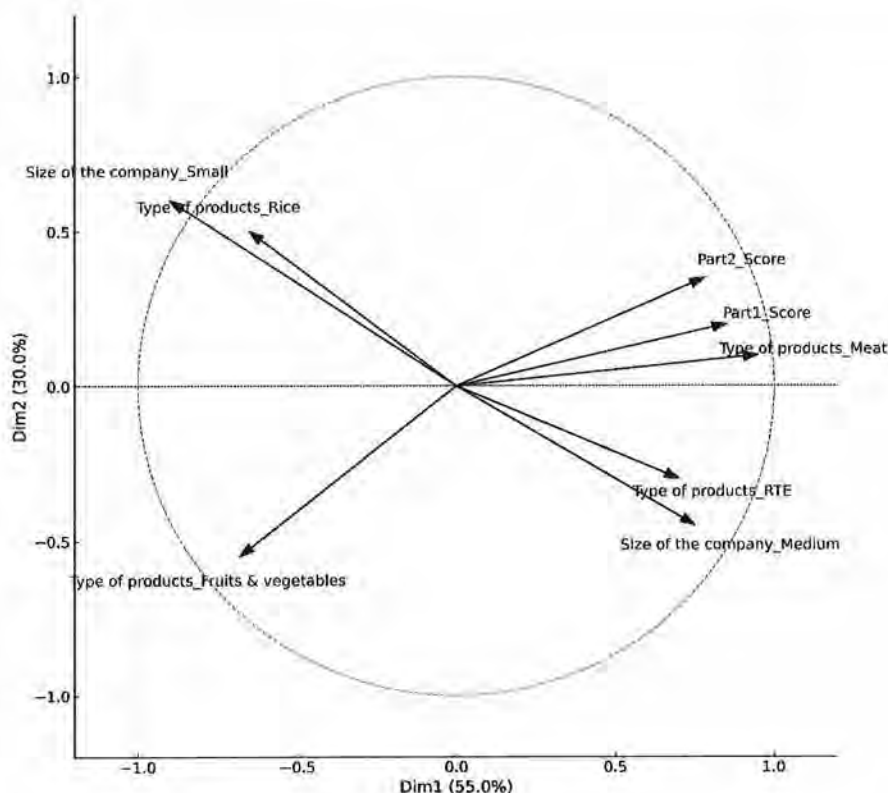


**Figure 2.** PCA biplot illustrating associations between HACCP compliance scores, company size, and product categories among certified organic food processors.

In the diagram (Figure 2), vectors representing Part I score and Part II score are closely aligned, indicating a strong positive correlation between documentation and functioning components of HACCP compliance. The type of product, meat, and the RTE vector are in the positive quadrant near the documentation and functioning scores, indicating that these processors also have a strong HACCP system implementation. The Rice vector lies in the negative Dim1 and positive Dim2 quadrant, which places it opposite the documentation and functioning scores. This implies a negative correlation. The fruits & vegetables vector points in a moderate negative direction on both dimensions, suggesting that performance among these processors is mixed. The vector for small companies lies in the strong negative direction along Dim1, nearly opposite to the documentation and functioning vectors. This suggests that small enterprises consistently score lower on HACCP compliance. The Medium-sized company vector is placed in a positive Dim1 and negative Dim2 quadrant, closer to the origin. This reflects a moderate positive association with HACCP documentation and functioning.

#### 4. Discussion

We set out to understand HACCP compliance in the organic food processing sector in Kerala, India, focusing on how compliance levels vary by company size and product type. The statistical analysis of audit data from 100 certified organic enterprises revealed clear patterns that contribute to the broader understanding of food safety implementation in emerging organic markets.

A primary finding was the consistent relation between company size and HACCP compliance,

with large enterprises showing significantly higher conformity across documentation, system functioning, and total compliance. Similar results were revealed by authors worldwide citing resource availability, technical capacity, and structured management systems as important accelerators of HACCP performance in larger companies [32–35]. Even though the use of HACCP has been extensively researched in the conventional food processing industry, there is an inadequate amount of empirical data that focuses on organic food processing businesses, especially in developing nations. By offering audit-based data that connects HACCP compliance with the structural features of organic processors, our study helps close this gap. Moreover, Large companies have often dedicated food safety teams, formal documentation protocols, and greater exposure to international standards, especially when engaged in export-oriented production [32,36,37]. In contrast, small and medium enterprises, which form the backbone of India's organic sector, tend to operate with limited resources, minimal technical support, and informal management practices, all of which hinder effective HACCP system development and execution [6,38–41]. A study revealed that certified food businesses often failed to maintain full compliance in the functioning of HACCP principles, especially regarding verification procedures, determination of critical control points (CCPs), and corrective actions [38,42–45]. HACCP systems are frequently implemented inconsistently throughout the world, with monitoring, verification, and corrective actions being performed insufficiently. In small and medium-sized businesses, this is made worse by a lack of technical expertise, excessively complicated documentation, and a lack of regulatory support [41,42,46–49].

Other than company size, the type of product processed also plays a decisive role in HACCP outcomes, and some authors have discussed the food safety compliance in fruits and vegetable industries [50–52]. Furthermore, companies engaged in the processing of high-risk foods such as meat and RTE products recorded higher compliance scores. Many incidents of food safety-related issues in RTE products have been discussed by authors from different countries [53–57]. These products, due to their susceptibility to microbial contamination and perishability, are subject to stricter food safety regulations and are often more aligned with international trade requirements [8,23,33,58,59]. On the other hand, processors of rice-based and dairy products, particularly at smaller scales, were found to have relatively lower levels of compliance [60–63]. These product categories are commonly associated with minimal processing or traditional methods and are often handled by smaller facilities with limited access to food safety expertise and oversight [61,64,65].

Interestingly, we found a significant interaction effect between company size and product type, indicating that the impact of size on HACCP performance is not uniform across product categories [59]. This suggests that the hazard profile of the product may amplify the structural limitations of smaller enterprises, making it more difficult for them to meet compliance standards in high-risk categories [36]. Moreover, researchers [18–20] have identified significant knowledge gaps among organic food company operators in selected EU nations about the principles and execution of HACCP systems, particularly in terms of documentation and hazard analysis. Although enhancing HACCP implementation in underdeveloped countries faces considerable challenges, such as inadequate regulatory infrastructure, insufficient technical knowledge, and low hygiene awareness, this difficulty also presents a significant opportunity [48,49]. Furthermore, as the global demand for organic food continues to rise [66–68], and taking advantage of this popularity, developing nations can enhance food safety and public health, and position themselves competitively in growing global organic markets.

This work makes a novel scientific contribution by conducting structured HACCP audits on a large, diversified sample of certified organic food processors in India, an area with relatively little research. Most HACCP studies either focus on conventional food sectors or individual commodities, with little emphasis given to organic systems, despite their growing importance in India's food landscape. Most researchers focus on conventional food systems, with limited attention given to the unique challenges of organic processing in developing countries. By linking audit outcomes with structural characteristics such as size and product category, this research contributes to a more detailed understanding of how food safety systems operate in resource-constrained and diverse production environments. Despite its valuable insights, this study has certain limitations: The sample was limited to 100 organic food processing units in Kerala, which may not fully represent the broader national landscape. Additionally, audits were conducted by a single trained auditor; despite adherence to standardized Codex-aligned criteria, the employment of a single auditor may create subjective bias, even though this maintained consistency in audit application and scoring.

## 5. Conclusions

In this study, we include an in-depth assessment of the HACCP system in certified organic food processing enterprises in Kerala, India using a structured audit tool aligned with Codex Alimentarius principles. We statistically analyzed multiple product categories and business sizes. The findings showed that HACCP compliance varies across the organic industry and is heavily influenced by the type of product processed and the size of the company.

High-risk product categories, such as meat and RTE products, had comparatively higher compliance scores, particularly among larger enterprises. This can be described as increased regulatory scrutiny, export market demands, and resource availability for system adoption. In contrast, poorer compliance levels were reported in rice-based and dairy processing units, particularly among small businesses, with significant nonconformities in hazard identification, documentation methods, and corrective action procedures.

The use of advanced statistical tools enabled in-depth interpretation of the patterns and interactions within the dataset. This study contributes to the food safety literature as one of the first to thoroughly analyze HACCP compliance in India's organic processing sector, which is rapidly growing but under-researched. The findings highlight the critical need to incorporate HACCP principles into organic certification methods to ensure that environmental and public health goals are addressed.

The findings offer policymakers some insight into promoting the development of tailored training programs, particularly for small-scale organic processors handling high-risk commodities. Certification bodies and government agencies (such as FSSAI, APEDA, and PGS-India) may benefit from introducing risk-based audits and capacity-building workshops to increase compliance. Furthermore, improving HACCP implementation in the organic industry will raise consumer confidence in domestic markets while increasing India's competitiveness in the international organic market.

## Use of AI tools declaration

The authors declare they have not used Artificial Intelligence (AI) tools in the creation of this article.

## Conflict of interest

The authors declare that they have no conflicts of interest.

## Author contributions

Conceptualization, A.P.M. and J.T.; methodology, A.P.M.; software, A.P.M.; validation, J.T. and S.S.N.; formal analysis, A.P.M.; investigation, A.P.M.; resources, A.P.M.; data curation, A.P.M.; writing- original draft preparation, A.P.M.; writing-review and editing, J.T.; visualization, A.P.M.; supervision, J.T.

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Signature

A handwritten signature in blue ink, appearing to read 'Joanna Trafialek', is written over a light blue horizontal line.



## Article

# Sustainability and Compliance in Organic Food Industries: A Comparative Study of India and Italy

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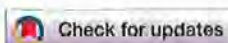
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## Abstract

Food safety, quality management, and ecologically conscious practices must be successfully integrated throughout supply chains to guarantee the sustainability of organic food systems. There is little empirical data on how these factors interact in various institutional and regulatory contexts, despite the growing significance of the organic sector for sustainable food transitions. This study examines sustainability-focused compliance procedures in Italian and Indian organic food processing businesses. A systematic questionnaire was used to gather primary data from 300 certified organic businesses (150 per nation), and non-parametric statistical methods were used to examine firm-size and cross-country variations. The results show notable differences between the two contexts in terms of food safety rules and sustainability performance. Because of a more developed regulatory framework and more robust enforcement mechanisms, Italian businesses demonstrate greater and more consistent sustainability performance. On the other hand, Indian businesses, especially small ones, show more unpredictability, which suggests that they have limited ability to implement sustainable practices and environmental management. The performance of quality management systems in both nations is similar, indicating the contribution of international certification standards to the harmonisation of quality governance. In contrast to Italy, where they operate as separate operational domains, correlation research shows that sustainability, food safety rules, and quality management are more closely interwoven in Indian businesses. The study emphasises the importance of the company's size and the regulatory environment in determining how sustainability is integrated into organic food chains. The findings present beneficial guidance for small and medium-sized businesses by highlighting important areas where targeted capacity building and regulatory assistance can improve sustainability and compliance performance and it is one of the first enterprise-level empirical evaluations of food safety rules, quality management, and sustainability in organic food processing across different regulatory contexts. The findings provide actionable insights for small organic processors by highlighting priority areas for targeted regulatory support, technical help, and capacity building to improve the incorporation of sustainability practices.

**Keywords:** organic food; sustainability; quality management; food safety



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## 1. Introduction

With the growing consumer concerns about chemical residues, environmental degradation, and the long-term health effects of conventional food production, the organic food industry has experienced significant global expansion in recent decades [1–4]. Systems for organic certification were created to solve these problems by encouraging natural inputs, traceability, and environmentally responsible production practices [5,6]. In addition to farming techniques, strict hygiene management, contamination control, supply chain coordination, and adherence to processing standards are all necessary for food safety in organic chains [7]. These requirements depend on the ability, knowledge, and actions of various stakeholders throughout the value chain and go beyond organic agricultural regulations [8,9].

Despite its significance, maintaining food safety in organic supply networks is still difficult, particularly in areas where compliance cultures, technological support systems, and regulatory frameworks are still developing [10]. Businesses in India differ greatly in how closely they follow food safety regulations, documentation systems, and sustainable practices, especially in Kerala, a state with a quickly growing organic industry [11–13]. This heterogeneity is caused by a number of factors, including inconsistent regulatory enforcement, inadequate infrastructure support, differences in personnel competencies, and reliance on external certification audits [14,15]. On the other hand, organic processors in Italy and the larger European Union function under a highly institutionalised regulatory structure that is governed by well-established environmental directives, harmonised organic standards, and stringent hygiene laws [16–18].

In addition to producing high-quality goods, organic food processing technologies are anticipated to have wider institutional, social, and environmental advantages from the perspective of sustainability [19,20]. In this context, sustainability goes beyond adhering to organic standards and includes the long term survival of businesses within food value chains, pollution prevention, waste minimisation, and responsible resource usage [21,22]. Therefore, improving environmental performance while preserving consumer confidence and market credibility requires the effective integration of food safety rules, quality management, and sustainability policies [9,23].

There is still a big knowledge gap regarding how food safety rules, quality management, and sustainability are operationalised at the enterprise level within organic processing industries, despite the fact that a lot of research has looked at consumer trust, certification efficiency, and agronomic aspects of organic production [7,24]. Since contemporary food governance literature highlights the necessity of multi-dimensional compliance systems that address product safety, process dependability, and environmental responsibility, the integration of these three domains is especially crucial [25–27]. However, few empirical comparison studies assess these domains in various regulatory contexts [28,29]. Additionally, little focus has been placed on how organisational attributes like market orientation, company size, and resource availability affect compliance behaviour in the organic sector [27,30].

The organic food sectors in Kerala, India, and Italy are systematically compared in this study, which focuses on three connected areas: sustainable practices, quality management, and food safety rules. The study assesses how business size affects organisational performance, looks at cross-country disparities, and investigates correlation patterns among compliance dimensions using structured questionnaire data and non-parametric statistical methods. This research contributes to the current understanding of how institutional pressures, organisational capabilities, and governance systems interact to determine food safety assurance in organic value chains by comparing two very distinct regulatory settings.

Policymakers, certifying organisations, and industry stakeholders looking to enhance the integrity, durability, and sustainability of organic food systems will benefit greatly from the findings. Furthermore, by emphasising the difficulties and inequalities associated with guaranteeing safety in organic production and processing settings, this work makes a significant contribution to the larger academic conversation on food safety governance. The following research questions were developed to direct the analysis in light of the study's objectives:

RQ1: How differently are food safety rules, quality management, and sustainability approaches implemented by organic food processing companies in Italy and India?

RQ2: What is the relationship between enterprise size and compliance performance in these three operational domains?

This study adds to the existing literature in three significant ways. First, it conducts an integrated empirical examination of three interrelated operational domains in organic food processing enterprises: food safety rules, quality management, and sustainability. Second, it presents a cross-country comparison of two regulatory environments: a mature European system (Italy) and a developing organic governance framework (India). Third, it investigates the impact of business size on compliance performance, revealing how organisational capability influences the application of safety and sustainability measures.

## 2. Materials and Methods

### 2.1. Study Design

The study employed a cross-sectional design to evaluate the differences and similarities in food safety rules, quality management, and sustainability approaches among organic food industries in Kerala (India) and Italy (Figure 1). Italy and Kerala, India, were chosen as representations of different institutional and regulatory frameworks in the organic food industry. Italy functions under a developed and highly institutionalised regulatory framework of the European Union, which is distinguished by standardised food safety laws, reputable certification programs, and robust enforcement measures. Kerala, on the other hand, is an example of an emerging organic governance framework in India. The research explores how company size and national regulatory environment influence the food safety rules, quality management, and sustainable approaches in each country. Quality management is defined as the systematic implementation of procedures and control systems to ensure product quality, process consistency, traceability, and regulatory compliance, such as supplier qualification, internal auditing, corrective and preventive actions, documentation control, and certification management. Sustainability practices are defined as the systematic implementation of environmental management measures aimed at minimising resource use and environmental impact, such as waste reduction, water and energy efficiency, pollution prevention, emission reduction, and the safe management of by-products and expired materials.

### 2.2. Data Collection

The study was conducted among organic food industries certified under nationally or internationally recognized certification bodies. The current study focuses on processing firms since they are the primary operational stage where food safety, quality management, and sustainability compliance systems intersect. However, excluding primary producers and distribution stakeholders limits full value-chain interpretation, future studies should use a thorough farm-to-market analytical methodology. These two regions were selected to capture contrasting governance systems—a developing state-supported organic framework (India) [31,32] and a mature, EU-aligned regulatory structure (Italy) [33].

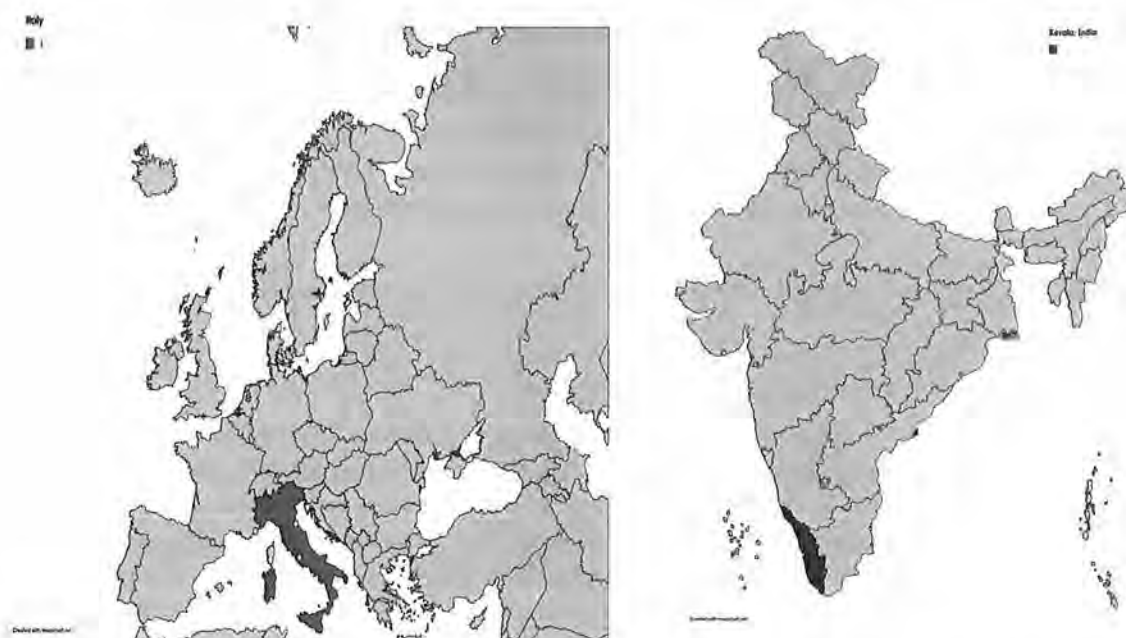


**Figure 1.** Geographic location of the study areas showing Italy and the state of Kerala in India. Map created using <https://www.mapchart.net/>.

A stratified purposive sampling method was applied to ensure adequate participation of small, medium, and large enterprises. Company size was classified based on annual turnover according to EU & MSME [34] guidelines.

Small:  $\leq$ INR 50 Crore/ $\leq$  €10 Million.

Medium: INR 50–250 Crore/€10–50 Million.

Large:  $>$ INR 250 Crore/ $>$ €50 Million.

A total of 300 valid responses (150 from each country) were collected. The sample size was determined using standard statistical power estimation. Respondents were quality managers, food safety officers, or production leads who are directly involved in compliance and certification management.

A structured questionnaire was designed as the tool for primary data collection, which was divided into 3 sections with suitable questions in accordance with country and international guidelines (Table 1). A thorough evaluation across all three domains was made possible by the structured questionnaire's 31 items, which included 14 questions on food safety rules, 8 questions on quality management, and 9 questions on sustainable practices. Each question used a 3-point ordinal scale; Yes = 1, Maybe = 0.5, No = 0. A 3-point ordinal scale was utilised to simplify the response process, decrease respondent burden, and improve reliability across organisations with various levels of managerial and technical competence. The shortened scale reduced complexity in the evaluation of compliance activities. Composite scores were calculated for each section for overall compliance.

The study tool was reviewed by experts from both countries to ensure content validity. A pilot test was carried out involving 10 results from each country, and minor modifications and structure changes were performed as a result of the pilot study.

Data collection was conducted between the period of May 2024 and May 2025. In India, data were gathered through online forms and direct visits. In Italy, the questionnaire was translated by a native speaker, and the responses were collected through online forms via industry associations and research collaborations. Completed questionnaires were anonymised and coded for statistical analysis.

**Table 1.** Overview of questionnaire sections and operational indicators.

| Sections                     | Areas Covered                                                                                               | Example Questions                                                                                                     |
|------------------------------|-------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| <b>1. Food safety rules</b>  | HACCP, hygiene & sanitation, documentation, training, Pest Control Management, Allergen Management          | Does the company implement a documented HACCP plan?<br>Are regular staff hygiene and food safety trainings conducted? |
| <b>2. Quality Management</b> | Supplier evaluation, corrective action, preventive actions, audits, certifications, and food fraud.         | Are suppliers formally evaluated and approved?<br>Are internal quality audits conducted regularly?                    |
| <b>3. Sustainability</b>     | Waste reduction, carbon emission, SDGs, water treatment, pollution control, and expired product management. | Does the company implement waste reduction measures?<br>Is wastewater treated before discharge?                       |

### 2.3. Statistical Analysis

All statistical analyses were conducted using SPSS (version 27) and MS Excel version 365. Preliminary data screening was performed to ensure completeness and accuracy of responses. Descriptive statistics, including mean, median, standard deviation, and interquartile range, were computed to summarize the central tendency and dispersion of scores for each section—food safety rules, quality management, and sustainability practices for both countries.

As the response data were ordinal in nature, non-parametric tests were employed for inferential analysis. The Mann–Whitney U test was used to determine whether statistically significant differences existed in the mean scores. To examine the associations among food safety rules, quality management, and sustainability, Spearman’s rank correlation analysis ( $\rho$ ) was applied, as it is appropriate for assessing monotonic relationships between ordinal variables. A significance level of  $p < 0.001$  was adopted for all analyses. Results were interpreted based on test statistics,  $p$ -values, and correlation coefficients.

## 3. Results

The results of the questionnaire revealed clear trends in all three areas. Food safety rules were the most inconsistent, and quality management was shown to be the strongest area. Particularly among smaller enterprises, sustainability procedures were the weakest and least consistent, suggesting a lack of capability or a lack of emphasis on environmental measures. These trends illustrate that different areas have varying levels of maturity, with food safety rules and sustainability exhibiting more firm-to-firm variation and quality management being rather well-established.

Table 2 shows with both the mean and median at 0.7 and comparatively little variability, quality management exhibits the highest and most consistent performance of the three dimensions, suggesting widespread and consistent adoption across organisations. Food safety regulations perform moderately (mean and median of 0.6) with greater dispersion, indicating variations in the degree of application across businesses. In comparison to quality management and food safety regulations, sustainability practices have the lowest median value (0.5) and significantly higher variability, suggesting uneven adoption and emphasising sustainability as a somewhat weaker and less regularly implemented facet.

Table 3 summarises the organic food industries in Italy, which demonstrate excellent food safety rules and well-established quality management systems; sustainability practices also appear consistent. Both the mean and median for quality management and sustainability are 0.7, indicating consistent efforts toward maintaining product quality and sustainable production. In summary, Italy’s organic food industry excels in safety

and quality standardization but would benefit from further development of consistent sustainability initiatives to strengthen its long-term environmental performance.

**Table 2.** Descriptive statistics for compliance performance among organic food enterprises in India.

| Variables          | Median | Mean | Std. Deviation | IQR | 95% CI |       |
|--------------------|--------|------|----------------|-----|--------|-------|
|                    |        |      |                |     | Lower  | Upper |
| Quality management | 0.7    | 0.7  | 0.2            | 0.4 | 0.6    | 0.7   |
| Food safety rules  | 0.6    | 0.6  | 0.3            | 0.4 | 0.5    | 0.6   |
| Sustainability     | 0.5    | 0.6  | 0.3            | 0.4 | 0.5    | 0.6   |

IQR: Interquartile Range, CI: Confidence interval.

**Table 3.** Descriptive statistics of quality management, food safety rules, and sustainability in Italy.

| Variables          | Median | Mean | Std. Deviation | IQR | 95% CI |       |
|--------------------|--------|------|----------------|-----|--------|-------|
|                    |        |      |                |     | Lower  | Upper |
| Quality management | 0.7    | 0.7  | 0.2            | 0.2 | 0.7    | 0.7   |
| Food safety rules  | 0.8    | 0.8  | 0.2            | 0.1 | 0.7    | 0.8   |
| Sustainability     | 0.7    | 0.7  | 0.1            | 0.1 | 0.7    | 0.7   |

The results of the Spearman correlation analysis examining the interrelationship among quality management, food safety rules, and sustainability in India's organic food industries indicate strong and statistically significant positive correlations among all three variables. A very high correlation was observed between quality management and food safety rules ( $r = 0.824$ ,  $p < 0.001$ ), suggesting that higher standards of quality management are closely associated with stronger compliance with food safety rules. Furthermore, sustainability is significantly and positively correlated with both quality management ( $r = 0.279$ ,  $p < 0.001$ ) and food safety rules ( $r = 0.374$ ,  $p < 0.001$ ), implying that organizations emphasizing quality and safety are also more inclined to adopt sustainable operational practices.

For Italy, the Spearman correlation results demonstrate weak and statistically insignificant relationships among the variables. The correlation between quality management and food safety rules is minimal ( $r = 0.014$ ), while sustainability shows slight negative correlations with both quality management ( $r = -0.038$ ) and food safety rules ( $r = -0.104$ ). None of these associations reaches statistical significance, suggesting that in Italy, the three domains function largely independently rather than as interconnected dimensions.

Table 4 presents the results of the Mann–Whitney U test, which revealed no statistically significant difference in quality management between India and Italy ( $p = 0.94$ ), indicating comparable performance across the two countries. In contrast, significant differences were observed for both sustainability ( $p < 0.001$ ) and food safety rules ( $p < 0.001$ ). The comparative mean performance scores for quality management, sustainability practices, and food safety regulations between the organic food businesses in Italy and India are shown in Figure 2. The graph shows equal quality management mean scores in both nations, suggesting equivalent degrees of quality system implementation. Italy, on the other hand, has better mean ratings than India for sustainable practices and food safety regulations, indicating stronger and more consistent compliance in these areas.

Using mean, median, standard deviation, and Mann–Whitney U test statistics, Table 5 shows a size-wise comparison of quality management, food safety regulations, and sustainability practices between the organic food businesses in Italy and India. While sustainability scores do not differ much between nations, Italian small businesses do no-

ticeably better when it comes to quality management and food safety regulations. There are no statistically significant differences for medium-sized businesses in any of the three dimensions, suggesting that compliance behaviour is consistent. On the other hand, while food safety rule compliance is statistically identical, large Indian companies perform better than their Italian counterparts in quality management and sustainability. Overall, the table shows that cross-country compliance trends are significantly influenced by firm size.

**Table 4.** Quality, sustainability, and food safety compliance in India and Italy.

| Variables                | Country | Mean | Median | Std. Deviation | Test Statistic | <i>p</i> Value |
|--------------------------|---------|------|--------|----------------|----------------|----------------|
| Quality management       | India   | 0.66 | 0.63   | 0.27           | 9333.5         | 0.94           |
|                          | Italy   | 0.68 | 0.63   | 0.22           |                |                |
| Sustainability practices | India   | 0.59 | 0.77   | 0.27           | 5192.5         | <0.001         |
|                          | Italy   | 0.71 | 0.33   | 0.14           |                |                |
| Food safety rules        | India   | 0.47 | 0.71   | 0.31           | 7000.5         | <0.001         |
|                          | Italy   | 0.73 | 0.50   | 0.22           |                |                |

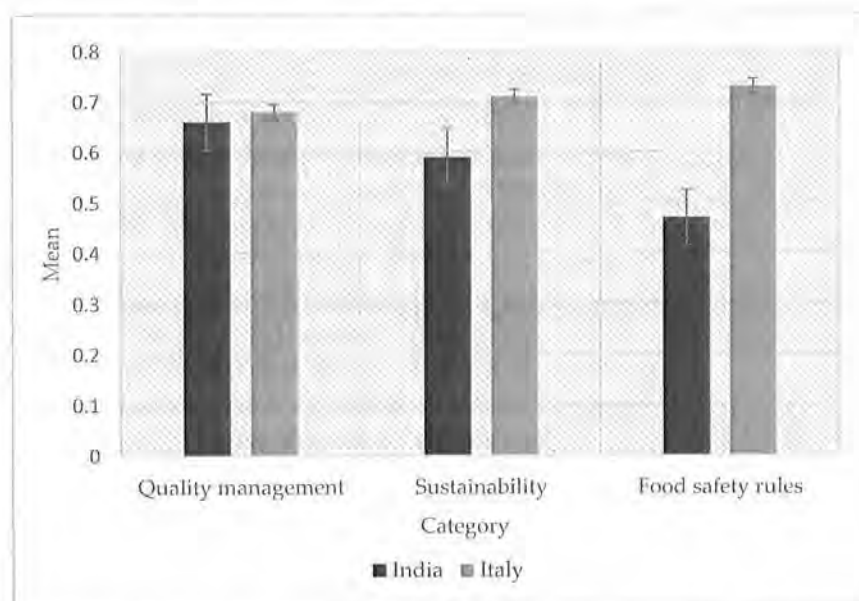


**Figure 2.** Mean scores of quality management ( $p = 0.94$ ), sustainability ( $p < 0.001$ ), and food safety rules ( $p < 0.001$ ) for India versus Italy.

**Table 5.** Quality management, Food safety rules, and sustainability between India and Italy across Different Company Sizes.

| Size  | Variables          | Categories | Mean      | Median | Std. Deviation | Test Statistic | <i>p</i> Value |
|-------|--------------------|------------|-----------|--------|----------------|----------------|----------------|
| Small | Quality management | India      | 0.4684932 | 0.5    | 0.195702       | 372.5          | 0.004          |
|       |                    | Italy      | 0.5407407 | 0.6    | 0.220592       |                |                |
|       | Food safety rules  | India      | 0.4268265 | 0.38   | 0.277166       | 91             | <0.001         |
|       |                    | Italy      | 0.6980453 | 0.77   | 0.199811       |                |                |
|       | Sustainability     | India      | 0.6203523 | 0.64   | 0.20581        | 471.5          | 0.084          |
|       |                    | Italy      | 0.5873016 | 0.4    | 0.301965       |                |                |

Table 5. Cont.

| Size   | Variables          | Categories | Mean      | Median   | Std. Deviation | Test Statistic | p Value |
|--------|--------------------|------------|-----------|----------|----------------|----------------|---------|
| Medium | Quality management | India      | 0.7591121 | 0.8      | 0.155762       | 1024           | 0.354   |
|        |                    | Italy      | 0.7833333 | 0.8      | 0.136668       |                |         |
|        | Food safety rules  | India      | 0.6948079 | 0.75     | 0.179267       | 1060.5         | 0.501   |
|        |                    | Italy      | 0.7240741 | 0.763889 | 0.171689       |                |         |
|        | Sustainability     | India      | 0.7089453 | 0.714286 | 0.195665       | 1058           | 0.496   |
|        |                    | Italy      | 0.652381  | 0.75     | 0.281204       |                |         |
| Large  | Quality management | India      | 0.975     | 1        | 0.044721       | 218            | <0.001  |
|        |                    | Italy      | 0.7325    | 0.7      | 0.220342       |                |         |
|        | Food safety rules  | India      | 0.8342014 | 0.875    | 0.051587       | 627            | 0.897   |
|        |                    | Italy      | 0.7951141 | 0.826389 | 0.222104       |                |         |
|        | Sustainability     | India      | 0.78125   | 0.75     | 0.112088       | 335            | 0.002   |
|        |                    | Italy      | 0.5645833 | 0.5      | 0.253373       |                |         |

### 3.1. Small-Sized Enterprises

For small-sized companies, the Mann–Whitney U test revealed significant differences between India and Italy in terms of quality management and food safety rules. Italian firms reported higher mean scores for quality management (0.54) compared to Indian firms (0.47), with the difference being statistically significant ( $p = 0.004$ ). Similarly, food safety rules were considerably higher in Italian companies (mean = 0.70) than in Indian ones (mean = 0.43), showing a highly significant difference ( $p < 0.001$ ). However, the difference in sustainability performance between the two countries was not statistically significant ( $p = 0.084$ ), indicating comparable sustainability practices among small enterprises in both nations. While sustainability procedures are largely similar between the two nations, small organic food enterprises in Italy typically exhibit higher levels of quality management and food safety law compliance than their Indian counterparts (Figure 3).

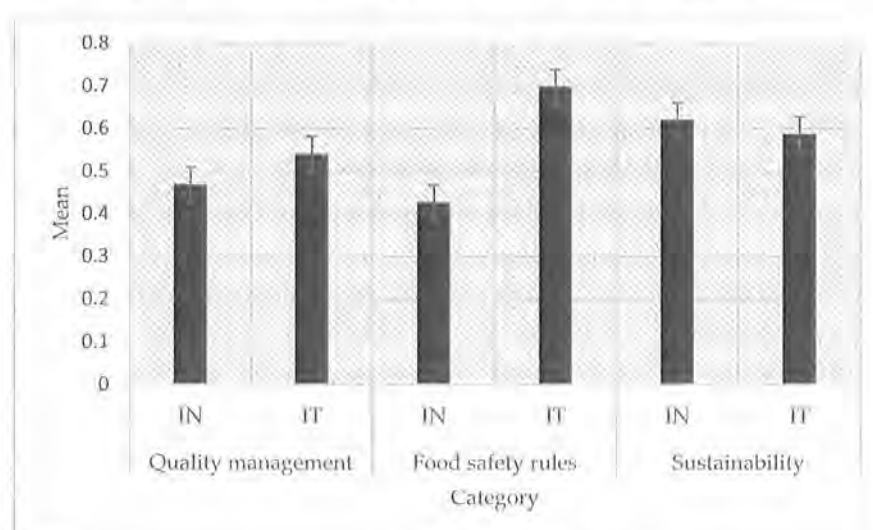


**Figure 3.** Mean performance scores in small-sized companies for quality management ( $p = 0.004$ ), food safety rules ( $p < 0.001$ ), and sustainability ( $p = 0.084$ ) in India (IN) versus Italy (IT) with error bars indicating variability.

### 3.2. Medium-Sized Enterprises

Among medium-sized companies, the Mann–Whitney U test results showed no statistically significant differences between India and Italy across all three variables. The  $p$ -values for these comparisons were 0.354, 0.501, and 0.496, respectively, all exceeding the 0.05 significance level. This suggests that medium-sized firms in both countries exhibit similar levels of quality management, sustainability, and food safety rules, with no notable variation in their practices (Figure 4).

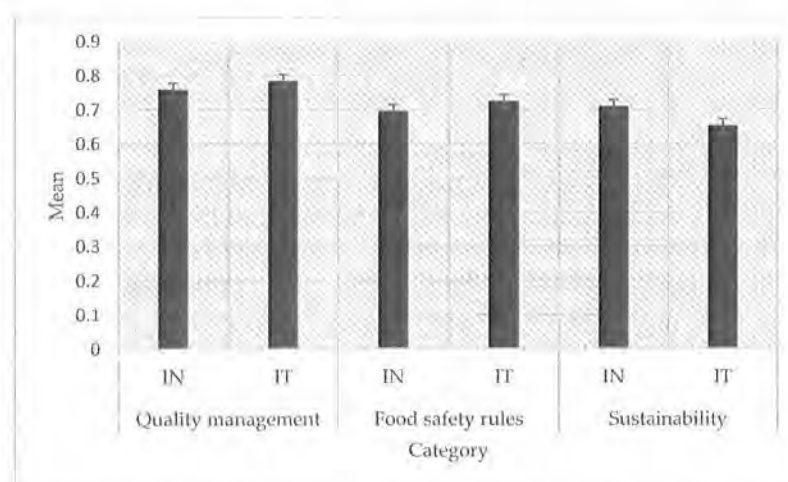


**Figure 4.** Mean scores for quality management, sustainability, and food safety rules in India versus Italy in medium-sized companies.

### 3.3. Large-Sized Enterprises

As shown in Figure 5, for large companies, significant differences were observed between India and Italy in quality management and sustainability. Indian firms reported a higher mean value for quality management (0.975) than Italian firms (0.733), indicating a statistically significant advantage for India ( $p < 0.001$ ). Likewise, sustainability scores were higher for Indian companies (0.781) compared to Italian companies (0.565), also showing a significant difference ( $p = 0.002$ ). In contrast, food safety rules did not differ significantly between the two countries ( $p = 0.897$ ), suggesting similar compliance levels among large enterprises in both regions.

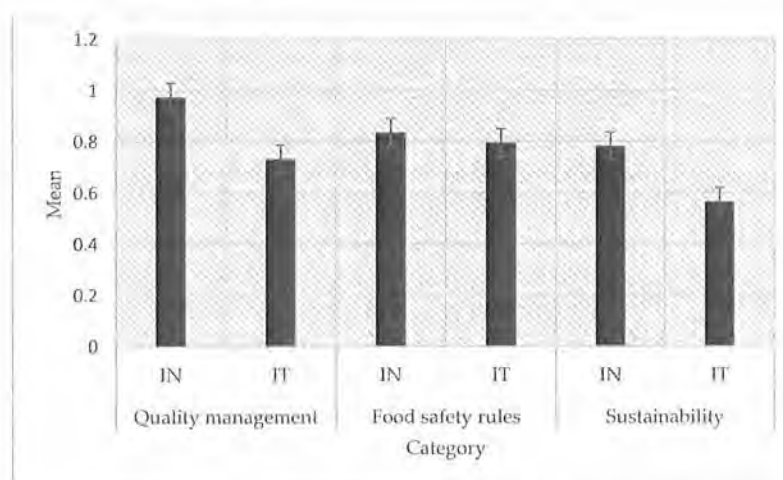


**Figure 5.** Mean scores of large companies' quality management ( $p < 0.001$ ), food safety rules ( $p = 0.897$ ), and sustainability ( $p = 0.002$ ) for India (IN) versus Italy (IT).

#### 4. Discussion

The results show distinct structural and operational differences between the organic food industries in Italy and Kerala, India. These differences reflect the impact of resource allocation, industry organisation, and regulatory maturity on food safety rules, quality management systems, and the adoption of sustainability (Table 6). While both nations show a dedication to organic production standards, there are significant differences in the breadth, uniformity, and integration of these techniques.

**Table 6.** A comparison of compliance performance in organic food processing firms in Italy and Kerala (India) across three operational domains.

| Sections           | Italy                                                                                                                        | India                                                                                             | Key Differences                                                                                                                      |
|--------------------|------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| Food safety rules  | High and consistent implementation: strong adherence to hygiene, documentation, and HACCP requirements under EU regulations. | Moderate implementation with considerable variability, particularly among small companies.        | Italy shows higher and more uniform compliance due to stronger regulatory enforcement.                                               |
| Quality management | Well established quality systems including supplier control, internal audits, and certification; consistent across firms.    | Similar implementation levels demonstrate the influence of international certification standards. | There are no significant cross-country differences; global standards function as a standardisation process.                          |
| Sustainability     | Relatively high and stable adoption of environmental measures such as waste management and resource efficiency.              | Lower and more uneven implementation; sustainability weakest among small companies.               | Italy demonstrates stronger and more consistent environmental performance; India shows greater variability and capacity constraints. |

Italy consistently fared better than India in terms of sustainability and overall food safety rules, as seen by considerably higher mean scores and less variability in these areas. The consumer perception about organic foods in Italy was studied by a few authors [6,35]. The European Union's strict and uniform regulatory frameworks [33], which require the agri-food industry to systematically adopt HACCP, traceability, hygiene management, and environmental performance monitoring, are probably responsible for this tendency. Italian organic businesses are part of an established ecosystem where sustainability, quality control, and certification are integrated into daily operations and strengthened by regular audits, collaborative networks, and high customer expectations for openness [36,37].

India, on the other hand, showed more variation in both sustainability and food safety metrics [12,38]. Although many businesses showed robust internal quality management systems, the greater variation in ratings points to irregularities in the application of environmental management, documentation procedures, and hygiene standards [39,40]. These disparities could be caused by differences in technical capability, infrastructure constraints, and the various stages of development of Indian organic businesses. Additionally, businesses are still developing a standardised compliance culture due to the relatively recent growth of the organic industry in regions like Kerala [10,12].

Both nations performed well in quality management, despite differences in sustainability and safety. This convergence implies that, regardless of location, quality management mechanisms such as documentation, traceability systems, supplier evaluation, and corrective preventive actions have become essential components of organic industries [33,41–44].

The prevalence of certification programs (such as ISO 22000, FSSC 22000, NPOP, etc.) that have standardised quality management cultures globally may help to explain this [45–47].

The equivalent quality management performance between Italy and India suggests that, despite differences in wider regulatory regimes, certification-driven requirements are acting as a “levelling mechanism,” establishing common operational baselines in documentation and process control [48,49]. According to research by Trienekens & Zuurbier (2008) [50], global certification programs encourage convergent quality cultures in global agri-food supply chains.

A deeper understanding of the structural logic of the two nations’ compliance systems is provided by the correlation patterns. In India, food safety rules, quality management, and sustainability have substantial positive relationships, indicating that these areas function as an integrated management system. Because of shared resource pools and cumulative learning effects, businesses that invest in one area, like training or documentation, typically see improvements in other areas [51–53]. This validates the “spillover effect” theory put forth by Pagell & Wu (2009) [54], which holds that improving quality management capabilities improves overall sustainability and safety performance.

On the other hand, functional segmentation is shown by the lack of strong relationships in Italy. Food safety rules, quality management, and sustainability seem to be viewed by Italian businesses as separate operational pillars, each with its own set of rules, audit specifications, and performance metrics [37,55]. This is indicative of an advanced, specialised compliance environment in which management systems have developed into separate vertical domains as opposed to interconnected systems [56]. The division is consistent with European compliance cultures where quality management (ISO 9001), food safety (HACCP/ISO 22000), and environmental management (ISO 14001) all follow separate audit cycles and do not necessarily interact [46,57,58].

Firm size emerged as a significant determinant of compliance outcomes, reaffirming existing literature that links larger organizational scale with greater resource availability, technical capacity, and sophistication in safety and sustainability practices [13,59].

In India, sustainability received the lowest and most inconsistent results, especially from small businesses. This is in line with findings made worldwide that the organic industry’s integration of sustainability is still developing beyond mere regulatory compliance [60–62]. Larger businesses are more receptive to global market demands on resource efficiency, carbon reduction, and circular packaging, whereas small businesses frequently lack the financial capacity or incentive structure for environmental innovation [63].

The findings provide clarified answers to the research questions. Regarding RQ1, the findings show that the two countries’ compliance policies differ. Organic food processing companies in Italy displayed greater and more consistent performance in food safety practices and sustainability indicators, indicating the influence of a mature and strictly implemented regulatory system. In contrast, organisations in India demonstrated more disparity in these dimensions, particularly among smaller firms, indicating disparities in institutional support, technical capacity, and resource availability. In relation to RQ2, enterprise size was discovered to be an essential indicator of compliance performance. Larger enterprises demonstrated higher and more consistent implementation levels across all three domains, indicating better organisational capacity, resource availability, and familiarity with certification and audit processes. Smaller businesses, particularly in India, displayed lower and more variable performance, particularly in terms of sustainability practices, highlighting the operational and financial constraints that prevent the adoption of resource-intensive environmental initiatives.

This study has certain limitations that must be acknowledged when evaluating the results. It used self-reported questionnaire data, which could be affected by answer biases

such as over-reporting compliance behaviours and social desirability. Self-reported measurements may not accurately reflect real on-ground behaviours, even though anonymity was guaranteed and questions were designed to minimise subjectivity, particularly in regulated areas where non-compliance bears reputational penalties. Respondent's interpretations of questionnaire items may be influenced by cultural, linguistic, and regulatory contextual differences between Italy and India. Also, the responses provided by enterprise representatives, the risk of over-reporting compliance performance or underreporting operational issues cannot be fully ruled out. The cross-sectional design records compliance behaviour at an individual moment, thereby precluding the evaluation of temporal dynamics or causal linkages. And the geographical scope is restricted to Kerala in India and nationwide coverage in Italy, potentially limiting full cross-country representativeness. To improve external validity, future research should use longitudinal methods, accurate audit-based metrics, and broaden geographic coverage. Compliance culture and audit experience differ between countries, which may influence self-reporting behaviour. Enterprises operating in more mature regulatory frameworks may be more used to formal compliance reporting, whereas firms in emerging contexts may misrepresent performance or underreport problems due to uncertainty or perceived risk.

From a policy standpoint, the findings emphasise the importance of targeted improvement programs, streamlined documentation systems, combined technical support services, and financial incentives to assist small businesses in satisfying integrated safety and sustainability criteria. Overall, this study shows that although both Italy and India have established solid quality management systems, their approaches to food safety rules and sustainability are different in terms of their depth, consistency, and integration. Policymakers, certification organisations, and industry stakeholders looking to bolster the organic sector through focused interventions, capacity building, and standardisation will find these insights useful.

## 5. Conclusions

This research adds new empirical evidence by conducting one of the first enterprise-level comparative assessments that integrate food safety rules, quality management, and sustainability in organic food processing across different regulatory frameworks. The findings show that regulatory maturity and organisational capacity both influence the level and consistency of compliance performance. It reveals how enterprise characteristics, institutional support systems, and regulatory maturity influence compliance behaviour. From an operational point of view, the findings underline the need for specific initiatives to assist small and medium-sized organic producers. To make it easier to adopt integrated safety and sustainability practices, policymakers and regulatory agencies should prioritise training programs, simplified compliance tools, and technical advising help. Certification authorities may explore unifying audit standards across domains to reduce administrative overhead, while industry stakeholders should improve internal training and allocate more resources to environmental management.

By showing that Indian companies have more integrated links between food safety rules, quality management, and sustainability, whereas Italian companies maintain domain-specific, compartmentalised operational systems, the study significantly advances our knowledge of the structural logic of compliance systems. Firm size was found to have a substantial impact in all scenarios, with larger businesses exhibiting relatively stronger compliance profiles as a result of superior resources, training programs, and investments focused on certification. Together, these observations highlight the need for interventions that take into consideration enterprise-level capacity limitations as well as contextual regulatory frameworks in order to increase food safety assurance in organic industries.

The results identifies potential for certification authorities to create aligned indicators that support comprehensive compliance and expedite audit procedures.

This study creates a fundamental empirical dataset that can facilitate more sophisticated modelling, including context specific sustainability assessment tools, risk based inspection techniques, and predictive compliance analytics. The comparison methodology created here might be used to monitor how compliance practices change over time or expanded to other nations. In the end, the study offers proof in favour of the creation of more robust, transparent, and safety focused organic food systems, which enhances consumer confidence and boosts the organic industry's ability to compete globally. Policymakers and certifying authorities should prioritise targeted training programs for small businesses, promote integrated compliance frameworks that link food safety and sustainability criteria, and strengthen technical advisory support networks. The study's cross-sectional methodology, dependence on self-reported data, and sample geography should all be considered when interpreting the findings.

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## Abbreviations

The following abbreviations are used in this manuscript:

|       |                                                |
|-------|------------------------------------------------|
| EU    | European Union                                 |
| MSME  | Micro, Small, and Medium Enterprises           |
| INR   | Indian Rupee                                   |
| HACCP | Hazard Analysis and Critical Control Point     |
| ISO   | International Organization for Standardization |
| SDGs  | Sustainable Development Goals                  |
| IQR   | Interquartile Range                            |
| CI    | Confidence Interval                            |

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