Regulatory Requirements as Control Measures: A HACCP-Based Model for Food Safety Compliance in the EU

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Abstract

Ensuring food safety in the European Union requires food business operators (FBOs) to apply structured, risk-based systems that respond to a wide range of regulatory requirements. Operational Prerequisite Programs (OPRPs), as part of Hazard Analysis and Critical Control Point (HACCP) plans, offer a practical means of managing significant food safety hazards that are not addressed at Critical Control Points (CCPs). This perspective article discusses how regulatory expectations related to hygiene, traceability, allergens, chemical contaminants, and food contact materials can be translated into effective OPRPs. Emphasis is placed on how these measures can be implemented by small and medium-sized enterprises (SMEs), which often face challenges related to technical capacity, documentation, and auditing. The article highlights examples of OPRPs linked to sanitation, supplier control, production procedures monitoring, packaging safety, and water quality, and considers their role in supporting both compliance and system improvement. By aligning operational controls with compliance obligations through OPRPs, FBOs can enhance transparency, audit readiness, and consumer confidence. This perspective

provides a structured approach for integrating regulatory compliance into food safety management systems in a way that is practical, scalable, and adaptable to ongoing changes in the regulatory environment.

Keywords:

European food safety legislation; HACCP; OPRP; food safety management; risk assessment

1. Introduction

Food safety in the European Union is managed through a common regulatory system that applies across all stages of food production and distribution. The core of this system is the General Food Legislation, which defines basic principles such as risk assessment, traceability, taking preventive action in case of potential risks even without full scientific certainty, and the obligation of food business operators to ensure the safety of the products they place on the market [1]. The foundation for many of today's regulatory requirements was laid by the European White Paper on Food Safety, which emphasized prevention, transparency, and scientific risk assessment [2]. These principles are applied through a set of EU food hygiene Regulations, which include specific hygiene rules, sector-based requirements, and official control procedures conducted by national authorities [3].

FBOs must implement food safety systems based on the Hazard Analysis and Critical Control Point approach. However, applying detailed regulatory requirements within these systems can be challenging, especially for small and medium-sized enterprises [4,5,6]. European food legislation covers many technical areas, such as chemical contaminants, labelling, packaging, and food contact materials, which must be translated into practical controls [7–9].

In the context of food safety management systems, as structured by ISO 22000, the implementation of Prerequisite Programs (PRPs) is essential to establish and maintain a hygienic environment throughout the food chain. PRPs comprise the basic conditions and activities that are necessary to maintain food safety, such as cleaning and sanitation, pest control, maintenance, supplier approval, and personal hygiene, and are generally applied across all processing steps. In addition to PRPs, ISO 22000 introduces the concept of Operational Prerequisite Programs – preventive control measures – that are determined by hazard analysis as necessary to control significant hazards, but which do not meet the criteria to be managed as Critical Control Points. OPRPs require specific monitoring and verification procedures, and their management is more stringent than that of general PRPs due to their direct role in hazard control. The clear differentiation between PRPs, OPRPs,

and CCPs is a fundamental aspect of the ISO 22000 methodology, enabling food business operators to ensure effective hazard control and compliance with regulatory and customer requirements. When linked to compliance obligations, OPRPs also provide structured and verifiable evidence of compliance [4,10].

This article presents a practical approach for integrating food safety legislation into OPRPs. The aim is to help FBOs, particularly SMEs, develop systems that comply with EU food safety legislation, audit-ready, and adaptable to risk.

2. How European Food Legislation Supports HACCP Implementation

Food safety in the European Union is based on strict Regulations that apply across all Member States. The main reference to applicable legislation is Regulation (EC) No 178/2002, which introduces key principles such as the precautionary principle, traceability, risk analysis, and the statutory responsibility of FBOs to ensure the safety of food placed on the market [1]. It also establishes the European Food Safety Authority (EFSA) as the scientific body responsible for risk assessments.

To apply these principles in practice, the EU adopted comprehensive food hygiene Regulations, commonly referred to as the Hygiene Package, which includes Regulations (EC) No 852/2004 [11] and 853/2004 [12], as well as Regulation (EU) 2017/625 on official controls. Regulation (EC) No 852/2004 requires all FBOs to follow hygiene rules based on HACCP principles. It also defines key supporting measures, such as sanitation, water quality monitoring, and pest control, as PRPs [3,11]. According to ISO 22000:2018, some PRPs that control specific hazards may be classified as OPRPs [4].

Regulation (EU) 2017/625 ensures that official inspections are applied consistently across Member States. It requires competent authorities to use a risk-based approach and to assess the effectiveness of HACCP systems, including OPRPs. It also establishes rules for transparency and enforcement [3].

These Regulations provide the regulatory basis for turning food safety requirements into practical, documented control systems that can be monitored and audited [13].

3. Critical Regulatory Requirements for Integration into OPRPs

Operational Prerequisite Programs help food business operators implement food legislation in a practical way. They are used to control significant food safety hazards that are not

addressed at Critical Control Points. Instead of relying on a single control step, OPRPs are integrated into daily activities and preventive measures. Several areas of EU food legislation align closely with the structure of OPRPs and can be incorporated into HACCP-based systems.

3.1. Food Hygiene and Microbiological Criteria

Regulation (EC) No 2073/2005 establishes safety and hygiene limits for microorganisms in food, including *Listeria monocytogenes* in ready-to-eat products and *E. coli* in meat [5]. It defines microbiological criteria for different categories of food and specifies sampling plans, testing methods, and actions to be taken when limits are exceeded. These legislative requirements are typically addressed through OPRPs involving environmental monitoring, cleaning procedures, and cold chain temperature controls [4]. In most cases, the presence of *Listeria monocytogenes* or *Salmonella* is not controlled by a single step, but through a combination of hygiene measures, proper handling, and refrigeration, making them typical examples of hazards managed by OPRPs [5]. Actually, all specific microorganisms for which microbiological criteria are laid down by Regulation (EC) No 2073/2005 may be identified as food safety hazards related to the safety of each officially defined food category.

3.2. Food Additives, Flavourings, and Smoke Substances

The use of additives and flavourings is controlled under Regulations (EC) 1333/2008, 1334/2008, and 2065/2003. Additionally, Regulation (EU) 2024/2067 removed ten smoke flavourings from the Union list [14,15,16,17]. To comply, food operators must ensure that only approved substances are used. OPRPs can include procedures such as checking ingredient lists, requesting supplier specifications, verifying that discontinued flavourings are not used, and ensuring that weighing equipment used for additives is properly calibrated. Detailed guidance on the application of Regulation (EC) No 1333/2008 is also provided by the European Commission to help food businesses understand how to apply additive and processing aid rules in practice [18]. These controls are often integrated into purchasing, receiving, and production control procedures.

3.3. Labelling, Allergens, and Consumer Information

Regulation (EU) 1169/2011 requires clear labelling and the correct declaration of allergens [7]. Failure to declare allergens properly can result in regulatory non-compliance and potential harm to consumers. In addition to allergens, the regulation also covers ingredients that may cause food intolerances, such as lactose and gluten, which must also be clearly declared on the label. OPRPs in this category can include cleaning of production lines between allergen and non-allergen products, verifying label accuracy before packaging,

personnel training on allergen management, and maintaining records for traceability and recall [19].

3.4. Contaminants and Residues

Regulation (EC) 396/2005, Regulation (EC) 37/2010 and Regulation (EU) 915/2023 define maximum allowable levels for chemical hazards such as pesticide residues, veterinary drug residues and food contaminants (e.g. heavy metals and mycotoxins), respectively [8,20,21]. Chemical hazard identification and determination of acceptable levels, as part of a hazard analysis, may be based primarily on the above regulatory requirements. To control these risks, OPRPs may focus on supplier approval, raw material testing, and reviewing certificates of analysis. These procedures are especially important in sensitive product categories such as baby food, cereal products, and seafood. In addition to supplier controls, food business operators should carry out internal verification, such as periodic in-house testing, to confirm compliance with established limits.

3.5. Food Contact Materials and Packaging

Regulation (EC) 1935/2004, as well as Regulations (EU) 10/2011 and 2025/40 establish rules for the safety and sustainability of packaging and food contact materials [9,22,23]. These Regulations aim to prevent harmful substances from migrating into food and promote the use of recyclable and safe materials. OPRPs in this area may include collecting supplier declarations, testing for compliance with migration limits, avoiding materials containing substances such as per- and polyfluoroalkyl substances (PFAs) or bisphenol A (BPA), and auditing packaging suppliers.

3.6. Water Quality and Process Inputs

Directive (EU) 2020/2184 on the quality of water intended for human consumption requires that water used in food production is clean and suitable for human consumption [24]. Monitoring system and verification activities for OPRPs related to water safety often include regular microbial and chemical testing, checking the function of filters or disinfectants, and keeping records of results and corrective actions [25].

The application of European food safety legislation within HACCP systems relies on the ability to convert compliance obligations into structured and verifiable control measures. Table 1 outlines indicative EU regulatory requirements and demonstrates how these can be systematically addressed through corresponding OPRPs, ensuring both compliance and operational consistency.

Table 1: Indicative EU legislation and their corresponding OPRPs within HACCP systems.

EU Regulation	Hazard Controlled	Example OPRP Measure
Reg. 852/2004 (Hygiene)	Microbiological contamination	Check of the effectiveness of cleaning and sanitation schedules
Reg. 853/2004 (Animal-origin foods)	Animal-origin contamination	Check of Food Chain Information, temperature controls
Reg. 2073/2005 (Microbiological Criteria)	Listeria, Salmonella	Cold chain monitoring, environmental testing
Reg. 1169/2011 (Labelling)	Allergen cross-contact	Check of product labelling and equipment sanitation
Reg. 1333/2008, 2024/2067 (Additives, Smoke)	Unauthorized additives	Ingredient verification, supplier specifications
Reg. 1935/2004, 10/2011, 40/2025 (Packaging)	Chemical migration from packaging	Supplier declarations, migration testing
Reg. 396/2005, 915/2023 (Pesticides, Contaminants)	Pesticide residues, heavy metals	Review of certificates of analysis, raw material testing
Dir. 2020/2184 (Water)	Unsafe water use	Water analysis, filter maintenance
Reg. 37/2010 (Pharmacologically active substances)	Veterinary drug residues	Supplier validation, residue monitoring

By integrating legislative requirements, such as those on hygiene, additives, labelling, and contaminants, into clear and structured OPRPs, FBOs can create food safety systems that are practical to apply, easy to verify, and compliant with EU Regulations. This also helps prepare for inspections, improves operational reliability, and supports continuous improvement across the food chain.

4. Applying Regulatory Requirements through OPRPs in HACCP Systems

To effectively apply European food safety legislation within HACCP-based systems, the food industry must convert regulatory requirements, such as those concerning hygiene, labelling, and contaminants, into practical control measures. Operational Prerequisite Programs, as defined in ISO 22000:2018, are designed to manage significant hazards that are not controlled at Critical Control Points but still require documented, preventive action. Compared to general Prerequisite Programs, which provide basic conditions for food safety, OPRPs focus on targeted hazards and require regular monitoring, and verification [4].

4.1 Determining OPRPs Using HACCP and ISO 22000 Criteria

The ISO 22000:2018 standard provides a structured method for categorising control measures to be managed as OPRPs, or at CCPs. Controls that are essential to food safety and do not require critical limits' establishment for their monitoring, but measurable or observable specifications instead, are typically designated as OPRPs [4]. Meeting or achieving these specifications, defined as "action criteria" in ISO 22000:2018, indicates that the OPRPs are functioning as intended. Examples of OPRPs include monitoring cold chain temperatures, validating sanitation between allergen runs, verifying supplier documentation, and controlling physical hazards through visual inspection. These measures are part of preventive systems and typically involve regular checks and documented procedures to demonstrate consistent performance and compliance with food safety regulations.

4.2 Integration of Regulatory Requirements into OPRPs

Several parts of EU food legislation can be applied in practice through well-designed OPRPs. For example, to meet the requirements of Directive (EU) 2020/2184 on water used in food processing, an OPRP may include regular monitoring to ensure that filtration and disinfection systems are maintained in good working condition [24]. In the case of allergen control, Regulation (EU) 1169/2011 requires clear labelling and the prevention of allergen cross-contact. An OPRP can support these goals by including proper cleaning between product batches, visual checks, ATP testing, label verification, and personnel training [7,19]. Similarly, to comply with Regulation (EC) 396/2005, Regulation (EC) 37/2010 and Regulation (EU) 915/2023 regarding chemical hazards, as well as with Regulation (EC) 2073/2005 regarding microbiological hazards, the food industry may establish OPRPs involving monitoring of incoming materials and supplier approval, through reviewing certificates of analysis and microbiological examination results.

Regulation (EU) 2024/2067 bans the use of certain smoke flavourings, requiring the food industry to update ingredient lists, obtain confirmation from suppliers, and carry out internal checks to ensure these substances are not used [17]. For food contact materials and packaging, Regulation (EC) 1935/2004 and Regulation (EU) 2025/40 establish rules on safety and recycling. OPRPs can be used to ensure that packaging materials are approved by suppliers, tested for compliance with chemical migration limits, and free from harmful substances such as per- and polyfluoroalkyl substances or bisphenol A.

These examples show how the food industry can turn regulatory requirements into everyday control procedures that are clear, effective, and easy to monitor.

Figure 1 illustrates the sequential process of establishing Operational Prerequisite Programs (OPRPs) based on EU regulatory requirements, following the hazard analysis and control measure categorization approach defined in ISO 22000.

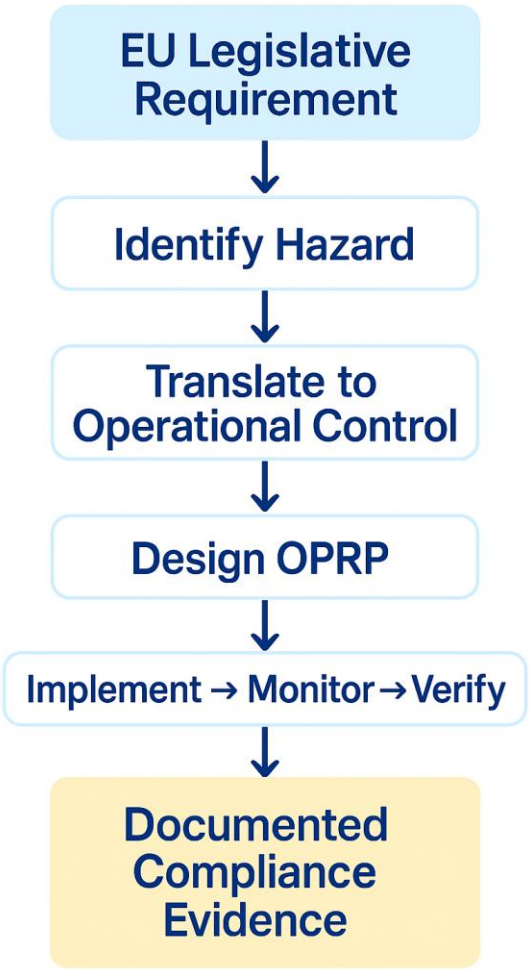

Figure 1. OPRP development process based on EU regulatory requirements.

4.3 Documentation, Monitoring, and Verification

Each OPRP must be clearly documented and include evidence that it functions effectively in practice. The documentation should describe the control measure in detail, define who is responsible for its implementation, and explain how it should be carried out. Monitoring records are essential and may include cleaning and temperature logs, or supplier documentation. To confirm that the OPRP is working as intended, verification activities, such as internal audits, third-party laboratory testing of end product samples, regular microbial and chemical testing of water quality, or cross-checks like label inspections and traceability exercises, are often used [13,26]. When a problem occurs, it is necessary to investigate the root cause, implement corrective actions, and apply preventive measures to reduce the likelihood of recurrence.

This structured approach supports consistency, traceability, and readiness for both internal reviews and official inspections.

4.4 Linking OPRPs to Regulatory Compliance

When an OPRP is clearly derived from a regulatory requirement, it functions not only as a food safety control but also as documented evidence of compliance with the legislation. For instance, temperature monitoring in ready-to-eat foods – although not classified as a CCP – helps demonstrate that the microbiological limits established by Regulation (EC) 2073/2005 are being met [5]. Similarly, OPRPs related to hygiene support the requirements set out in Regulation (EC) 852/2004 [11]. During official inspections, authorities operating under Regulation (EU) 2017/625 may use OPRP records to confirm that a business is fulfilling its compliance obligations and managing food safety risks effectively [3].

By integrating regulatory requirements into clear and structured OPRPs, the food industry enhances transparency, reduce the risk of non-compliance, and strengthen their systems for long-term improvement.

5. Implementing Legislation in HACCP Systems: Challenges for SMEs

Although OPRPs provide a practical approach for applying EU food safety legislation, small and SMEs often face significant challenges in their implementation. These difficulties are both technical and structural in nature, and they may affect the consistency and reliability of HACCP-based food safety systems.

5.1. Lack of Internal Expertise

Many SMEs do not employ personnel with sufficient knowledge of food legislation or HACCP system design. Extensive and strict legislation, such as Regulation (EC) 396/2005 on pesticide residues and Regulation (EU) 2025/40 on packaging and sustainability requirements, can be difficult to interpret without technical guidance [9,20]. For this reason, many businesses rely on external consultants. While this may be helpful in the short term, it often reduces system ownership and limits continuity over time [4,6].

5.2. Complexity of Documentation

SMEs frequently have difficulty managing the volume and overlap of regulatory obligations. Regulatory requirements related to traceability under Regulation (EC) No 178/2002, hazard control as defined in ISO 22000, microbiological safety under Regulation (EC) 2073/2005, food additives usage under Regulation (EC) 1333/2008, and contaminant limits under Regulation (EU) 915/2023 all require structured documentation [1,4,5,8,14]. Without clear guidance, businesses may produce either too many or too few records, increasing the risk of non-conformities during audits and reducing operational efficiency.

5.3. Inconsistent Auditing Practices

Despite the intent of Regulation (EU) 2017/625 to harmonize official controls, differences remain in how national authorities evaluate OPRPs [3]. Some inspections focus heavily on documentation, while others prioritize on-site performance. This inconsistency creates confusion and may lead SMEs to adapt their systems to individual inspector expectations rather than follow a risk-based approach [13].

5.4. Weak Supplier Verification

Supply chain compliance is essential, especially when dealing with restricted substances such as banned smoke flavourings under Regulation (EU) 2024/2067 or materials regulated under food contact legislation, such as Regulation (EC) 1935/2004 [17,22]. However, SMEs may lack the leverage or technical capacity to demand full transparency from their

suppliers. This exposes them to a higher risk of supplier non-compliance and makes it harder to show that proper controls have been followed.

5.5. Resource Limitations

Many SMEs operate with limited resources, which makes it difficult for them to invest in tools such as final product testing, digital traceability systems, external laboratory analyses, or structured employee training on food legislation [4,19,27]. This limits their ability to keep food safety systems up to date, especially as EU legislation continues to evolve.

Despite these challenges, support measures such as simplified OPRP templates, targeted training, and risk-based audit approaches can help SMEs strengthen regulatory compliance and improve the overall effectiveness of their food safety systems [25].

6. Discussion: From Regulatory Compliance to Food Safety Culture

The role of OPRPs in food safety goes beyond meeting compliance obligations. When regulatory requirements are integrated directly into daily processes, they support a broader shift in food safety thinking from basic compliance to a culture of responsibility, transparency, and continuous improvement.

6.1. Regulatory Requirements as a Basis for Improvement

EU legislation, such as Regulation (EU) 2025/40 on packaging and Regulation (EU) 1169/2011 on food information, can support more than just minimum standards. These regulatory requirements provide a structured approach that encourages companies to strengthen traceability, improve supplier control, and promote sustainable packaging design [7,9,13]. When applied in this way, legislation becomes a tool for advancing operational maturity and supporting better decision-making, even in complex or high-risk situations such as product recalls.

Integrating regulatory requirements into structured OPRPs also contributes to broader environmental, social, and governance (ESG) goals. Clear documentation, traceable sourcing, and safe packaging design not only ensure compliance, but also align with corporate sustainability strategies. In this context, food safety becomes part of a company's social responsibility and long-term value creation.

6.2. Increasing Trust Through Transparency

Clear alignment between Operational Prerequisite Programs and regulatory requirements, such as hygiene practices under Regulation (EC) 852/2004 or allergen management under Regulation (EU) 1169/2011, demonstrate that a business is complying with the legislation and acting responsibly [7,11,28]. This level of transparency helps build trust with regulators, customers, and certification bodies. It also makes food safety efforts more visible, consistent, and measurable.

6.3. Empowering Food Handlers

When personnel understand that their actions, such as cleaning, final product testing, or label verification, are not only part of daily routines but also stem from specific legislative requirements aimed at protecting public health, they become more committed to performing them correctly [19]. This strengthens awareness, personal ownership, and teamwork. With proper training and clear communication, frontline personnel can help transform food safety from a checklist activity into a shared responsibility [26].

6.4. Turning Compliance into Competitive Advantage

Businesses that align OPRPs with legislative requirements can differentiate themselves in the marketplace. Well-documented systems support certifications, export approvals, and participation in supply chains that prioritize sustainability and traceability [27]. For these businesses, food safety becomes not just a legislative obligation, but a strategic advantage.

By treating legislation as part of daily operations and not just as an external demand, the food industry can improve their systems, build trust, and support a stronger food safety culture at all levels.

7. Conclusions and Policy Recommendations

Integrating European food safety legislation into HACCP-based Operational Prerequisite Programs is not merely a regulatory obligation, it is a strategic approach to building stronger, more adaptable food safety systems. By incorporating official requirements into routine operational controls, the food industry can establish systems that are not only compliant with EU legislation, but also clear, auditable, and responsive to emerging risks. OPRPs provide a practical means of translating strict rules on hygiene, contaminants, labelling, packaging, and sustainability into daily activities, aligning food operations with regulatory expectations while supporting long-term performance.

However, many small and SMEs continue to face significant challenges when attempting to translate regulatory requirements into effective procedures. Frequent difficulties include limited access to regulatory expertise, lack of technical capacity, and inconsistent inspection practices, all of which can delay or disrupt implementation efforts. These factors make it difficult for SMEs to establish HACCP-based systems that are fully aligned with current EU regulatory expectations.

To support practical implementation, policy efforts should focus on making food safety legislation more accessible at the operational level. This includes developing sector-specific guidance that translates regulatory requirements into applicable OPRPs, expanding training for both frontline personnel and SMEs managers, and promoting digital tools—such as templates and simplified verification systems—to reduce complexity. Risk-based audits should also recognize well-documented OPRPs as valid evidence of compliance, especially in low-risk settings.

Innovation also plays a key role in advancing food safety. Tools such as smart packaging and environmental performance indicators can help integrate regulatory compliance with sustainability. Ongoing collaboration between authorities, the food industry, and certification bodies is crucial to ensure that HACCP systems adapt to evolving regulatory and societal demands.

When OPRPs are used as practical tools for applying food legislation, they enable FBOs to move beyond basic compliance. This approach enhances transparency, strengthens stakeholder trust, and supports the EU’s goals for a safe and sustainable food system.

Figure and Table

Table 1: Indicative EU legislation and their corresponding OPRPs within HACCP systems.

Figure 1. OPRP development process based on EU regulatory requirements.

Conflict of Interest

The authors declare no conflict of interest.

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