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RESEARCH ARTICLE

Prerequisite Programmes in Occupational Safety and Health Management Systems on the Road to Sustainable Development

Elisabete Brito[1,2] | Marta Vasconcelos Pinto[3,4] | Martinha Pereira[5] | Manuela Vaz-Velho[3] | Joana Santos[3]

[1]Escola Superior de Tecnologia e Gestão, Instituto Politécnico de Viana do Castelo, Viana do Castelo, Portugal | [2]CICS – Centro Interdisciplinar em Ciências da Saúde, ISAVE – Instituto Superior de Saúde, Amares, Braga, Portugal | [3]CISAS, Escola Superior de Tecnologia e Gestão, Instituto Politécnico de Viana do Castelo, Viana do Castelo, Portugal | [4]Instituto Politécnico de Coimbra, Escola Superior de Tecnologia da Saúde de Coimbra, Coimbra, Portugal | [5]2Ai – Applied Artificial Intelligence Laboratory, Instituto Politécnico do Cávado e do Ave, Barcelos, Portugal

Correspondence: Joana Santos (joana@estg.ipvc.pt)

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ABSTRACT

The commitment to the Sustainable Development Goals (SDGs) is notable for its alignment with the ISO 45001 and ISO 22000 standards, excluding SDGs 14–15, as well as its affinity with the principles of sustainable production, with the exception of SDGs 1–4 and 14–16. Prerequisite Programmes (PRPs) represent a proven and effective approach in food safety management systems. This study aims to incorporate PRPs into Occupational Safety and Health Management Systems (OSHMS). An approach was developed based on the *Codex Alimentarius* and ISO standards, following a high-level structure. The comparative analysis conducted shows that incorporating PRPs into the OSHMS significantly reduces risks. Despite the lack of information on the parallelism between the two standards, the new proposal promotes improvements including the prevention of incidents and occupational illnesses, risk management, process performance, stakeholder satisfaction and sustainable development. The intention is to submit this proposal for consideration by ISO/TC 283.

1 | Introduction

According to Food and Agriculture Organisation (FAO) and World Health Organisation (WHO) (2022), the *Codex Alimentarius* currently consists of a collection of 230 standards, 81 guidelines and 55 codes of good practices, which include the Prerequisite Programmes (PRRs).

As pointed out by Lee et al. (2021), PRPs are characterised by essential food safety practices that need to be established before

Abbreviations: AFGDS, automatic fire and gas detection system; CAC, Codex Alimentarius Commission; CCP, critical control point; CL, consequence level; E, environment; EC, European Commission; EC Marking, european conformity marking; EU, European Union; F, ISO 22000; FAO, Food and Agriculture Organisation; FMEA, failure mode and effects analysis; FSMS, food safety management system; G, good practice or operating procedures; H, ISO 45001; HACCP, hazard analysis critical control point; HAZOP, hazard and operability study; HLS of Annex SL, high-level structure of annex SL of ISO standards; HVACR, heating, ventilation, air conditioning and refrigeration; IEC, International Electrotechnical Commission; IMS, integrated management systems; ISO, International Organisation for Standardisation; L, people; O, principles of sustainable production; OSH, occupational safety and health; OSHMS, occupational safety and health management system; P, probability or likelihood; PDCA, plan, do, check and act; PL, probability level; PPE, personal protection equipment; PRA, preliminary risk analysis; PRPs, prerequisite programmes; R, significance of the risk; RL, risk level; S, severity or seriousness; SDG1, no poverty; SDG10, Reduced inequalities; SDG11, sustainable cities and communities; SDG12, responsible consumption and production; SDG13, climate action; SDG14, life below water; SDG15, life on land; SDG16, peace, justice and strong institutions; SDG17, partnerships for the goals; SDG2, zero hunger; SDG3, good health and well-being; SDG4, quality education; SDG5, gender equality; SDG6, clean water and sanitation; SDG7, affordable and clean energy; SDG8, decent work and economic growth; SDG9, industry, innovation and infrastructure; SDGs, sustainable development goals; TC, technical committee; U, resources; UKCA, United Kingdom Conformity Assessed; WHO, World Health Organisation.

and during the implementation of Hazard *Analysis Critical Control Point* (HACCP).

HACCP is a preventive control system with verifiable results. It is characterised by a systematic, proactive and scientific approach to implementing a system for monitoring the manufacturing process. It is an internationally recognised system that can be applied to the entire food industry, as well as downstream and upstream services. It makes it possible to identify and analyse the hazards associated with the different stages of the production process, as well as to define and ensure the effective use of means to control these hazards.

In 2004, the European Commission (EC) promulgated Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004, which lays down the general rules on the hygiene of foodstuffs. As established by the EC (2004) in force, all organisations in the agri-food sector operating in the European Union (EU) have been obliged to implement the HACCP system since 2006. In recent years, HACCP has been applied in the field of medical devices, covering all phases from design to distribution.

The PRPs serve as the foundation on which the HACCP system rests, working symbiotically with HACCP as a preventive control system; however, according to Lee et al. (2021), HACCP and the PRPs are not recognised as interdependent.

The *International Organisation for Standardisation* (ISO) incorporated the principles of HACCP and PRP into ISO 22000, which was published in 2005 and is titled the Food Safety Management System (FSMS) (Lee et al. 2021). This standard underwent a revision in 2018 and is now in its second edition, instituted by ISO 22000 (2018b).

According to Santos et al. (2018), ISO 45001 resulted from the migration of OSHAS 18001 standards in 2018. It is therefore the first ISO standard on Occupational Safety and Health (OSH) and it is in its first edition, as stated in ISO 45001 (2018a).

Based on data from the ISO Survey (2022), ISO 22000 and ISO 45001, two of the five most representative standards in the international context stand out. In the third place is ISO 45001 with 397,339 valid certificates in 512,069 locations, and in the fifth place is ISO 22000 with 45,459 certificates disseminated in 51,535 locations worldwide (ISO Survey 2022). Although ISO 45001 is the most recent in this normative *sub-ranking*, the number of valid certificates has increased exponentially from 11,952 certificates issued in 2018 to 190,481 in 2020 and to 397,339 in 2022 (ISO SURVEY 2022; Rodríguez-Martín et al. 2023).

In the words of Pauliková et al. (2022), work-related accidents and illnesses cost the EU at least 476 billion euros a year, and the global costs of 2680 billion euros represent 3.9% of the world's gross domestic product. On the global stage, Pauliková et al. (2022) report that there are more than 2.78 million deaths per year due to accidents at work or occupational diseases, in addition to 374 million non-fatal injuries and illnesses.

Standards are technical documents that establish rules, characteristics of products or services that are the result of consensus, impartiality and based on the results of science, technology and experience. They are subject to a periodic review at least every 5 years. Their application is voluntary, except when referred to in legislation or contract (Portuguese Quality Institute 2021).

The ISO 22000 and ISO 45001 standards are a response to the progressive increase in awareness and the growing expectations of stakeholders (e.g., society, organisations, workers) in terms of safety and health.

The ISO 22000 standard supports organisations in ensuring food safety at all stages of the food chain, preventing food-borne illnesses and promoting the implementation of strict hygiene practices, as well as the safety of facilities where food is handled (Neves 2020).

ISO 45001 is a standard that helps organisations prevent incidents and, in the long term, prevent occupational diseases (Fernandes 2019). Implementing Occupational Safety and Health Management System (OSHMS) ensures that organisations provide their employees with safe and healthy workplaces (Pinto 2019).

Both ISO 45001 and ISO 22000 are applicable to management systems, but they have different premises. The focus of FSMS is on preserving health of consumers, while the emphasis of OSHMS is on preserving the health of workers.

OSHMS and FSMS have some common clauses in the field of safety and health, aligned with the High-Level Structure of Annex SL of ISO standards (HLS of Annex SL). The key requirements for implementing and certifying ISO standards are between Sections 4 and 10. These seven sections are aligned with the Plan, Do, Check and Act (PDCA) approach, as mentioned by Santos et al. (2018).

The existence of common clauses and requirements within these standards facilitates their integration into Integrated Management Systems (IMS), which serve as a unified structure designed to coordinate various domains related to an organisation's activities, in alignment with multiple standards, including ISO 45001 and ISO 22000. This approach not only promotes compliance with standards but also contributes to the continuous improvement of organisational processes and resource optimisation, allowing for more efficient and cohesive management.

Following the criteria established by the EC (2004) and Codex Alimentarius Commission (CAC) (2022), PRPs constitute basic activities and conditions that are necessary in an organisation to maintain food safety, in relation to structural, operational and hygiene requirements.

As emphasised in CAC (2022) and ISO 22000 (2018b), the PRP approach can include a set of good operational practices (e.g., good agricultural practices; good veterinary practices; good production practices; good manufacturing practices; good marketing practices; good distribution practices), in addition to good hygiene practices and good maintenance practices.

It should be ensured that the PRPs are properly defined prior to the risk assessment, as it is beneficial for organisations that the PRPs are complied with, as highlighted by Neves (2020), since the PRPs are the basis for the successful implementation of an FSMS.

Freitas (2022) emphasises that risk assessment should always start with a preliminary risk analysis (PRA) or other similar methods, as it is quick and allows for a cost–benefit analysis. Freitas (2022) emphasises that, by applying risk assessment, it is possible to determine which elements require a more exhaustive analysis and which are of greater interest from an OSH point of view.

PRPs and PRAs play a crucial role in the design and operationalisation phases. This is especially relevant during the construction of new facilities or the expansion of organisations, resulting in a further strengthening of the preventive approach. Before starting activities or operating equipment, if the PRPs and PRAs are not compliant, they need to be redefined.

Although the PRP and the PRA have similar purposes, the PRP is more effective because of its systematised requirements, which are applied before the risk assessment.

PRA is not always applied in OSHMS, unlike PRP, which is always applied in FSMS. In ISO 45001, no requirement is based on PRPs, nor on a system based on the control of structural and operational conditions that allows risks to be minimised before they are assessed.

In turn, it is thought that prior to establishing risk assessment methodologies, PRP or PRA should be put in place for the FSMS and OSHMS, respectively.

The aim of this study is basically to develop a proposal for incorporating prevention based on PRPs into ISO 45001, in accordance with HLS of Annex SL, the *Codex Alimentarius* and the ISO 22000 standard.

The rest of the document is structured as follows: the second chapter presents the contextual analysis; the third chapter discusses the approach analysis and adaptation; the fourth chapter describes the proposed methodologies, including a comparative analysis; the fifth chapter addresses the results, considering the approach implications, practical implications and limitations; finally, the sixth chapter draws conclusions and presents future prospects.

2 | Contextual Analysis

According to Neves (2020), there is a growing quest to identify and fill challenges around of health and safety. Neves (2020) emphasises that the efforts undertaken are continually challenged by the complexity and constant change of processes and resources.

Stakeholders (e.g., organisations and professionals—managers, safety technicians, occupational physicians) face challenges related to the OSHMS and FSMS, along with the corresponding standards. According to Micheli et al. (2018), challenges can arise at different stages of OSH intervention, covering design, implementation and control, which are conceptually and temporally related. Some of these challenges are identified by Eurostat (2023), Fernandes (2019), Jaldestad et al. (2021), Micheli et al. (2018), Moreira (2019), Pęciłło (2020), Stoyanova et al. (2022) and Hernandez and Saquido (2018), thus reinforcing the relevance of these issues. Given the current situation in the brittleness, anxiety, non-linearity and incomprehensibility environment, it is crucial to complement the identification of challenges with proposals. Table 1 lists challenges within the scope of FSMS and OSHMS, according to identified and proposed sources by the authors.

Based on the proposals for identifying the challenges, it is considered relevant to adopt a PRP approach in the OSHMS to overcome them. The novelty of this approach lies in the perspectives and benefits, which are detailed below:

a. Perspective on approach:
   i. In ISO 22000, this necessarily implies compliance with clause 8.2 regarding PRPs, unlike ISO 45001, where PRPs do not apply. ISO 45001 could benefit from including the practices adopted by ISO 22000 since 2005, especially in relation to PRPs.
   ii. The aim is to take advantage of the proven methodology for guaranteeing consumer safety from ISO 22000 and incorporate it into ISO 45001, from the point of view of worker health and safety.
   iii. In line with the CAC (2022) and ISO 22000 (2018b) approach to PRPs, it is relevant to present a proposal focussing on their classification into good practices or operating procedures, resources, environment and people.

b. Preventionist perspective:
   i. In both ISO 45001 and ISO 22000, there is a commitment to a culture of prevention. However, ISO 45001 stands out for having a less advanced preventive approach compared to ISO 22000, especially at stages that precede risk assessment.
   ii. Although preventive measures are adopted in the OSH plans, it is not previously assumed that there are PRPs to be complied with and monitored. Indeed, in the plans resulting from the risk assessment, several critical risks are identified. Organisations face difficulties in implementing and monitoring control measures for a variety of high-level risks.

c. Integrative perspective vs. optimisation perspective:
   i. With the proposed revision of ISO 45001, the aim is not to integrate the ISO 22000 and ISO 45001 standards to create a multi-part management system, which includes IMS. Because of this, it is intended to use some requirements related to ISO 22000 that can help optimise the OSHMS.
   ii. The aim is to propose improvements to ISO 45001 as it is more recent, considering the knowledge acquired in the first and second versions of ISO 45001 and ISO 22000, respectively. This research intends to propose a new approach to ISO 45001, reflecting the methodology applied in ISO 22000.

TABLE 1 | Challenges within the scope of FSMS and OSHMS, according to identified and proposed sources by the authors.

Challenges within the scope of FSMS and OSHMS		
Management elements	**Challenges**	**Sources**
FSMS		
ISO 22000 standard	Not recognised by the Global Food Safety Initiative	Moreira (2019)
Incident management	Ineffective incident management (e.g., communication)	Stoyanova et al. (2022)
Change management	Difficulty in making future forecasts	Stoyanova et al. (2022)
	Ineffectiveness of the forecasts made	
OSHMS		
ISO standard 45,001	Absence of OSH PRPs preceding risk assessment	Proposal by the authors
Risk management	Low-risk perception	Micheli et al. (2018)
	Ineffectiveness of OSH interventions	
	Seeking an acceptable level of risk and not reaching the optimum situation	Pęciłło (2020)
	Tendency towards subjectivity in risk assessment	Proposal by the authors
	Tendency towards criticality in risk assessment	
	Predominance of risks of a complex nature (e.g., chemical, fire, explosion)	
	Incorrect and/or incomplete risk assessments	
	Absence or poor implementation of control measures	
	Lack of methodology for assessing the effectiveness of control measures or failure to implement them	
	No or little risk reassessment	
Labour health	A tendency to prioritise occupational safety over occupational health	Fernandes (2019)
	Lack of early detection of occupational diseases	
	Lack of planning and/or implementation of age management interventions	Jaldestad et al. (2021)
	Lack of integrated reform planning with OSH	Proposal by the authors
	Increased incidence of shift work-related problems in older workers	Jaldestad et al. (2021)
	Inequality between workers in the way they deal with pressure at work	
	Variation in the strategies adopted by workers to acquire and sustain energy throughout the working day	

(Continues)

TABLE 1 | (Continued)

Challenges within the scope of FSMS and OSHMS		
Management elements	**Challenges**	**Sources**
Organisational roles, responsibilities and authorities	Decentralisation of decisions (e.g., by sections, departments)	Pęciłło (2020)
	Ambiguous demarcation of roles and responsibilities between some authorities	Hernandez and Saquido (2018)
	Ineffective coordination by some organisations (e.g., supervisory bodies)	
	Lack of a dedicated body to oversee OSH initiatives in all organisations and sectors	
Leadership and commitment	Difficulty of leadership on the part of top management in some organisations (e.g., at nano-, micro-, meso-levels)	Micheli et al. (2018)
	A tendency to prioritise production over OSH	
Resources	Shortage of resources (e.g., human, technological, economic, time) to implement control measures	Micheli et al. (2018)
	Lack of resources (e.g., human, technical, financial, time) for enforcement actions	Proposal by the authors
	Lack of qualified technicians (e.g., specialised occupational physicians, safety technicians) to meet needs	
	Dependence on external technicians (e.g., security technicians)	
Training and human behaviour	Lack of commitment and/or health and safety training for stakeholders (e.g., top management, workers), especially on critical points	Micheli et al. (2018)
	Limiting learning capacity to mistakes or incidents only	Pęciłło (2020)
	Limitations of human behaviour (behavioural change, resistance to change, level of involvement) of stakeholders (e.g., top management, employees)	Fernandes (2019); Micheli et al. (2018)
Communication	Under-reporting of serious accidents at work in the face of reality by some organisations and sectors	Eurostat (2023)
	Non-existent or ineffective communication (e.g., between top management and employees)	Micheli et al. (2018)
	Little interaction between entities (e.g., between unions and organisations)	
Documented information	Emphasising procedures over people	Fernandes (2019)
	Informal operational management by some organisations (e.g., at nano-, micro- and meso-levels)	Micheli et al. (2018)

(Continues)

Challenges within the scope of FSMS and OSHMS		
Management elements	**Challenges**	**Sources**
Legal, regulatory and normative compliance	Weaknesses in organisations' compliance with legislation, regulations and standards	Hernandez and Saquido (2018)
	Lack of technical and legal support for some organisations (e.g., at nano-, micro- and meso-levels)	Micheli et al. (2018)
	Dissatisfaction on the part of stakeholders (e.g., governments, inspection bodies, trade unions, certification bodies) with expectations regarding the level of compliance with legislation, regulations and standards	Proposal by the authors
	The need for additional control over suppliers and/or subcontractors on the part of some organisations (e.g., certified organisations) wishing to raise health and safety standards in the light of the requirements of legislation, regulations and standards	
Performance evaluation	Absence or scarcity of audits and/or inspections in the area of OSH by some entities (e.g., organisations, inspection bodies)	Proposal by the authors
	Lack of or ineffective visits to workplaces by qualified technicians (e.g., occupational physicians, safety technicians) in relation to needs	

iii. The PRP-based approach in ISO 45001 can be an asset for OSHMS, particularly by contributing to a prevention strategy that minimises the risks associated with professional activities.

iv. By proposing the inclusion of PRPs in ISO 45001, we are not seeking the implementation of HACCP per se.

a. Sustainable development perspective:

i. In order to effectively achieve the Sustainable Development Goals (SDGs) in line with the United Nations (2015), it is essential to align the latter with the elements of the OSHMS and FSMS. The study by Pauliková et al. (2022) was used to analyse the correspondence between the SDGs and ISO 45001. At the same time, a correspondence analysis was carried out between the SDGs and management system standards, based on ISO 45001 (2018a) and ISO 22000 (2018b). In addition, the PRPs were classified into four categories: good practices or operating procedures, resources, people and environment, with a view to being in line with the SDGs. In addition, the latest guidelines established by the EC (2022) on food safety were followed to ensure compliance with the SDGs. As a complement and based on the study conducted by Viles et al. (2023), 34 relationships were identified between the 10 principles of sustainable production and 10 of the 17 SDGs. Based on a detailed analysis of these studies, the Sankey diagram shown in Figure 1 was drawn up. This diagram represents the relationships between the SDGs and the various elements of the OSHMS and FSMS, demonstrating how they contribute to sustainable development. Only SDGs 1–2 and 14–15 have no connection with OSHMS. On the other hand, only SDGs 14–16 are not aligned with the FSMS. SDGs 1–4 and 14–16 do not relate to the principles of sustainable production. It should be noted that SDGs 14 and 15 are not related to the ISO 45001 and ISO 22000 standards. All the other SDGs are perfectly aligned with the elements assessed. Figure 1 illustrates the alignment between the practices and principles of the OSHMS and the FSMS with the SDGs, emphasising their significant contribution to sustainable development. Each element of the OSHMS and FSMS is systematically mapped to the corresponding SDGs, thereby highlighting the synergy between occupational health and safety management, food safety and the overarching global objectives. Furthermore, Figure 1 serves as a visual guide, effectively demonstrating how the implementation of OSHMS and FSMS can not only fulfil regulatory requirements but also foster a positive impact towards sustainable development and facilitate the achievement of the SDGs.

ii. According to ISO and the International Electrotechnical Commission (IEC) (2024), a new criterion called 'climate impact' has been incorporated into HLS of Annex SL, covering all management systems, which in turn requires a fundamental reflection on ISO 45001. Following this, ISO 45001 (2024a) and ISO

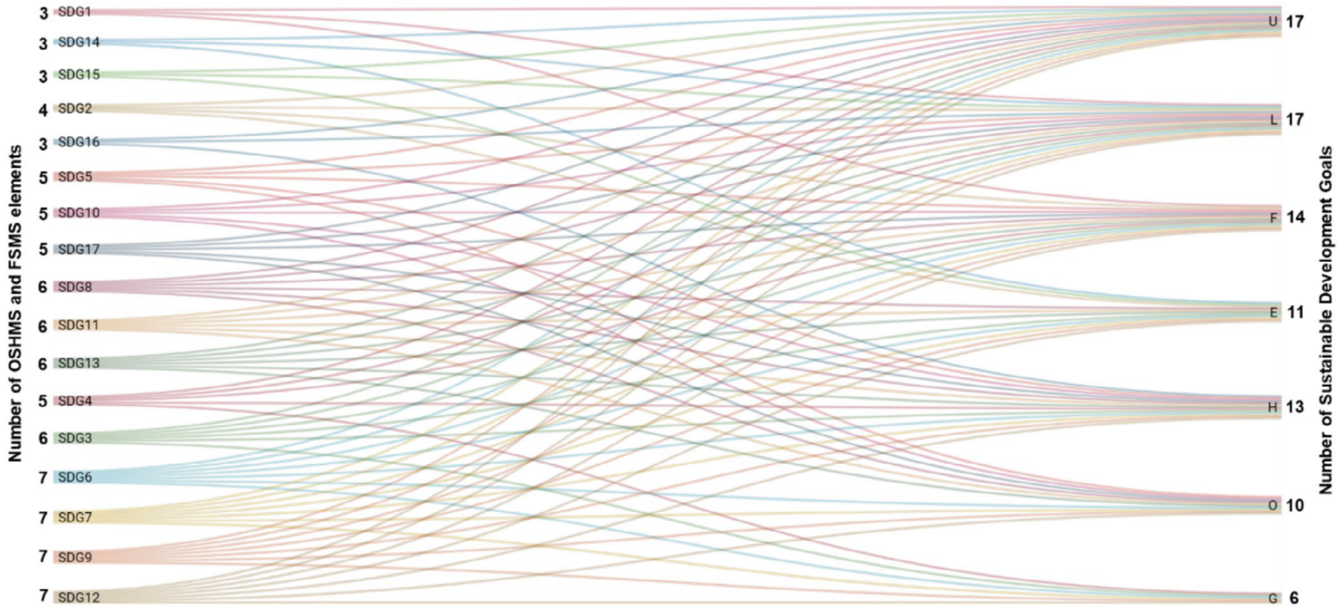

FIGURE 1 | Correspondence between the SDGs and the elements of the OSHMS and FSMS that contribute to sustainable development. Elements of the OSHMS and FSMS: E, Environment; F—ISO 22000; G—Good practice or operating procedures; H—ISO 45001; L—People; U—Resources; O—Principles of Sustainable Production; SDGs: SDG1—No poverty; SDG2—Zero hunger; SDG3—Good health and well-being; SDG4—Quality education; SDG5—Gender equality; SDG6—Clean water and sanitation; SDG7—Affordable and clean energy; SDG8—Decent work and economic growth; SDG9—Industry, innovation and infrastructure; SDG10—Reduced inequalities; SDG11—Sustainable cities and communities; SDG12—Responsible consumption and production; SDG13—Climate action; SDG14—Life below water; SDG15—Life on land; SDG16—Peace, justice and strong institutions; SDG17—Partnerships for the goals.

22000 (2024b) incorporate climate change considerations when analysing the context and relevant stakeholders. Climate impact is related to most of the SDGs, as is evident from the analysis presented in Figure 1.

3 | Materials and Methods

A literature review was carried out, focussing on internationally relevant documents in the field of safety and health. In this context, various sources were consulted, including scientific and technical articles and standards. In addition, databases containing structured, tabular (ISO Survey) and relational (Eurostat) information were used.

3.1 | Risk Analysis in Management Systems

As stated by Lee et al. (2021), the Critical Control Point (CCP) is a point in a step where a control must be applied for the prevention or elimination of a hazard or for the reduction to an acceptable level. In the context of OSH, a CCP can be a workstation, a work environment, work equipment, an activity, a process or even a step, where control must be applied to mitigate a risk to acceptable levels.

Various methodologies, methods, tools and/or approaches can be used to identify CCPs, the most common being the decision tree established in the CAC (2022), from which various adaptations have arisen. Only significant risks make it into the decision tree to determine whether the step is a CCP. With the adoption of an RPP, many of the CCPs are eliminated, leaving only those that require monitoring.

In FSMS, risk assessment is carried out for each process, while in OSHMS, it is applied to each activity, machine and/or workplace (Freitas 2022; Neves 2020).

For Lee et al. (2021), the risk assessment methodologies, methods, tools and/or approaches used in FSMS include *Failure Mode and Effects* Analysis (FMEA) and *Hazard and Operability Study (*HAZOP).

Methodologies, methods, tools and/or approaches used in OSHMS are varied, adapting to the specificities of diverse activities and professional sectors, and these particularities are related to the dynamics of design, organisation and execution (Nunes 2010). According to Freitas (2022), proactive methodologies, methods, tools and/or approaches (e.g., PRA, FMEA, HAZOP, William T. Fine, event tree), as well as reactive methodologies, methods, tools and/or approaches (e.g., fault matrix, cause tree), stand out in OSHMS.

The weighting of risks is based on the binomial probability of occurrence and severity of their effects on health, in accordance with Atambayeva et al. (2022). Equation (1) shows the calculation formula and its variables:

$$R = P^{*} S \tag{1}$$

In which, R: Significance of the risk. P: Probability or likelihood. S: Severity or seriousness.

The combination of the level of probability and the level of consequence results in the determination of the level of risk, in terms of Equation (2) (Freitas 2022):

$$RL = PL^{*}\ CL \tag{2}$$

In which, RL: Risk level. PL: Probability level. CL: Consequence level.

Equations (1) and (2) can be used in both OSHMS and FSMS.

The level of risk is usually determined using risk matrices (Pinto 2019). These can be applied to both OSHMS and FSMS.

3.2 | Approach Adaptation

Approach analyses and adaptations were conducted based on the literature review.

3.2.1 | Parallelism Between ISO 45001 and ISO 22000

Although the structure of ISO 45001 and ISO 22000 is based on the HLS of Annex SL, they differ in content and organisation. A comparative analysis was carried out between the two standards, considering their content. The main clauses were matched up in accordance with the HLS of Annex SL. The result of this comparative analysis is shown in Table 2.

3.2.2 | Risk Assessment Matrix

Although there are several standardised and validated risk assessment methodologies according to the widely adopted and harmonised IEC 31010 (2019) standard, risk classification criteria related to the existence of PRPs in the context of OSH are not addressed.

To this end, a risk matrix was developed (Table 3) based on the adaptation of Doğan et al. (2023). This is a semi-quantitative risk assessment methodology known as the L-Type Matrix (5×5) from the US military standard MIL-STD-882D.

As mentioned by Doğan et al. (2023), it is a method that analyses the effect between the probability of occurrence of hazards and the severity of the resulting damage, using rating data for each element provided in Tables 4 and 5.

If the risk is considered minor, there is no need to implement additional measures beyond the PRPs. In other cases, it will be necessary to apply additional measures, according to prioritisation criteria.

4 | Results

4.1 | Proposed Approach

Various proposals for improvement in OSH were developed, including the adaptation of an approach based on the literature review. It should be emphasised that some of these proposals can be applied exclusively within the scope of OSHMS and are not necessarily incorporated into the ISO 45001 standard.

4.1.1 | Proposal for the Incorporation of PRPs Into ISO 45001

It is pertinent and crucial to adopt an approach that identifies prerequisites in the OSHMS, categorised into good practices or operating procedures, resources, people and environment, as an assumption before proceeding with the risk assessment, as identified in Table 6.

4.1.2 | Proposed Revision of the ISO 45001 Clauses

The use of the PRP identification approach in the OSHMS requires a revision of ISO 45001. The parallelism presented in Table 2 led to the design of the proposed clauses shown in Table 7. The most notable differences between ISO 45001 and the proposed revision are centred on sections 8—Operationalisation and 10—Improvement.

4.1.3 | Proposed Approach for Building the OSHMS Using the PDCA Cycle

The proposal presented in Table 7 enables the construction of an OSHMS approach based on the PDCA cycle, as illustrated in Figure 2. This provides a detailed specification of the proposed clauses in section 8—Operationalisation, which highlights the most significant differences between the current proposal and ISO 45001 (2018), resulting from the incorporation of the PPR. Both Figure 2 in its entirety and section 8 incorporate the PDCA into their structure, as defined in the HLS of Annex SL. In the 'Do' phase of the PDCA cycle, non-conformities solely related to risk management are addressed, while in the 'Act' phase, other non-conformities arising from incidents, along with other relevant aspects, are managed.

4.1.4 | Proposed Risk Management Flowchart and Its Interactions

Figure 3 illustrates a proposed flowchart for risk management. The various interactions can be adjusted according to the evolution and consolidation of risk management within organisations. In this proposal, each organisation may use the risk assessment method it deems relevant in step 2. The risk management proposal in OSHMS includes the introduction of two new steps: in step 1, PRPs are established, while in step 3, CCPs are assessed. The PRPs play a fundamental role both in the initial phase of step 1 and in the conclusion of step 7 of the risk management cycle. Steps 2, 4, 5 and 6 are generically applied in OSHMS, and step 7 introduces the possibility of reviewing the PRPs.

4.1.5 | Proposed Approach for Risk Assessment and Monitoring of CCPs

Following the steps outlined in Figure 3, it is necessary to identify the PRPs in advance before carrying out the risk assessment,

TABLE 2 | Correspondence between the main clauses of the ISO 45001 and ISO 22000 standards.

Sections and clauses of ISO 45001	Sections and clauses of ISO 22000
4—Context of the Organisation	4—Context of the Organisation
4.1—Understanding the organisation and its context	4.1—Understanding the organisation and its context
4.2—Understanding the needs and expectations of employees and other stakeholders	4.2—Understanding the needs and expectations of stakeholders
4.3—Determine the scope of the OSHMS	4.3—Determine the scope of the FSMS
4.4—OHSMS	4.4—FSMS
5—Leadership and worker participation	5—Leadership
5.1—Leadership and commitment	5.1—Leadership and commitment
5.2—OSH policy	5.2—Food safety policy
5.3—Organisational roles, responsibilities and authorities	5.3—Organisational roles, responsibilities and authorities
5.4—Consultation and employee participation	—
6—Planning	6—Planning
6.1—Actions to address risks and opportunities	6.1—Actions to address risks and opportunities
6.2—OSH objectives and planning to achieve them	6.2—Objectives of the FSMS and planning how to achieve them
8.1.3—Change management	6.3—Planning changes
7—Support	7—Support
7.1—Resources	7.1—Resources
7.2—Competences	7.2—Competences
7.3—Awareness	7.3—Awareness
7.4—Communication	7.4—Communication
7.5—Documented information	7.5—Documented information
8—Operationalisation	8—Operationalisation
8.1—Operational planning and control	8.1—Operational planning and control
—	8.2—PRP
—	8.3—Traceability system
8.2—Emergency preparedness and response	8.4—Emergency preparedness and response
—	8.5—Hazard control
—	8.6—Updating the information specifying the PRPs and the hazard control plan
—	8.7—Monitoring and measurement control
—	8.8—Verification related to PRPs and the hazard control plan
—	8.9—Control of product and process non-conformities
9—Performance evaluation	9—Performance evaluation
9.1—Monitoring, measuring, analysing and evaluating performance	9.1—Monitoring, measurement, analysis and evaluation
9.2—Internal audit	9.2—Internal audit
9.3—Management review	9.3—Management review

(Continues)

TABLE 2 | (Continued)

Sections and clauses of ISO 45001	Sections and clauses of ISO 22000
10—Improvement	10—Improvement
10.1—General	—
10.2—Incident, non-conformity and corrective action	10.1—Non-conformity and corrective action
10.3—Continuous improvement	10.2—Continuous improvement
—	10.3—Updating the FSMS

Note: —, Direct correspondence between ISO 45001 and ISO 22000 is not applicable. *x*, Sections. *x.x* or *x.x.x*, Clauses. *x* represents any digit between 1 and 9.

using the decision tree, and establishing the respective control measures (step 3). Table 8 shows the proposed risk assessment approach applied to the OSH area.

If no CCPs are identified, it is sufficient to monitor the control measures according to the prioritisation and review them whenever necessary. For identified CCPs, it is essential to monitor them. Table 9 shows the proposed approach for monitoring CCPs applied to the OSH area.

Once the CCPs have been monitored, corrective actions are implemented, and their effectiveness assessed as necessary.

4.2 | Comparative Analysis—Comparison of Traditional and Proposed Approaches for the Specific Case of Cutting Risk

We analysed a specific case of a common risk for the FSMS and OSHMS, which concerns the risk of cuts caused by contact with the blade of a ham-slicing machine. It is categorised as a mechanical and biological risk depending on the material component of the work, environmental conditions, processes and other factors. These factors encompass the implementation of effective operational procedures, the quality and condition of equipment, and the training and competence of personnel. Additionally, they include the organisation of work processes, the maintenance and inspection frequency of machines, and the availability and proper use of Personal Protective Equipment (PPE). Finally, workplace conditions such as lighting and cleanliness, as well as environmental factors like temperature and humidity, must also be considered to ensure a comprehensive risk management approach.

This risk is characteristic of meat processing industries and establishments that sell unpackaged meat or meat in bulk. These sectors were chosen to demonstrate the applicability of the proposed approach and to identify possible faults, even without the intention of implementing IMS.

This analysis was carried out in organisations located geographically in the north of Portugal.

Comparative analyses were applied to this specific case to identify the differences and competitive advantages in the field of risk mitigation, using the risk assessment methodology (Table 4).

In fact, the flowchart of the traditional OSH risk management approach (Figure 4a) was compared with the flowchart of the proposed risk management approach (Figure 4b). In Figure 4a, there are five steps, while in Figure 4b, there are seven steps, which demonstrates a greater detail in the risk management process.

The inclusion of PRP in ISO 45001, as specified in Table 6 and in the Annex, and applied in the comparative analysis, is resulted in the data shown in Table 10.

4.2.1 | Traditional Approach

Since some control measures proved ineffective, it became necessary to implement corrective actions.

With the implementation of additional control measures, the risk was reduced from a 'moderate level' (9) to a 'minor level' (6), thereby achieving acceptable levels.

4.2.2 | Proposed Approach

The acceptance level and critical control limit were established based on the selected risk assessment methodology presented in Table 3.

Considering that the machine is semi-manual and that the residual cutting risk persists, it is classified as tolerable. Therefore, the acceptable level is set at 6, which corresponds to a 'minor risk'.

The critical control limit is the point at which a risk becomes unacceptable and therefore requires intervention. In this context, the critical control limit is considered to be established from a 'moderate risk' (8–12), where it is necessary to implement monitoring and response actions. Thus, the value of the critical control limit is considered to be equal to or greater than 8. The transition to a 'catastrophic or major risk' (15 or greater) indicates the need for immediate and more rigorous corrective actions.

As the value of the acceptable level (6) is lower than the value of the critical limit (8), this indicates that as long as the risk remains below 6, no corrective actions are required, as the risk is under control. However, if the risk reaches or exceeds the critical limit of 8, immediate corrective actions will be necessary to avoid consequences.

TABLE 3 | Risk matrix and respective risk classification to determine the level of risk (adapted from Doğan et al. 2023).

Risk level		Consequence 1 (Rare)	2 (Unlikely)	3 (Possible)	4 (Likely)	5 (Almost certain)
Probability	1 (Inconceivable)	1 (Insignificant)	2 (Minor)	3 (Minor)	4 (Minor)	5 (Minor)
	2 (Remote)	2 (Minor)	4 (Minor)	6 (Minor)	8 (Moderate)	10 (Moderate)
	3 (Conceivable)	3 (Minor)	6 (Minor)	9 (Moderate)	12 (Moderate)	15 (Major)
	4 (Possible)	4 (Minor)	8 (Moderate)	12 (Moderate)	16 (Major)	20 (Major)
	5 (Most likely)	5 (Minor)	10 (Moderate)	15 (Major)	20 (Major)	25 (Catastrophic)

Note: Catastrophic or major risk (≥15): Attention is needed; immediate action is required; additional measures need to be implemented beyond the PRPs; Moderate risk (8–12): Management through specific monitoring or response procedures; requires reinforced action; additional measures need to be implemented beyond the PRPs; Minor or insignificant risk (≤6): Management through routine procedures; control measures are dealt with utilising PRPs, no CCPs required; probably requires no action; risk is tolerable.

TABLE 4 | Probability of an event (Doğan et al. 2023).

Probability of an event	
Possibility	**Rating stages for probability of appearance**
1	Remote possibility
2	Low probability (once a year)
3	Possible
4	Often (once or several times a month)
5	Very often (constant-almost every day)

TABLE 5 | Severity rating (Doğan et al. 2023).

Severity rating	
Scale	**Definition**
1	Requires first aid (no loss of working hours)
2	Requires first aid, requires outpatient treatment (no lost workdays)
3	Minor injury
4	Serious injury
5	Death

As all the control measures have proven effective, there is no need to implement additional measures or corrective actions. However, it was deemed important to draw up a corrective action plan to ensure a rapid and effective response in the event of unforeseen situations. Once these actions have been implemented, the need to review the risks, the PRPs or the control measures can be assessed.

There was no need to review the risks, the PRPs or the control measures, since the risks are under control and the assessment of the effectiveness of the control measures yielded positive results. As emphasised by Doğan et al. (2023), risk updating should be conducted in situations such as workplace relocation or changes in buildings, alterations in materials or equipment, modifications in production technology, following a near miss or

TABLE 6 | Proposed prerequisite programmes for an OSHMS.

PRPs for an OSHMS	
Classification	**Name**
Good practice or operating procedures	Supplier evaluation
	Good operating practices
	Good hygiene practices
	Good maintenance practices
Resources	Structures
	Equipment
	Components
Environment	Environmental control
	Waste and effluent management
People	Health and personal hygiene
	Training and human behaviour

workplace accident, when there are changes in the limit values established by legislation, after environmental measurements and health surveillance or when a new risk arises.

The implementation of the proposed and traditional approaches in the comparative analysis led to different results, as summarised in Tables 11 and 12.

It was not possible to obtain sufficient results to include in the comparative analysis, especially regarding breakdown rates, anti-error systems, incidents, non-conformities and measurements such as illuminance.

However, quantitative results were obtained from a risk management perspective, as expected. In the traditional approach, the initial risk level was 9, but after the review, it was reduced to 6. On the other hand, in the proposed approach, the initial risk level was 6, which eliminated the need for a review since it was within acceptable levels. The control measures proved to be effective, and the risks were adequately controlled. This demonstrates that

TABLE 7 | Proposed revision of the ISO 45001 clauses.

Structure of the ISO 45001 standard	
Sections	**Clauses**
4—Context of the Organisation	4.1—Understanding the organisation and its context
	4.2—Understanding the needs and expectations of employees and other stakeholders
	4.3—Determine the scope of the OSHMS
	4.4—OSHMS
5—Leadership and worker participation	5.1—Leadership and commitment
	5.2—OSH policy
	5.3—Organisational roles, responsibilities and authorities
	5.4—Consultation and employee participation
6—Planning	6.1—Actions to address risks and opportunities
	6.2—OSH objectives and planning to achieve them
7—Support	7.1—Resources
	7.2—Competences
	7.3—Awareness
	7.4—Communication
	7.5—Documented information
8—Operationalisation	8.1—Operational planning and control
	8.2—PRP
	8.3—Emergency preparedness and response
	8.4—Risk control
	8.5—Updating the information specifying the PRP and the risk control plan
	8.6—Monitoring and measurement control
	8.7—Verification related to the PRP and the risk control plan
	8.8—Control of non-conformities
9—Performance evaluation	9.1—Monitoring, measuring, analysing and evaluating performance
	9.2—Internal audit
	9.3—Management review
10—Improvement	10.1—Incident, non-conformity and corrective action
	10.2—Continuous improvement
	10.3—Updating the OSHMS

the implementation of PRPs before the risk assessment allows the risk to be mitigated from the outset.

5 | Discussion

The inclusion of climate change in the HLS of Annex SL represents a significant advancement in achieving the SDGs, especially for organisations implementing ISO 45001 and/or ISO 22000.

The study reflects the affinity of the ISO 45001 and ISO 22000 standards with most of the SDGs, excluding SDGs 14 and 15. Furthermore, there is a consistent alignment between the SDGs and the principles of sustainable production, with the exception of SDGs 1–4 and 14–16.

5.1 | Approach Implications

In ISO 22000, risks are mitigated by the existence of PRPs. As the 2018 version of ISO 45001 does not include PRPs, risks are treated as CCPs. To overcome these discrepancies and promote early mitigation of control measures, it is crucial to integrate the PRPs into the OSHMS.

The inclusion of PRPs in the OSH area is justified mainly by the lack of an approach for identifying PRPs prior to risk assessment, the subjectivity of risk assessment and the existence of numerous critical risks.

Based on the comparative analysis of the risk of cutting, which is common in both OSHMS and FSMS, it is possible to demonstrate the applicability of the proposed approach, as well as its added value for ISO 45001.

5.2 | Practical Implications

The comparative analysis of the traditional and proposed approaches, specifically aimed at the risk of cuts caused by a slicing machine, applicable to food industries of various sizes, considered the common risks in OSHMS and FSMS. This analysis emphasises the importance of implementing good practices related to work equipment, such as error-proof systems and UKCA/CE marking. These elements should be considered as PRPs from the perspective of the proposed approach.

Regardless of whether organisations conduct risk assessments or reassessments, it is essential that PRPs are incorporated before hazards are identified to ensure a proactive approach to risk management and to promote employee safety from the outset of processes.

From a practical point of view, the proposed approach extends the advantages of the traditional approach by incorporating a greater level of detail and the introduction of relevant initial (PRP) and intermediate (PCC) steps. As a result, process performance becomes more efficient.

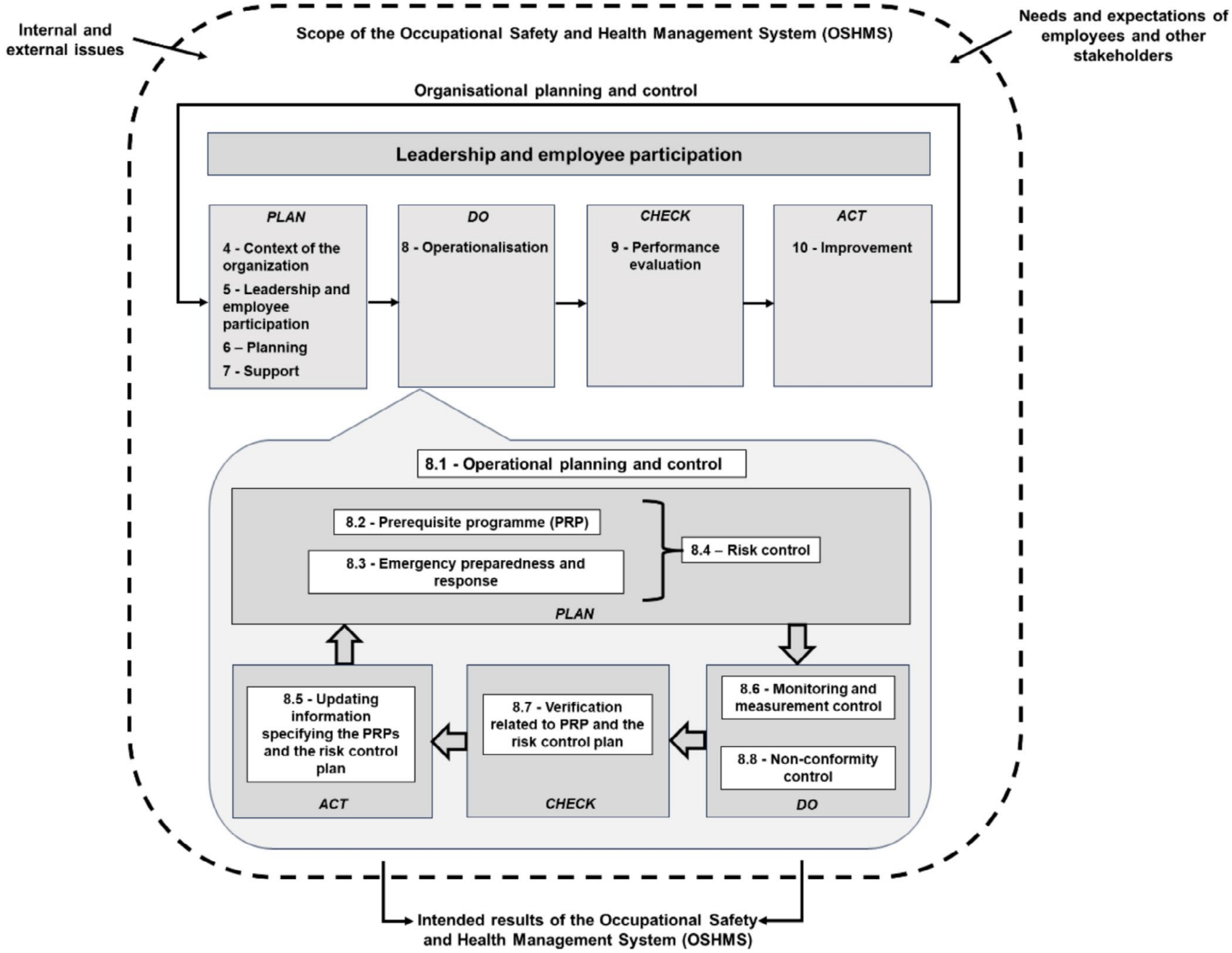

FIGURE 2 | Proposed approach for constructing the OSHMS using the PDCA cycle.

Although the proposed approach includes a number of steps that can make the risk management process more complex and time-consuming, it is important to emphasise that it is capable of eliminating and/or controlling the majority of upstream risks compared to the traditional approach.

The use of the proposed approach can contribute to enhancing the responsibility of organisations and/or other stakeholders, particularly in situations where risks are more challenging to mitigate and/or control.

It is important to note that the proposed categorisation into good practices or operating procedures, resources, people and environment was successfully applied to various PRPs in the comparative analysis, demonstrating its high applicability.

The results of this study are highly relevant, with potential practical applications spanning various sectors of industry, as well as fields such as science, technology, education and standardisation.

The practical implications for organisations are significant, especially in contexts where risk assessment and control activities are imprecise, monitoring and measurement are scarce or ineffective, and nano-, micro- and meso-level structures have poorly defined decisions. The implementation of OSHMS can significantly contribute to mitigating these limitations.

5.3 | Limitations

During this study, difficulties were encountered, mainly centred on the lack of information available on the parallelism between the ISO 22000 and ISO 45001 standards and the lack of information on PRPs in the OSH area.

These obstacles were overcome by drafting and validating the information contained in the proposed revision of ISO 45001, considering the consultation of a wide variety of documents and standards, regulations and legislation in force at the international level.

Although these constraints required more time-consuming research and data analysis, they did not affect the results of this study, considering the proposed objectives.

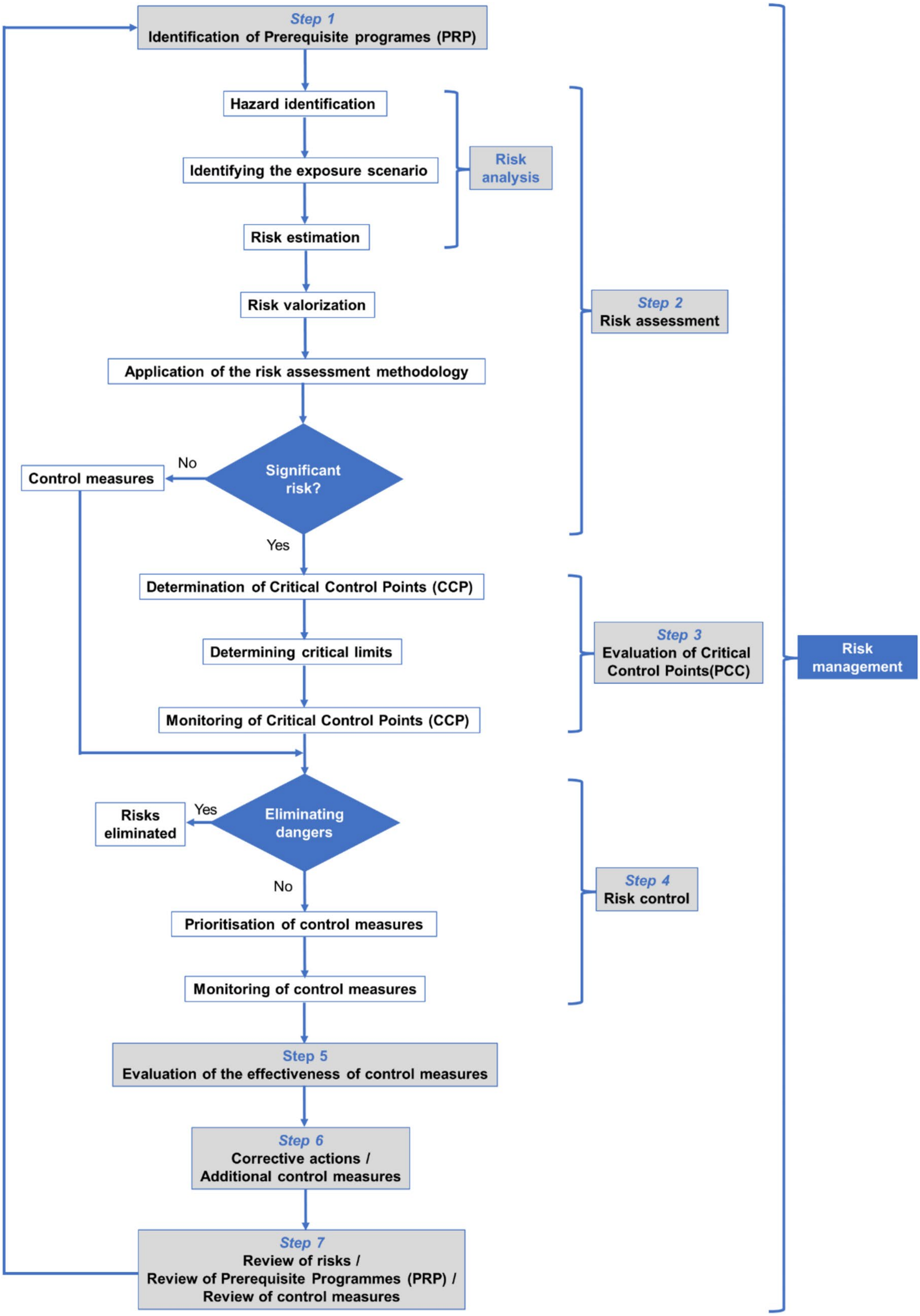

FIGURE 3 | Proposed risk management flowchart and its interactions.

TABLE 8 | Proposed risk assessment approach applied to the OSH area.

Activity, machine or workplace	Hazards	Causes	Risks	Type of risk	PRP	Risk assessment				Significant risk?		Control measures	Decision tree questions				CCP?	
						Probability	Severity	Risk level	Acceptable levels	Yes	No		Question 1	Question 2	Question 3	Question 4	Yes	No

The results obtained for certain parameters and/or periods in the comparative analysis between the traditional and proposed approaches were insufficient, particularly concerning the indicators and measurements. This significant limitation arises from the nature of micro-, nano- and meso-structures, which operate either without an OSHMS or with one that is still in its early stages.

With the application of the comparative analysis, the level of risk and the existence of PRPs stand out as the most significant differences between the two methodologies analysed. It was possible to prove that the prior definition of PRPs allows for a significant reduction in risk, anticipating risk assessment and dispensing with additional measures at later stages.

Given that the central focus of the research was on the comparative analysis between the traditional approach and the proposed one, it is prudent to avoid extrapolations beyond the limits set by this study.

Although the comparative analysis is not exhaustive, it represents a preliminary step in the process of validating the proposed approach.

6 | Conclusion and Future Prospects

In terms of quantitative results, the effectiveness rate of the control measures implemented proved to be the most representative indicator between the two approaches, with a difference of 30%. This demonstrates that the proposed approach provides a significant improvement in process performance and shows promise for future applications in case studies, particularly when utilising the 5x5 risk assessment methodology.

With this study, it can be concluded that both the ISO 45001 standard and OSHMS can benefit significantly from the introduction of PRPs and CCPs.

The most notable differences between ISO 45001 and the proposed revision are centred on sections 8—Operationalisation and 10—Improvement, with emphasis on the incorporation of PRPs.

The proposed revision of the ISO 45001 standard is expected to lead to greater efficiency in implementation and certification. This normative revision has the potential to be a precursor to wider and more practical application in various professional activities, responding to the needs of the global market, both now and in the future.

In this way, organisations can achieve better results in the prevention of incidents and occupational illnesses, in risk management, in process performance, in the satisfaction of the stakeholders involved in the value chain and in sustainable development.

It is expected that the proposal to revise ISO 45001 will be submitted to ISO TC 283 (Technical Commission for Occupational Safety and Health Management) for consideration, and that any

TABLE 9 | Proposed approach for monitoring CCPs applied to the OSH area.

CCP	Activity, machine or workplace	Type of risk	Risks	Control measures	Critical limits	Monitoring CCPs			
						Method	Frequency	Records	Responsible

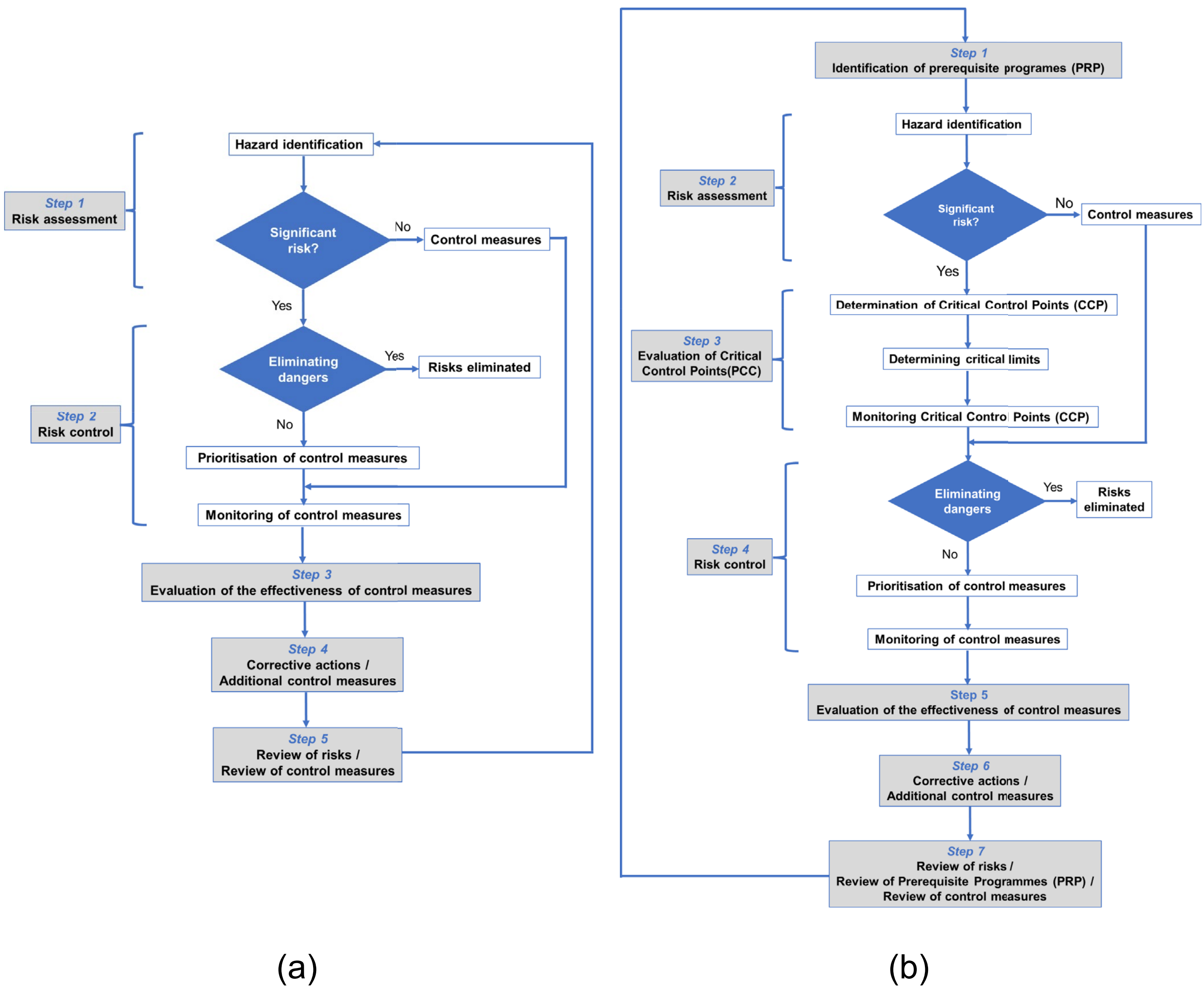

FIGURE 4 | Flowcharts with the main processes and stages applied in the traditional (a) and proposed (b) approaches.

adjustments will have to be made. As a result, the proposed ISO 45001 standard could be simplified by a multidisciplinary team, with a view to harmonise different countries and use in a unified market, in the face of possible legal or regulatory changes that may arise, and thus be more attractive to organisations when it comes to implementation and/or certification.

The proposed revision of ISO 45001 considered potential challenges that could affect the validation of technical and/or scientific information, as well as the expectations of stakeholders (e.g., reviewers, speakers, auditors, accreditation bodies, certification bodies, organisations) at various stages of the approval process:

- *Before approval*: Reviewers have information to support decisions regarding the approval and/or revision of various requirements.
- *At the time of approval*: Members from different countries have information to support decisions for voting and/or

TABLE 10 | PRPs applied in the comparative analysis using the proposed approach.

PRPs applied in the comparative analysis utilising the proposed approach		
Classification	**Name**	**Description**
Good practice or operating procedures	Supplier evaluation	Compliance with the assessment of suppliers of goods (machinery, maintenance products, safety signs, PPE)
		Compliance with the assessment of service providers (machine maintenance, verification of the machine's United Kingdom Conformity Assessed (UKCA)/ European Conformity (EC) marking)
	Good operating practices	Compliance with good practice when utilising the machine
	Good hygiene practices	Compliance with the cleaning and disinfection plan in accordance with the defined periodicity
		Mandatory use of PPE—protective gloves
	Good maintenance practices	Compliance with the maintenance plan according to the defined periodicity
Resources	Structures	Checking the adequacy of first aid equipment
	Equipment	Verification of the machine's UKCA/EC marking
		Compliance with the machine's operating instructions
	Components	Cutting risk warning signs  Biological risk warning signs  Signalling the mandatory use of PPE—protective gloves 

(Continues)

TABLE 10 | (Continued)

PRPs applied in the comparative analysis utilising the proposed approach		
Classification	**Name**	**Description**
Environment	Environmental control	Checking environmental conditions (e.g., lighting, thermal environment)
	Waste and effluent management	Compliance with the waste management plan
People	Health and personal hygiene	Compliance with the health and safety plan
	Training and human behaviour	Compliance with the specific training plan for workers (e.g., machine operating instructions, machine maintenance instructions, risks, control measures)

TABLE 11 | Comparative analysis using the proposed and traditional approaches.

Criteria		Traditional approach	Proposed approach
PRPs		✗	✓
CCP		✗	✓
Evaluation of the effectiveness of control measures		✓	✓
Corrective actions or additional control measures		✓	✓
	Of Risks	✓	✓
Review	Of PRPs	✗	✓
	Of control measures	✓	✓

Note: ✓ Applicable. ✗ Not applicable.

TABLE 12 | Main quantitative results of the traditional and proposed approaches.

Quantitative results		Traditional approach	Proposed approach
Risk level	Initial	(9)	(6)
	Revised	(6)	
Indicators	Rate of implementation of control measures	100%	100%
	Risk control rate	100%	100%
	Effectiveness rate	70%	100%
	Incident rate		
	Breakdown rate		
	Error rate (before and after implementation of the anti-error system)		
	Non-conformities		
Measurements	Illuminance		

Note: Indicates that there was no need to review the risk. Indicates that data are insufficient for certain parameters and/or periods.

revision of various requirements, as well as conducting a comparative analysis with the HLS of Annex SL.

- *After approval*: Organisations, auditors, certification bodies and accreditation bodies have the opportunity to easily consult the requirements; there are no doubts when applying the requirements; and organisations can seamlessly implement IMS.

Furthermore, the proposed revision of ISO 45001 can be implemented throughout the value chain and improved continuously.

As a way of supporting stakeholders in the implementation of new clauses and requirements in various organisations and sectors, it is pertinent to build an interpretative guide to the proposed revision of ISO 45001.

It is worth emphasising the relevance of creating a vocabulary guide, containing new terms and definitions, aimed at various stakeholders in the value chain (e.g., managers, security technicians), in line with the proposed approach and revision of ISO 45001.

The comparative analysis explored in this study can be validated through case studies conducted in different contexts, especially in the manufacturing and construction industries. These studies will allow for the validation of PRPs' applicability before the hazard identification stage, as well as the monitoring and measurement of CCPs. To ensure a more comprehensive and effective approach to risk management, it is essential to include the assessment of inefficiencies, occurrences, non-conformities and specific OSH indicators related to process performance.

In the context of the evolution of the ISO 45001 standard and the consolidation of the proposal presented in this study—particularly concerning the comparative analysis—it is relevant to expand the risk assessment, as outlined by Fargnoli et al. (2020). To this end, it is proposed that, if the proposal presented in this article is accepted by peers as an asset, a Delphi panel be conducted, including two distinct groups: one composed of experts in OSH in the food industry and the other composed of specialists in machine safety. Additionally, it is recommended to analyse statistics on serious and fatal workplace accidents in the food sector, covering various countries. Incidents recorded under the OSHMS can provide valuable insights to enrich the data analysis related to the PRPs, the control measures implemented and their effectiveness evaluation.

This study paves the way for further research across diverse sectors globally, emphasising the practical application of incorporating PRP into OSHMS for enhanced IMS.

The proposed approach has the potential to respond to the need to develop new risk management methodologies and/or tools, driving developments in the field of OSH, as well as facilitating informed decision-making.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.