# Critical success factors during the implementation of ISO 22000:2018

Monge-Mora, P.M.<sup>1,2)</sup>, Oliveira, D.L.G.<sup>1,2)</sup>, Shevchenko, K.<sup>1,2)</sup>, Cabecinhas, M.<sup>3,4)</sup> and Domingues, P.<sup>3,4)</sup>

<sup>1)</sup> Faculty of Sciences, University of Porto, Porto, 4169-007, Portugal

<sup>2)</sup> Department of Biological Engineering, University of Minho, Campus Gualtar, 4710-057, Braga, Portugal

<sup>3)</sup> Department of Production and Systems, Braga, 4710-057, Portugal

<sup>4)</sup> ALGORITMI Research Centre, School of Engineering– University of Minho, Campus Azurém, 4800-058, Guimarães, Portugal

# STRUCTURED ABSTRACT

**Purpose** - The purpose of the paper is to evaluate why companies still struggle with ISO 22000 implementation and maintenance, identifying which aspects are key for its success.

**Design/methodology/approach** - A literature review was carried out based on Scientific articles and implementation guides collected from Google Scholar, ScienceDirect and ResearchGate.

**Findings -** Nine aspects seem to have a broader impact on organizations' maintenance of ISO 22000 and other FSMS. Furthermore, the empirical research reveals that having an efficient food safety management system is a prerequisite for company's competitiveness.

**Practical implications -** The findings show that many of the critical success factors for a FSMS implementation are based on regular and adequate management of people inside the company.

**Originality/value -** A novel model of segmenting critical success factors is presented, which has practical implications for ISO 22000 achievement.

Keywords: ISO 22000, implementation, critical success factors, FSMS.

Paper type: Research paper.

#### **INTRODUCTION**

Over the last few decades, the food supply chain has become a complex and highly controlled structure within the food companies, mainly as a result of globalization and science advances, since it's well known that small-scale mistakes can lead to global food poisoning catastrophes (Griffith, 2006). This way, mismanaging the food production chain may harm consumers' health and risk food manufactures' reputation. Today, the biggest responsibility of food manufactures, way beyond mere aspects of taste, innovation, or nutrition, is to ensure high quality food products, which should be clean and safe to consumers (Chung et al., 2020). Food quality embraces a wide range of subjects, among them, food safety (FS). A FS hazard is defined in ISO 22000:2018 as a "biological, chemical or physical agent in food with the potential to cause an adverse health effect".

Implementing a food safety management system (FSMS), such as BRC, IFS, HACCP, or ISO 22000, is key to achieve FS (Qijun and Batt, 2016). Hence, firms may implement a FSMS for a variety of reasons, which can be internal, such as the voluntary perception that the benefits should outweigh the costs, or external, in the case of a forced-up situation by customers or public authorities (Taylor, 2001; Karipidis et al., 2009). Some of the benefits of having a FSMS are the improvement of product quality and safety; increased competitiveness in the global market, granting the access to new markets; fewer customer complaints, superior productivity, improved company reputation or image and greater consumer confidence (Qijun and Batt, 2016). On the other hand, there are plenty of constraints that may impact upon the adoption of a FSMS, such as a lack of financial resources, a lack of formal management; a lack of awareness; a lack of motivation; a lack of top management commitment or other external factors (Yapp and Fairman, 2006).

Industries can get certified by the ISO 22000 Standard, which is getting increasingly popular as a solution to improve food safety. This Standard combines aspects of the ISO 9001 Quality Management System and the HACCP Food Safety System, covering organizations through the whole food chain. Since September 2005, when ISO 22000 was first published, it has been widely adopted by many companies around the world. However, it has being recently updated into ISO 22000:2018, making it necessary for the companies to adapt to this new version until maximum 3 years after this publication, as established by the International Accreditation Forum (IAF).

One of the differences between ISO 22000:2005 and ISO 22000:2018 is that the latter version has introduced a High Level Structure alignment (HLS), which is based on a text and structure that is common to all ISO management system standards, making it easier for organizations to combine ISO 22000:2018 with other management systems. Other major differences between these two versions include new changes in some definitions and vocabulary; the inclusion of animal food (which is the

food for animals that are not intended to be eaten and therefore are not part of the human food chain); and more detailing of the objectives (ISO, 2018).

Adequate ISO 22000 implementation provides organized and effective communication with stakeholders, such as health authorities, customers, suppliers, and business partners (Escanciano, et al., 2014). According to Faergemand (2008), an ISO 22000 certified company increases its credibility with food safety authorities, allowing them to reduce the frequency of audits and inspections by demonstrating the company's commitment to food safety. Today, there are approximately 32,139 companies worldwide certified with ISO 22000, China being the country with the largest number of certifications (DQS, 2017). This way, identifying which factors may influence a company to achieve a successful ISO 22000 implementation is fundamental. Hence, the objective of this study is to determine the critical success factors during the implementation of ISO 22000:2018, dividing them between internal and external aspects that deserve to be highlighted.

#### **RESEARCH METHODOLOGY**

For the development of the research paper, the investigation process was done mainly by using Google Scholar, ScienceDirect and ResearchGate and required the use of the keywords "ISO 22000", "implementation", "critical success factors" and "FSMS". Due to the novelty of the topic, the available information is limited, specially related to the study cases and the implementation of the Standard in the organizations. Therefore, the literature review was based on the reading of the abstracts of approximately 100 articles and further selection of the pertinent ones, comprising data between the years of 2001 and 2020. Also, a careful examination of the versions 2005 and 2018 of the ISO 22000 Standards was performed, as well as a critical review of the available ISO 22000 implementation guides.

The selection and analysis of the critical success factors was performed against the requirements of the Standard ISO 22000:2018, as well as the cases of success in the implementation of the Standard found in the literature. Since the topic is very recent, the most important internal and external factors were explored, because they will have a relevant impact in the implementation. The factors with lesser impact were not considered because the scarce available evidence.

#### RESULTS

Today, many enterprises, mainly medium and small ones, still struggle with the implementation of FSMS (Taylor, 2001). The understanding and analysis of critical success factors amid ISO 22000

implementation is paramount. In this context, there were identified nine factors that are key to the successful implementation of ISO 22000, which can be divided between internal and external elements (Table 1).

INTERNAL FACTORS	EXTERNAL FACTORS
Leadership	Context of the organization
Staff training	Risk and opportunities
Performance evaluation	Stakeholders
Planning	Support
Financial resources	

Table 1. Main critical success factors for the implementation of ISO 22000

# Internal success factors

## Leadership

The ISO 22000:2018 itself highlights the importance of leadership and commitment by the top managers when it comes to being successful. The senior manager must be able to command and guide employees through the process, as well as show responsibility to establish, implement and maintain food safety policy (Purwanto, Asbari and Santoso, 2019). Also, the establishment of the food safety policy can include aspects that are specific to each company's context, making it necessary to engage in particularities apart from those directly required. The top management must be able to communicate properly with all parties, ensuring the management system is well understood and continuously available, assigning pertinent responsibilities to each member of the team and making sure all team members have the experience or appropriate training to accomplish their tasks successfully.

Besides, leadership style can be divided in transformational or transactional, generating different results (Purwanto, Hutagalung and Yanthy, 2020). Transformational leadership is about leading a team by identifying collectively the aspects that need change, creating a vision to guide the transformation through inspiration and connecting workers to a sense of collective identity (Odumeru and Ogbonna, 2013). On the other hand, transactional leadership focuses mainly on supervision and performance, implementing both rewards and punishments. Studies show that transformational leadership has the biggest impact on employee performance and promotes higher job satisfaction, while transactional leadership is more effective during crisis or emergency situations (Odumeru and Ogbonna, 2013; Isnawati et al., 2016; Rahim et al., 2018). Hence, it is decisive that top managers lead

with a transformational approach, inspiring the team to give their best performance and guaranteeing a sustainable food safety culture.

# Staff training

Many problems with food safety come out of a lack of competent staff, which ultimately results in flaws in the good manufacture practices (GMPs). In macro enterprises (more than 1000 employees) with a more complex production chain, many of the difficulties detected were related to constant staff training (Xiong et al., 2017).

Staff training can be conducted internally or in partnership with accredited companies and universities. In an investigative study made over Turkish poultry industry, the majority of companies limited their staff training to annual courses (Kök, 2009), which is a potential vulnerability for ISO 22000. Both managers and employees must comprehend the meaning and function of the management system as a way of controlling foodborne hazards and quality assurance, implementing its principles in a continuous and proper way (Sofos, 2008).

## Performance evaluation

In terms of performance evaluation, there are tools to diagnose the performance of an implemented FSMS (diagnostic tools), tools to help a selection process (selection tools), and tools to improve the FSMS performance (improvement tools) (Jacxsens et al., 2011). Also, the establishment of an internal audit department is key to improve the effectiveness of the food safety control measures and to help the company to achieve its objectives. An internal audit aims to evaluate the company's internal controls, ensuring compliance with laws and regulations. It also helps to identify problems and make corrections before they are discovered in an external audit.

The SMEs tended to have a poor understanding of food safety management system and insufficient finance support resulting in limited adoption of FSMS (Fielding, Ellis, DrBeveridge, & Peters, 2005). The smaller enterprises needed more incentives and faced more difficulties in allocating resources to food safety systems.

Ultimately, it is of utmost importance that all evidence is kept in the form of documented information, so that results can be periodically evaluated. (Duman et al., 2017).

#### Planning

Far beyond being responsible for producing safe food for consumers, it is expected that food companies demonstrate transparency on how food hazard control is made, planning actions to guarantee products are harmless (Pozo, Barcelos and Kazue, 2018) At the same time, change is an

inherent part of the process, so organizations must be able to address transformation making precise adjustments, planning necessary improvements for short, mid and long term.

## Financial resources

It is indispensable to remark that the difficulties involving performance evaluation are far most evident in small and medium enterprises (SMEs) (KÖK, 2009). According to Xiong et al. (2017), smaller enterprises tend to have a poor understanding of FSMS and more limited financial resources. This, consequently, may result in an imperfect ISO 22000 implementation or in a complete withdrawal of the system. According to Taylor and Kane (2005), most of the small enterprises (67%) operate with deficient staff training frequency, which is suggestive of their inability to provide more frequent training courses, probably as a result of the great financial burden that FSMS implies on them (Taylor and Kane, 2005). Thus, more monetary incentives are needed to face those difficulties and make ISO 22000 attainable for all organizations.

#### External success factors

## Context of the organization

The national and international commerce is a competitive scenario in constant evolution (Mensah and Julien, 2011). The higher competitivity in national and international commerce and the access to international markets is one of the greatest motivations for organizations to implement FSMS, and the certification with ISO 22000 can provide high revenue compared to the effort.

The implementation of safety and quality standards can help food companies to be more competitive in the market (Kafetzopoulos and Gotzamani, 2014; Weyandt et al., 2011). In this sense, ISO 22000 implementation proves to be a very important tool to manage food safety. One of the objectives of this Standard is promoting trust in the company capability to offer a high-quality product, and therefore, obtaining a competitive advantage for future sales (Karipidis et al., 2009).

# Risk and opportunities

The evaluation of the external risks and opportunities allows the incorporation of stakeholders' status in the implementation of the Standard. The organization can see this factor as a tool to enhance their objectives involving all the external components. In the "Planning" section, the ISO 22000:2018 establishes some key points to manage the risks and opportunities, stating the risk as an opportunity to improve the organization from both sides: inside and outside (ISO, 2018).

Basically, the first step to perform is the determination of the risk and opportunities, in order to obtain a clear view of all related factors (Chen *et al.*, 2020). Determination of risks and opportunities can be achieved by different analytical ways, which must be chosen by the organization, considering their necessities and goals. This analysis is the first step to detect the undesired effects, thereby preventing, reducing and improving them until the accomplishment of the required standard (Pedraza, 2019).

Once the organization employed the analytical risk tool, it is mandatory to create a plan with the associated actions to manage those factors. All actions should be fitted in into the FSMS implementation plan and must be corroborated to check the desired success. As a result, these actions will be equivalent to the needs and requests made by the customers and all the participants in the food chain (ISO, 2018.; Pérez, 2019; Chen *et al.*, 2020).

There are many methods to evaluate and analyze internal and external factors into the organization. These analytical methods are an efficient tool to uncover the features related to the external and internal factors and regularize them to fulfil the requirements. Several tools are well known, but two of them are the most important and widely used (Gürel, 2017; Pedraza, 2019): PESTLE (Political, Economic, Social, Technological, Legal and Environmental) and SWOT (Strengths, Weaknesses, Opportunities and Threats).

When PESTLE analysis is used, there is an overall view about how national and international elements influence on the organization, making easier to notice the possible impact that those elements may have in it. As an example, the analysis of legal factor involves all the legislation that is around of the organization's interest, in this case, food legislation (Rastogi and Trivedi, 2016; Stoyanova, 2019).

SWOT is a very common methodology, because it shows the actual situation around the organization, specifically about the organization environment from the internal (Strengths and Weaknesses) to the external perspective (Opportunities and Threats), providing an useful tool to find risks and convert them into opportunities (Peña, 2017; Nielsen, 2018; Zaman, 2019).

## Stakeholders

To achieve success in the FSMS implementation, the whole organization must be motivated. One of the greatest motivations for implementing management systems, like ISO 14001, ISO 22000, or IFS 5, is the confidence boost in their clients (Weyandt et al., 2011), once the organization is certified by third parties. None of the FSMS produces safe food by itself, but after the proper implementation and application of the Standard it can be assured to the customer a minimum level of food safety, increasing their trust towards the products done by the certified organization.

Given the fact that the modern customer is every day more conscious regarding food safety, and also more interested in obtaining a product that is not just safe, but with a high quality, the implementation of FSMS can work as a key factor in the acquisition of certain product. Both ISO 22000 Standard as

other internationally recognized food safety standards can guarantee that the certified organization has the capability of manufacturing safe products, avoiding sickness and losses related to accidents caused by unsafe food (Pozo, Barcelos and Kazue, 2015), increasing trust in their customers regarding their products and the organization itself.

#### Support

There are 6 critical points involved in the successful implementation of ISO 22000:2018 related to external factors: people (specifically subcontractors), infrastructure (mainly transportation), externally developed elements of the food safety management system, control of externally provided processes, products or services, competence and external communication (ISO, 2018; Chen *et al.*, 2020).

As noted in the "People" factor stated in the Standard, the organization's human resources should provide guarantees of their skills to fulfil a task, therefore the Standard demands that in case of absence of duly trained and prepared workforce, it will be required to hire external services, like subcontractors. These external services must comply with all requisites defined by the organization, but also, they must adapt to the requirements demanded by the Standard (ISO, 2018; Pedraza, 2019).

Transportation is an element of the infrastructure clause 7.1.3, and it needs to be controlled during the implementation of the ISO 22000:2018. Certainly, transportation involves the import of raw materials and the distribution of the product; both can be done by external support. However, this external support must comply the Standard specifications, and therefore the organization must ensure the conformity towards their goals (Purwanto *et al.*, 2020; Purwanto, Santoso and Asbari, 2020).

In the FSMS implementation, it is necessary that the organization uses external elements to achieve their improvement and actualization, and these elements cannot be exempt from the Standard requirements but must comply them. The external FSMS elements must be adequate to the type of organization and to the product or service provided. Therefore, they not only should fulfil the organization objectives, but also, they must be fully implemented and adjusted by the food safety team. It will always be needed to document every detail done to implement these elements, being extremely careful about keeping these documents updated to maintain control on the development and management of all external elements (Pozo, Barcelos and Kazue, 2018; Pedraza, 2019; Purwanto *et al.*, 2020).

The previous critical point should be evaluated by the organization, assuring that is consistent with the objectives and requirements of the company, to avoid that the organization is affected by situations that can be evaded. It is necessary to establish strategies, protocols and criteria that will be used in the external element evaluation, as well as the methodology to prove and document that the control step is done and kept updated (ISO, 2018; Kafetzopoulos and Gotzamani, 2014).

Inside its working group, the organization must be able to have trained people with adequate and actualized skills for each function they are hired for. However, not all companies achieve this step (Ochoa and Pernett, 2019). Therefore, the organization can also implement two solutions to ease this problem: train their staff to keep them as their own working force inside the organization (Grijalba and Paz, 2019) or hire external services that are required to comply with the requirements. The external services hiring is justified when the company does not have the skills in their own organization, and, they are needed in some punctual occasions, such as plague control, internal audits, staff training, among others (ISO, 2018; Peñafiel and Lucero, 2019; Chen *et al.*, 2020). However, if the organization hires external services as staff, they must have adequate mechanisms to evaluate them and test that the hired services comply with the necessary skills to fulfil its objectives, keeping updated records of the process (Peñafiel and Lucero, 2019).

External communication is more than just reaching clients and suppliers, since there are legal authorities that regulate the organization's activity, as well as others external components that influence in the organization environment. This communication must be clear, effective (Escanciano and Santos-Vijande, 2014; Pedraza, 2019), and use the right language to each receptor, and extremely careful measurements should be taken when reporting information regarding food safety where there is not space for mistakes. Therefore, the food safety team has the responsibility to keep all their information fully updated (Chivandi and Maziriri, 2017; Chen *et al.*, 2020).

#### CONCLUSIONS

The main conclusion to be drawn from this study is that there are many aspects that can determine the success of ISO 22000 implementation. However, some internal factors (Leadership, Staff training, Performance evaluation, Planning, and Financial resources) and external factors (Context of the organization, Risk and opportunities, Stakeholders, and Support) seem to have a broader impact on organizations' maintenance of FSMS, with many of those critical aspects depending upon the correct and consistent management of people inside the company.

It has been noticed that the internal factors can show how the organization is operating, revealing its capacity and limitations, consequently providing a good tool to approach the organization goals to implement the Standard, increasing the chance of success in the process. These internal factors give an entire view of the organization performance because they analyze every related area and promote

their improvement, providing more control over the internal environment and making it capable to work according to the requirements of the Standard.

Also, the external factors can be useful to the same purpose but related to control the surroundings of the organization. If the organization is as strict with the external environment as with his own internal issues, the success rate in the implementation of the Standard is higher. These factors can be determinant to obtain the best Standard implementation, so the organization has to work harder with these factors because they are not easily controllable as the internal factors. However, this task is not impossible and if every detail is established in conformity of the organization goals, the result can be very satisfying. Additionally, it is a good way to encourage other organizations to improve their owns standards and making their work better, creating an entire system of certified organizations to be competitive in the economic sector.

Furthermore, the empirical research conducted in this paper reveals that having an efficient food safety management system, such as ISO 22000, is a prerequisite for the company to remain competitive. The segmentation of critical success factors into internal and external factors can be a useful tool to analyze how elements can be controlled, which ultimately can lead to better planning and achievement of a company's goals.

Due to the novelty of this Standard and the current implementation worldwide, the evidence for successful strategies is still under development. Therefore, this is a topic with continuous growth and should be explored after new successful strategies are available.

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