

THE ASSESSMENT OF COMPLIANCE WITH LEGAL REQUIREMENTS IN FOOD SAFETY MANAGEMENT SYSTEM

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Purpose: The purpose of this article is to present the requirements of the ISO 22000:2018 standard relating to food law and the methods that organisations with an implemented food safety management system (FSMS) can use to assess compliance with legal requirements.

Design/methodology/approach: To achieve the aim of the work, an analysis of the requirements of the ISO 22000:2018 standard was used, as well as a review of the literature on FSMSs and the assessment of their effectiveness.

Findings: The lack of inclusion of requirements in the ISO 22000:2018 standard that would explicitly oblige organisations to periodically assess compliance with legal requirements may be a factor that reduces the effectiveness of FSMSs. However, despite the absence of such requirements, organisations should implement system solutions that provide them with information on the results achieved in the area of compliance. Only then will FSMSs be an effective tool to support organisations in the production of safe food that meets the requirements of food law.

Research limitations/implications: The criteria and measures of assessment of compliance with food law and the criteria of self-assessment of the maturity of the process of ensuring compliance with legal requirements proposed in the paper are of a very general nature and do not take into account the different circumstances of the organisation in food chain, which may limit their applicability.

Practical implications: The results can be applied by organisations with an FSMS in place to design and implement methods and tools to support their regulatory compliance assessment activities. They can also be an inspiration for organisations with other standardized management systems, which, like FSMSs, oblige organisations to ensure compliance with the law and periodically assess this compliance.

Originality/value: The originality of the obtained results lies in proposing tools, in the form of criteria and metrics for assessing compliance with food law, as well as criteria for self-assessing the maturity of the compliance process, which can be used by organisations to identify needs for improving the systemic solutions in place for compliance.

Keywords: ISO 22000, compliance assessment, legal requirement, food safety management system.

Category of the paper: Research paper.

1. Introduction

The food choices of today's consumers are increasingly conditioned by a growing awareness of the links between the quality and safety of the food they eat and their health (Kwiatek, Patyra, 2021; Antonio et al., 2020). For consumers, it is important that the food they consume is free from contaminants that pose a risk to their health. In order to ensure an adequate level of protection for consumers, as well as to increase their confidence in the safety of food products on the market, food safety issues are regulated by law (Stoyanowa, 2019). Compliance of food with legal requirements is a prerequisite for it to be considered safe and to be legally marketed (Regulation, 2002).

A key role in shaping food quality and safety play organisations in food chain that are responsible for the process of designing and manufacturing products that not only meet the requirements of applicable law, but also satisfy consumers in terms of nutritional value, sensory value and availability (Zimon, Madzik, Domingues, 2020). Declining consumer confidence in food safety, caused by food crises, is forcing organisations to look for opportunities to improve the solutions they use to reduce the risk of hazards in food that can cause adverse health effects (Silva, Fonseca, Sousa 2016; Kotsanopoulos, Arvanitoyannis, 2017).

The ISO 22000:2018 compliant food safety management system (FSMS) is a tool that can support organisations in the production of safe food taking into account the applicable legal requirements. This system can be a key determinant of an organisation's competitiveness, increasing consumer confidence in the safety of its products (Monge-Mora et al., 2020). Indeed, the system model described in the standard sets out requirements that oblige organisations to ensure that the products they produce comply with food law (Rosiak, 2020, Stoyanowa, 2019). When implementing a system, organisations define responsibility and authority, and formalise the activities involved in identifying the legal requirements applicable to the organisation's activities and its products, ensuring that personnel have access to these requirements, and implementing them in practice (International Organization for Standardization, 2022; Zimon, Madzik, Domingues 2020). As a result of the implementation of the FSMS, staff knowledge of the applicable legal requirements increases, and an organisational culture is formed, a key pillar of which is the commitment of staff at every level of the organisational structure to legal compliance, which organisations see as one of the main benefits of maintaining the system (Cierpiół, Wąsikiewicz-Rusnak, 2021). Compliance with the ISO 22000:2018 standard not only minimises the risk of non-compliance with food law, but also reduces the consequences of non-compliance, such as the need to compensate consumers for damage to their health caused by non-compliant food, the cost of withdrawing the product from the market or disposing of it, administrative fines imposed on organisations by the official food control authority, decisions by the authority to temporarily suspend production or ban activities, loss of reputation and damage to image (Szkiel, 2021).

Ineffective system solutions related to ensuring compliance with the legal requirements may be a source of non-compliance in the FSMS and the reason for the lack of effectiveness of the system in ensuring food safety. Therefore, an integral part of the periodic assessment of the effectiveness of the FSMS, both internally by organisations and externally by certification bodies, should be an evaluation of the activities carried out in the system to ensure compliance with the legal requirements and an assessment of how the organisation checks its compliance with these requirements.

The purpose of this article is to present the requirements of the ISO 22000:2018 standard relating to food law and the methods that organisations in food chain with an implemented FSMS can use to assess compliance with legal requirements. It has been hypothesised that the limitation of the FSMS model described in the standard, which results from its failure to include requirements relating to the assessment of compliance with legal requirements, is a factor reducing the effectiveness of the systems.

The paper poses the following research problems:

- what criteria and metrics for assessing compliance with legal requirements organisations can use within the FSMS,
- what criteria for self-assessment of the maturity of the compliance process can be used to assess the maturity of the process,
- what risks associated with the process of assessing compliance with legal requirements may affect the reliability of the assessment results, and thus the possibility of using them to improve the FSMS.

The issue of evaluating ISO 22000 compliant food safety management systems has been the subject of many studies. For example, there are publications devoted to the factors determining the effectiveness of systems (Monge-Mora et al., 2020; Purvanto, Hutagalung, Yanthy, 2020), as well as the assessment of their effectiveness (Psomas, Kafetzopoulo, 2015; Kiriezieva et al., 2013) and maturity (Glykas, 2024). The work also presents methods that organisations can use to assess and improve the effectiveness of the system, such as internal and external audit (Kotsanopoulos, Arvanitoyannis, 2017; Król, Chmiel, Brodziak, 2022) and management review (Lesiów, Orzechowska-Przybyła, Niewelt, 2014; Dzwolak, 2009). Research was also conducted on assessing the convergence of the results of external audits conducted by certification bodies in organisations with a certified FSMS with the results of inspections conducted in organisations by official food control authorities (Turku, Lepistö, Lundén, 2018; Powell et al., 2013; Psomas, Kafetzopoulo, 2015; Piira et al., 2021). However, in the area of assessment of FSMSs compliant with the ISO 22000:2018 standard, a research gap has been identified – no research has been conducted so far aimed at analyzing the role of conformity assessment with legal requirements in maintaining an effective FSMS and presenting methods supporting the conformity assessment process.

The originality of the paper results from two issues. Firstly, the issues of assessing compliance with food law as an integral element of FSMS are discussed to a negligible extent in the literature on the subject. Secondly, there is a lack of publications on the methods that organisations in food chain can use within the implemented FSMS to assess compliance with legal requirements. In turn, the originality of the obtained results lies in proposing tools, in the form of criteria and metrics for assessing compliance with food law, as well as criteria for self-assessing the maturity of the compliance process, which can be used by organisations in food chain to identify needs for improving the systemic solutions in place for compliance.

2. Research methodology

The research method used for achieving the aim of the paper was a review of literature on the comprehensive approach to food safety management. The review covered publications concerning the analysis of the requirements of the ISO 22000:2018 standard, as well as papers presenting the results of studies devoted to the evaluation of the effectiveness of FSMSs, including methods supporting the evaluation process, such as the internal and external audit, management review and self-assessment.

Another research method used in the study was an analysis of standards used by organisations to support the comprehensive approach to ensuring the safety of produced food. The analysis covered the ISO 22000:2018 standard describing requirements for the FSMS model, with particular emphasis on requirements related to ensuring compliance with food law. Apart from that, standards describing guidelines for auditing FSMS and for conducting self-assessments of standardised management systems were analysed.

3. Results

3.1. The requirements of the ISO 22000:2018 standard relating to food law

The FSMS model described in the ISO 22000:2018 standard has been designed to enable organisations in food chain to mitigate the risk of non-compliance with food law and demonstrate that they have exercised due diligence to ensure such compliance (Dzwolak, 2018a; International Organization for Standardization, 2020). The FSMS also helps organisations to flexibly adapt to the applicable legal requirements to ensure food safety, which is recognised by organisations as one of the main factors motivating them to implement the system and seen as a benefit of its implementation (Paunescu, Ruxandra, Miruna, 2018; Stoyanowa et al., 2022; Gonçalves et al., 2020; Granja et al., 2021). Meeting the applicable

legal requirements, in addition to meeting the requirements of the ISO 22000:2018 standard, is a condition for the organisation to obtain a certificate for the system.

Needs and expectations relating to an organisation's compliance with legal requirements may be formulated by different interested parties (table 1).

Table 1.

Examples of interested parties requirements relating to the organization's compliance with legal requirements

Interested party	Examples of requirements for organizations
Clients / Consumers	<ul style="list-style-type: none"> – ensuring conformity of products with the legal requirements – effective communication of information concerning the characteristics of the product and appropriate handling of the product in accordance with legal requirements – effective reporting of non-conforming products – effective response in the event of crisis situations related to non-compliance of products with the legal requirements
Suppliers	<ul style="list-style-type: none"> – effective communication of legal requirements for purchased products – effective notification of non-conformity of supplied products with the legal requirements
Employees	<ul style="list-style-type: none"> – effective communication of, and access to, legal requirements applicable to the organisation's activities and to the manufactured products – provision of legal requirements training – communicating the results of internal and external evaluations on compliance with legal requirements
Official food control authority	<ul style="list-style-type: none"> – compliance with the legal requirements applicable to the organisation's activities and the manufactured products – effective communication in the framework of ongoing compliance assessment inspections – provision of evidence of compliance with the legal requirements during inspections – effective implementation of actions in response to inspection results – effective reporting of and response to product non-conformity crises
Certification body	<ul style="list-style-type: none"> – communicating to the audit team, prior to the audit, the legal requirements applicable to the organisation's activities and the manufactured products – compliance with the legal requirements applicable to the organisation's activities and the manufactured products – providing evidence during audits of compliance with legal requirements

Source: own elaboration.

The requirements for ensuring that an organisation's operations and manufactured products comply with food law are addressed at many clauses in the ISO 22000:2018 standard (table 2).

Table 2.

The requirements of the ISO 22000:2018 standard relating to food law

Clause of ISO 22000:2018	Requirement
4.1.	Determination of issues from the legal environment of the organisation that are relevant to its purpose and affect its ability to achieve the intended FSMS results
4.2.	Consistent provide of products that meet legal requirements
5.1.	Demonstrating FSMS leadership by communicating the importance of compliance with the legal requirements
5.2.1.	Including, in the food safety policy, a commitment to satisfy the legal requirements
6.2.	Taking into account the legal requirements for FSMS objectives
7.4.2.	Establish and implement effective communication with statutory and regulatory authorities
7.4.3.	Keeping the food safety team informed of applicable legal requirements

Cont. table 2.

7.5.1.	Inclusion in FSMS documentation of information required by legislative bodies
8.2.3.	Identifying legal requirements when selecting and establishing prerequisite programmes
8.3.	Identifying legal requirements when establishing and implementing a traceability system
8.4.2.	Identifying emergency response legal requirements
8.5.1.	Identifying the legal requirements necessary to carry out a risk analysis
8.5.1.2.	Identifying legal requirements for raw materials, ingredients and product contact materials
8.5.1.3.	Identifying legal requirements for the end products
8.5.2.2.1.	Consideration of legal requirements when identifying food safety hazards

Source: own elaboration based on ISO 22000:2018 *Food safety management systems. Requirements for any organization in the food chain*.

The analysis of the ISO 22000:2018 standard shows that its requirements are aimed at indicating activities within the FSMS that should be implemented taking into account legal provisions. The legal requirements are one of the factors that form the context of an organisation that can affect the achievement of its food safety objectives (Stoyanova, 2019). Therefore, the organisation should ensure that it knows the legislation applicable to its operations and products, understands it properly and implements it in practice. However, the standard does not specify requirements that explicitly obliged organisations to periodically assess compliance with food law and document its results. It also does not indicate the methods and tools that should be used by organisations in the conformity assessment process. Failure to take into account the requirements in this regard in the FSMS model may result in the assessment not being carried out or being ineffective. Although the organisation is not obliged to formalise its food law compliance assessment activities, drawing up a documented procedure describing how to proceed in this area is reasonable, as it can contribute to the organisation's ability to operate in accordance with the applicable legal requirements and to adapt flexibly to changes in these requirements. Formalisation of activities also enables an organisation to gather evidence, in the form of records, that it knows the full picture of the applicable legal requirements, monitors changes to those requirements, takes them into account when updating the system and monitors the status of its compliance.

3.2. Methods for assessing compliance with legal requirements within the FSMS

As mentioned, the FSMS model described in the ISO 22000:2018 standard does not explicitly specify the methods that should be used by organisations to periodically assess compliance with legal requirements. However, this assessment can be carried out during periodic FSMS audits - both internal and external (Kotsanopoulos, Arvanitoyannis, 2017; Chen et al., 2020; Monge-Mora et al., 2020). In addition to the requirements of the standard relating to food law (table 2), the criteria for which auditors compare the evidence collected as a result of audit tests may be the legal provisions applicable to the activities and products of the organisation (ISO 19011, 2018).

The FSMS internal audit is a fundamental management tool that verifies the system's compliance with the requirements of the ISO 22000:2018 standard and its effectiveness, and ensures that actions are implemented to mitigate the risks associated with the business, including those associated with non-compliance with legislation (Król, Chmiel, Brodziak, 2022). Audit testing should be focused on confirming the ability of the FSMS to support the organisation in meeting regulatory requirements. For this purpose, auditors should check, among others:

- whether persons responsible for identifying applicable legal requirements and monitoring changes to those requirements have been appointed,
- what are the competences of the persons responsible for ensuring compliance with the legal requirements and what actions does the organisation take to increase these competences,
- whether the organisation maintains and updates the list of applicable legal requirements,
- how access to legal requirements is provided to personnel,
- how often and how the assessment of the organisation's compliance with legal requirements is carried out and how the results are documented.

Compliance with food legislation is also assessed during the FSMS external audits (certification and annual surveillance audits) conducted by the certification body, as a prerequisite for certification of the system, in addition to meeting the requirements of the ISO 22000:2018 standard, is the organisation's ability to consistently meet the legal requirements. These requirements may relate to:

- manufactured products and services provided,
- production processes,
- test methods for manufactured products,
- labelling,
- authorisation to operate and market the products,
- consumer rights.

The range of requirements applicable to the organisation's activities determines the duration of the audit, as well as the size and composition of the audit team (ISO/IEC 17021-1, 2015). In the event of a serious violation of legal requirements, the audit result is negative, which results in the failure to grant the organisation a certificate for the system.

The FSMS audit carried out by the certification body is one of the elements of a multifactorial approach to ensuring food safety (Powell et al., 2013). However, due to its sampling nature (the assessment of the system is based on the evaluation of a sample of information collected during the audit tests), it is not a verification of compliance with all the legal requirements applicable to the organisation's activities, as this is the responsibility of the official food control authorities. The system certificate can therefore not be seen as a declaration of full compliance with these requirements. However, due to the fact that to a certain extent the

scope and objectives of audits and inspections carried out by official food control authorities overlap, the organisation's certification for the system may to some extent justify a reduction in the frequency of inspections (Turku, Lepistö, Lundén, 2018). Therefore, a certified organisation, through the system solutions it has implemented, should be seen to be able to meet the legal requirements on an ongoing basis, as it manages its activities appropriately to ensure compliance with these requirements (International Organization for Standardization, 2022). This fosters confidence both within the organisation (management and staff) and the confidence of its external interested parties (food consumers, customers, official food control authorities, trading partners) in the FSMS as an effective tool to support the production of safe products taking into account the applicable legislation.

The assessment of compliance with legal requirements in external audits conducted by the certification body is similar in nature to the assessment during internal audits. The audit tests are designed to assess whether the adopted food safety policy, as well as the organisation's related objectives, are defined with regard to the legal requirements. The certification body's auditors also assess the extent to which management is aware of the risks of failing to meet these requirements and the effectiveness of the actions taken by the organisation to ensure compliance. It is also assessed how the organisation:

- identifies applicable legal requirements and periodically reviews changes to those requirements,
- takes into account the legal requirements and their changes in the FSMS,
- provides access to legal requirements and develops staff awareness of these requirements,
- implements the legal requirements for use in the organisation,
- conducts periodic assessments of compliance with legal requirements, including ensuring the competence of those conducting such assessments, establishing the scope and comprehensiveness of the assessment and documenting its results, and involving staff in the assessment process,
- takes the legal requirement into account when planning and carrying out internal system audits,
- incorporates the results of the periodic assessment of compliance with legal requirements in management reviews conducted by management,
- implements corrective and improvement actions for non-compliance with legal requirements.

A prerequisite for the award of the FSMS certificate to an organisation is that the auditors of the certification body gather evidence (through interviews with the organisation's management and staff, observation of the assessed processes, analysis of documentation describing the principles of the system's operation and evaluation of the records produced) of compliance with the legal requirements and the requirements of the ISO 22000:2018 standard relating to compliance with these requirements. Such evidence may include, for example:

- a food safety policy that includes a commitment to meet legal requirements,
- maintaining an up-to-date, complete list of applicable legal requirements,
- documentation of staff training on legal requirements,
- staff awareness surveys on legal requirements,
- a task, responsibility and authority sheet containing the assignment of tasks related to ensuring compliance with legal requirements to designated persons,
- reports on the periodic assessment of compliance with legal requirements,
- records of inspections carried out as part of official food controls,
- internal audit reports relating to the assessment of compliance with legal requirements,
- reports on management reviews by management dedicated to assessing compliance with legal requirements,
- non-compliance sheets and corrective actions taken in the event of non-compliance with legal requirements.

Regulatory compliance can also be assessed during periodic management reviews conducted by the organisation's management, the purpose of which is to confirm that the FSMS is relevant to the context in which the organisation operates, and is useful and effective (Dzwolak, 2019). Next to audits, the management review is the most important tool for system improvement (Dzwolak, 2009). During the review, management can assess whether the organisation's existing policies and assigned responsibility and authority related to compliance with legal requirements are appropriate and enable it to achieve its objectives in this area. Management reviews should therefore include information on:

- changes in legal requirements,
- the results of periodic assessments of compliance with legal requirements, including non-conformities identified and subsequent corrective action taken,
- the results of internal and external audits relating to compliance with legal requirements,
- the results of controls carried out by official food control bodies.

The results of the review should be an opportunity to identify compliance issues and implement improvement actions.

3.3. Criteria and metrics for assessing compliance with legal requirements

Organisations in food chain that want to effectively implement a legal compliance process should systematically measure and evaluate its results. To assess the extent to which its objectives and compliance outcomes are being met, the organisation can use criteria to describe the results achieved, as well as metrics - measurement tools that will enable it to assess the ability of the process to achieve the planned results, as well as to evaluate its effectiveness (Molenda, 2016; Rummler, Brache, 2000). The use of metrics ensures that evaluation is objective and, if carried out systematically at set intervals, enables the organisation to compare its performance over time and to analyse process trends. In addition, process monitoring enables

the organisation to identify process issues, identify process improvement needs and implement improvement actions (Bitkowska, 2017; Dobrowolska, 2017). Metrics, therefore, play a key role in process improvement and condition sound decision-making in this area (Rydzewska-Włodarczyk, Sobieraj, 2015; Wyrębek, 2016).

The ISO 22000:2018 standard does not specify requirements for the use of specific assessment criteria and metrics - these should be developed by the organisation, adapting them to its needs arising from the scope of its activities, its planned food safety objectives and the maturity level of its FSMS. When defining metrics, the organisation should ensure that they are consistent with the adopted strategy and food safety policy (Janczewska, Janczewski, 2021; Bitkowska, 2017).

Examples of criteria and metrics for assessing compliance with legal requirements that can be used within the FSMS are shown in the table 3.

Table 3.

Criteria and metrics for assessing compliance with legal requirements in FSMS

Criteria	Metrics
Results of controls carried out in the organisation by official food control authorities	Number of irregularities found as formulated in the inspection protocols
	Number of fines imposed on an organisation as a result of an inspection
	Number of administrative decisions issued against the organisation by the authority as a result of the audit
Dealing with emergency situations involving non-compliance of products with food legislation	Number of crises resulting in product recalls
	Number of emergency team meetings related to non-compliance with food legislation
	Number of notifications to the RASFF related to non-compliance of products with food legislation
Staff's knowledge of food law	Number of staff training courses on food legislation
	Results of questionnaires/tests on workers' knowledge of food legislation
Involvement of staff in ensuring compliance with food legislation	Number of reports by employees of identified cases of non-compliance with food legislation
Results of periodic internal audits for assessing compliance with food legislation	Number of food safety team meetings to assess compliance with food legislation
	Number of non-compliances found as a result of internal audits
	Number of cases where a non-compliant product has been withheld from the market
Results of laboratory tests on products	Number of test results confirming non-compliance of the product with food legislation
Costs associated with non-compliance with food legislation	Costs of withdrawing a non-compliant product from the market
	Costs of fines imposed on the organisation by the official food control authority
	Litigation costs
Image losses	Number of negative media reports related to cases of non-compliance with food law
	Number of lost customers / contracts as a result of the image crisis

Source: own elaboration.

For individual measures, the organisation can set target values (limits for meeting expectations) against which the results obtained will be compared in order to identify any deviations (Bitkowska, 2015; Rummler, Brache, 2000; Gudź, Gudź, 2020). Information on compliance performance, measured using specific criteria and metrics, should be used by the organisation's management to prioritise the updating and improvement of the FSMS, as well as

to plan and implement improvement activities. The results should also be communicated to the organisation's staff, as such actions support the creation of the organisation's food safety culture.

Systematic monitoring of compliance with legal requirements using designed meters requires determining responsibility for monitoring activities. This responsibility should be entrusted to those who are most knowledgeable in this field. In the FSMS, this responsibility is most often assigned to the food safety team.

3.4. Self-assessment of the maturity of the food law compliance process

The foundation of FSMS improvement is to know and understand the strengths and weaknesses of the processes implemented in the system. Therefore, in addition to assessing the effectiveness of the compliance process, the organisation can also assess its maturity. Process maturity can be understood as its ability to systematically improve the results obtained and considered in the context of the organisation's sophistication in applying process management methods and tools and the excellence of the implementation of process activities (Gabryelczyk, 2016).

To assess the maturity of the process of ensuring compliance with legal requirements, the organisation may use self-assessment – a method that makes it possible to assess the functioning of the process, identify its strengths and weaknesses, identify and maintain good practices related to the implementation of the process, identify opportunities for its improvement and improve the results achieved (Wiśniewska, Grudowski, 2019; Książek, Ligarski, 2015; Adamczyk, 2018). The results of the self-assessment make it possible to identify the links between compliance activities and the effects of these activities. They represent a knowledge resource that should be used by the organisation's management to make changes to the management system and the processes implemented (Szczepańska, 2017). The ISO 22000:2018 standard does not specify requirements for conducting a self-assessment, however, it can be an additional source of information for any organisation in food chain on the maturity of its food law compliance activities. These activities can be assessed as part of a separate self-assessment, or they can be assessed as part of a comprehensive FSMS self-assessment.

Self-assessment can be carried out according to different methodologies and there are many models for assessing the maturity level of the management system and the processes implemented in the system (Adamczyk, 2018). When applying self-assessment, organisations with a standardised management system in place most often use the guidelines contained in the ISO 9004:2018 standard (ISO 9004, 2018). According to these guidelines, when embarking on a self-assessment, an organisation should prepare the criteria against which it will assess its compliance solutions, as well as a scale for assessing levels of process maturity. Examples of criteria are shown in the table 4.

Table 4.
Criteria for self-assessment of the maturity of the compliance process

Obszar	Maturity level	
	Level	Description
Identification of legal requirements	1	Lack of formally defined rules and responsibilities related to the identification of legal requirements
		Legal requirements identification activities are carried out on <i>an ad hoc basis</i>
	2	Principles and responsibilities related to the identification of legal requirements have been formally defined
		Changes in legal requirements are monitored periodically
	3	Changes in legal requirements are monitored in a systematic and planned manner
		In the process of identifying legal requirements, the organisation uses various sources (online databases, forums and web portals, specialist press, cooperation with official food control authorities)
	4	The legal requirements identification process is effective
		Staff responsible for identifying requirements are systematically improving their competencies
		Changes in legal requirements are communicated to the organisation's staff on an ongoing basis
	5	The legal requirements identification process is systematically reviewed and updated, and any potential non-conformities are used to improve the process
Providing access to legal requirements	1	Lack of formally defined rules and responsibilities related to providing staff with access to legal requirements
	2	The rules and responsibilities associated with providing staff access to the legal requirements have been formally defined
	3	The organisation uses a variety of tool to ensure staff access to legal requirements (training, internal databases)
	4	The process of providing access to legal requirements is effective
	5	The legal requirements assurance process is systematically reviewed and updated, and any potential non-conformities are used to improve the process
Assessment of compliance with legal requirements	1	Lack of formally defined rules and responsibilities relating to conformity assessment with legal requirements
		Compliance assessment is carried out reactively, in response to food insecurity emergencies
		Results of conformity assessment are not documented
	2	The rules and responsibilities relating to the assessment of compliance with the legal requirements have been formally defined
		Evaluation of compliance with the legal requirements is carried out periodically
		Results of conformity assessment are not documented
	3	Assessment of compliance with legal requirements is carried out in a proactive, systematic and planned manner
		Personnel responsible for assessing compliance with the legal requirements systematically improve their competences
		The process of assessing compliance with the legal requirements involves the management of the organisation and personnel performing tasks that are crucial for the safety of the product
	4	The conformity assessment process is effective, identifying potential and actual non-conformities
		The results of the conformity assessment are communicated to all employees
	5	The conformity assessment process is systematically reviewed and updated, and any potential non-conformities are used to improve the process
		The organisation is aware of the hazards that may adversely affect the reliability of the assessment results and takes action to address the identified risks
		The legal requirements assessment process is integrated into the FSMS improvement process

Source: own elaboration.

A tool to support the conduct of the self-assessment can be a list of questions relating to the activities undertaken by the organisation related to the identification of legal requirements, the provision of access to regulations for staff and the periodic assessment of compliance. The assessment of the maturity level of the process using the designed criteria should be conducted on the basis of the evidence collected by the self-assessment team.

3.5. Risk associated with the process of assessing compliance with legal requirements

The ever-increasing number of legal requirements that govern an organisation's activities increases the risk of non-compliance. The FSMS can support organisations in mitigating these risks, as the system model described in the ISO 22000:2018 standard is based on the concept of risk-based thinking (ISO 22000, 2018; Rosiak, 2020). The concept is that the management of risks that may affect the ability of an organisation and its FSMS to achieve its performance targets should be an integral part of the system, and a pillar of the organisation's food safety culture (Dzwolak, 2018b; Kwiatek, Patyra, 2021). Risk management should also be an element of planning and controlling processes implemented in the system aimed at achieving the assumed effects, because each process may be associated with threats that may cause deviations from the planned results.

Organisations in food chain consider the correct evaluation of system performance, and therefore the effectiveness of system evaluation processes, as one of the key factors determining the success of FSMS implementation. The reliability of the evaluation results determines the possibility of using them to improve the system (Monge-Mora et al., 2020). The effectiveness of the FSMS can be significantly affected by the process of assessing compliance with legal requirements, and therefore, in line with the risk-based approach adopted in the ISO 22000:2018 standard, the organisation should be aware of the hazards that may adversely affect the process of this assessment and the reliability of its results, as well as the causes of these hazards (table 5).

Table 5.

Hazards associated with the process of assessing compliance with legal requirements and their causes

Hazards	Causes
– failure to carry out an assessment	– lack of assignment of responsibility and authority for conducting the assessment
– inappropriate scope of assessment (failure to assess all legal provisions applicable to the organisation's activities)	– lack of formalisation of the rules for conducting and documenting assessment results
– lack of objectivity on the part of those conducting the assessment	– the evaluators' direct reporting to the company management
– improperly carried out assessment	– lack of specific competence requirements for assessors
– lack of documentation of assessment results	– lack of competence of those carrying out the assessment
– loss or destruction of the documentation containing the assessment results	– lack of training for assessors
– lack of access to the data necessary to carry out the assessment	

<ul style="list-style-type: none"> – failure to include the results of periodic food law compliance assessments in management reviews – failure to take effective action in relation to non-compliances identified – failure to communicate the results of the assessment to the organisation's management 	<ul style="list-style-type: none"> – failure to allocate funds in the organisation's budget to improve the competencies of assessors – ineffective supervision of documentation related to the assessment – lack of management commitment to maintain and improve the FSMS – failure to adequately and comprehensively identify the applicable legal requirements – low motivation and commitment of those carrying out the assessment – lack of cooperation between the organisation's staff and the assessors
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Source: own elaboration.

The hazards related to the compliance assessment process, constituting a risk to the achievement of the organisation's objectives in the area of compliance, should be an impulse to introduce changes in the process (Brajer-Marczak, 2017). Therefore, once the hazards and their causes have been identified, the organisation should plan and implement actions to address them. By doing so, it can reduce the risk of negative consequences resulting from an inadequately conducted assessment, a failure to detect non-compliance with legal requirements and the provision of erroneous information on compliance status to management. These effects may include, for example:

- the lack of a reliable assessment of the effectiveness of the FSMS and thus the inability to identify needs and opportunities for improvement,
- loss of certification for FSMS due to the organisation's inability to demonstrate evidence of its ability to produce compliant safe food,
- loss of existing and potential customers who demand a certified FSMS from the organisation or who make cooperation with the organisation dependent on the effectiveness of the system.

4. Discussion

The assessment of compliance with food law under FSMSs has not been studied so far and, therefore, has not been extensively covered in the literature on the comprehensive approach to food safety management. Thus, the options presented in the paper for conducting assessments of compliance with legal requirements as part of system audits and management reviews, as well as the proposed criteria and measures of assessment of compliance with food law and the criteria for self-assessment of the maturity of the process of ensuring compliance with legal requirements fill the identified research gap.

Modern food safety management must take into account the needs of modern organisations in food chain regarding the implementation of an organisation management model making it possible to achieve goals in the area of ensuring compliance with legal requirements and to minimise the risk of non-compliance. Therefore, in order to ensure the effectiveness of FSMSs implemented in organisations in food chain and, consequently, to enhance the safety of food placed on the market, the FSMS model should be extended to include requirements requiring organisations to periodically assess compliance with legal requirements.

The organisation's use of proposed methods and tools for assessing compliance with legal requirements suggested in the paper will ensure a comprehensive approach to assessment. However, not all organisations will have to use such a broad scope of assessment - it can be flexibly adapted to their needs.

The obtained results made it possible to positively verify the research hypothesis. On the one hand, the lack of inclusion of requirements for the periodic assessment of compliance with legal requirements in the ISO 22000:2018 standard means that organisations in food chain may find it unnecessary to design and formalise their systemic solutions in this respect. This may result in an ineffective assessment of compliance that will not provide the organisation's management with reliable information about the status of compliance. On the other hand, the absence of such requirements may make it difficult for auditors of the certification body to assess the organisation's ability to meet legal requirements consistently and to evaluate the effectiveness of solutions adopted by the organisation in this area.

The research undertaken in this paper should be continued. Its aim should be to identify and evaluate systemic solutions related to food law compliance assessment that are used by organisations with an FSMS in place, as well as to validate the proposals presented in this paper in respect of their practical application and the identification of potential limitations of their application depending on various conditions of functioning of the organisation.

5. Conclusions

The process of assessing compliance with legal requirements is one of the most important processes in FSMSs implemented in organisations in food chain, as it provides management with information on the compliance status of the organisation's activities with the law with sufficient frequency, enables the detection of possible non-compliance and the taking of corrective action. Therefore, this process should be an integral part of the assessment and improvement of the effectiveness of the system and the results achieved by organisations in the area of food safety.

Based on the study, it can be concluded that the lack of inclusion in the ISO 22000:2018 standard of requirements that, following the example of other standards for management systems (e.g. ISO 14001:2015, ISO 45001:2018), would explicitly oblige organisations in food chain to periodically assess compliance with legal requirements, may be a factor that reduces the effectiveness of FSMSs. Thus it is essential that, despite the absence of such an obligation, organisations develop and implement their own system solutions to provide them with information on their compliance performance. Only this approach will ensure that FSMSs are an effective tool to support organisations in producing safe food that meets the requirements under food law. Perhaps as a result of the successive revisions of the ISO 22000 standard, conducted from time to time by the International Organisation for Standardisation, such requirements will be included in the FSMS model. This should be seen as an opportunity to increase the efficiency of the systems, improve the safety of food on the market and consequently increase consumer health protection.

In summary, based on the results of the conducted study, the following conclusions can be formulated:

1. The FSMS model described in the ISO 22000:2018 standard that is intended to address the needs of organisations in food chain with regard to compliance with food law requirements should evolve in the area of requirements concerning the assessment of compliance with these requirements.
2. Organisations that want to increase their capacity to meet legal requirements and respond flexibly to changes in these requirements should formalise activities related to the periodic assessment of compliance with food law.
3. When designing and formalising activities related to the assessment of legal compliance within the implemented FSMS, organisations should not rely solely on the requirements of the ISO 22000:2018 standard – they should also refer to standards that provide guidance for the assessment of standardised management systems (e.g. ISO 19011:2018, ISO 9004:2018).
4. In order to ensure the effectiveness of the assessment of compliance with legal requirements and, consequently, minimise the risk of non-compliance, it is essential to eliminate risks that may affect the reliability of the assessment results.

The considerations presented in this paper are of theoretical importance, as they complement knowledge of the limitations of the FSMS model described in the ISO 22000:2018 standard in terms of requirements relating to the assessment of compliance with legal requirements, as well as knowledge of the methods and tools that can be used to assess compliance. They also have practical applications, as they can be used by organisations in food chain with an FSMS in place to design and implement methods and tools that will support their food law compliance assessment activities. They can also be an inspiration for organisations with other standardised management systems in place, which oblige organisations to ensure compliance with legal requirements and assess this compliance.

The results of the research have a number of implications for a wide group of parties interested in food safety:

1. From the organisation's in food chain perspective, they can help increase their ability to produce safe food that meets the requirements of food law. This enables organisations to create a positive image among all of their stakeholders and, consequently, enhance their competitiveness.
2. From the consumers' perspective, they can build their confidence in the safety of food on the market.
3. From the perspective of official food control authorities, they can foster positive relationships with organisations in food chain under supervision.
4. From the state's perspective, they can promote the competitiveness of the food market, foster the improvement of public health and minimise the risk of food crises.
5. From the perspective of certification bodies, they can support the assessment of compliance with legal requirements through external audits carried out in organisations and build confidence in certificates for FSMSs issued by the body.

The criteria and measures of assessment of compliance with food law and the criteria of self-assessment of the maturity of the process of ensuring compliance with legal requirements proposed in the work are of a very general nature. This results in some limitations on their applicability for organisations in food chain whose activities are determined by various factors, such as the size of the organisation, the organisational structure or the specifics of the business. They should, therefore, be seen as proposals which, before being implemented, should be adapted by organisations to their needs and the context of their business.

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