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Εφαρμογή των συστημάτων διαχείρισης ασφάλειας τροφίμων GFSI στην Ελλάδα: Κίνητρα και δυσκολίες

MSc Thesis

Implementation of GFSI food safety management systems in Greece: Motivations and difficulties

Διευθυντής

Καθ. Τμήματος Επιστήμης και Τεχνολογίας Τροφίμων (ΠΑ.Δ.Α) Ιωάννης Τσάκνης

Λιούμπη Ελένη

Lioumpi Eleni

Δρ Ευσταθία Τσάκαλη, Επίκουρη Καθηγήτρια

Dr Efstathia Tsakali, Assistant Professor

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Faculty of Food Sciences

Department of Food Science and Technology

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FOOD INNOVATION, QUALITY AND SAFETY

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Lioumpi Eleni

19014

fiqs19014@uniwa.gr

Dr Efstathia Tsakali, Assistant Professor

AIGALEO 2021

Έγινε δεκτή

Ο διευθυντής του ΠΜΣ: Ioannis Tsaknis Digitally signed by Ioannis Tsaknis Date: 2021.09.19 19:26:04 +03'00'

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Παράβαση της ανωτέρω ακαδημαϊκής μου ευθύνης αποτελεί ουσιώδη λόγο για την ανάκληση του πτυχίου μου».

Η Δηλούσα

Ευχαριστίες

Ευχαριστώ θερμά όλους τους καθηγητές του μεταπτυχιακού προγράμματος για την εξαιρετική συνεργασία και ειδικότερα την κυρία Τσάκαλη για την πολύ σημαντική βοήθεια και την αμέριστη καθοδήγησή της στην εκπόνηση της διπλωματικής μου μελέτης.

Επίσης θα ήθελα να ευχαριστήσω την οικογένειά μου για τη στήριξή της σε όλο αυτό το εγχείρημα.

Αφιερώσεις

Αφιερώνω την εργασία αυτή στον γιό μου Γιώργο, για όλη τη στήριξη που μου προσέφερε.

Summary

The present thesis focuses on the importance of GFSI standards and the benefits companies have when using them. Also, the analysis of 44 ISO 22000:2015 audit reports from various Greek food companies and distributors, show the need to improve the food safety systems that are now followed in Greece. The data collected were categorized by the major group of programs they belonged in (PRPs, OPRPs, CCPs) and secondly by the chapter of the ISO 22000:2015 standard that referred to them. The analysis showed that the most findings were about PRPs and OPRPs, rather than CCPs. There appeared no relationship between the type of the company or the product and the findings. As it seems the major issue is that food safety is presented as an obligation and not as mindset from the management team, who plays a major role in the implementation of the safety and quality system.

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1. Introduction

This thesis is attempting to shed light on the complex world of FSMS and especially GFSI Schemes and ISO 22000. ISO 22000, although is one of many certifiable FS management standards, it is the only standard that is international in nature and can be applied to all links in the food chain, from product to table. The results of empirical research have shown that internal and external reasons, related to more effective management of the FSMS and the desire to enhance a company's competitive advantage, are the main determinants of to the selection of this standard when implementing the FSMS.

In order to explore the problems and issues companies are facing in Greece while implementing ISO 22000, 44 audit reports from various food companies and distributors, were analyzed and their results were grouped in 3 groups at first, and then a second categorization occurred, according to the ISO standard.

The aim of the above analysis is to search for possible patterns in findings between companies and understand which are the major issues right now in Greece, regarding food safety management systems implementation and control, and to show the differences between ISO 22000 and GFSI Standards, the implementation of which would be a huge improvement for Greek companies.

2. Theoretical Background

Food processing and manufacturing businesses around the world began to realize, in the 1990's, that the state of food safety was not what it should be. With food supply rapidly globalizing and a number of well-publicized food safety crises emerging, consumer confidence was falling fast. In order to address the issue, retailers tried to increase the numbers of food safety audits, as their customers demanded them. No good solutions were at hand at that point.

The problem was that first-, second- and third-party audits were not well-structured and did not offer what retailers expected. First-party audits were not consistent among suppliers, when second-party audits were expensive for retailers and a huge problem for suppliers who had to endure a different audit from each customer. Lastly, the primary issue with third-party audits was that auditors had widely variable expertise and credentials.

So, in 2000, in order to resolve the above issues, the heads of many international corporations met and decided to create the Global Food Safety Initiative (GFSI). GFSI would be accepted by major retailers around the world, as Walmart, Target and McDonald's, and also work as a standard for third-party auditors. GFSI was the result of a market-driven approach, as the suppliers would prove to any retailer that they had been found acceptable by a credentialed auditor to a well-known standard (Patil & Greenlee, 2019).

2.1 The GFSI foundation

The foundation on which the GFSI standard was built on, is Hazard Analysis Critical Control Points, also known as HACCP. HACCP is the fundamental principal of GFSI and the very first requirement in order to procced in any GFSI scheme.

HACCP was firstly created in the late 60s by NASA, the US Army labs and the Pillsbury company, in order to prevent food related illnesses among astronauts when being in space. Almost 20 years later HACCP began to be widely accepted and in 1993 it was recognized by both the World Health Organization and World Trade Organization and the "Guidelines for the Application of the Hazard Analysis Critical Control Point System" were also published as a food safety standard by the Codex Alimentarius Commission (Weinroth et al., 2018).

HACCP has since been evolved and remains the foundation of all safety plans, mainly because it is focused on avoiding hazards throughout the production and not only in the final product.

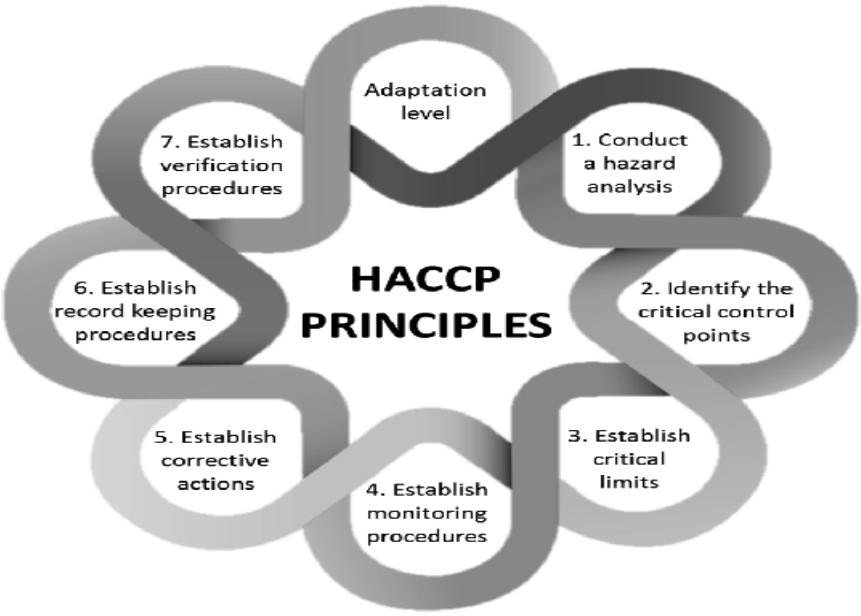


Image 1: The 7 principles of HACCP as described in Codex Alimentarius (Infantes et al., 2020)

2.2 Benefits of GFSI

Companies that have adopted GFSI schemes have seen uncountable benefits and rewards. The biggest benefit lies in the fewer product recalls and holds, things that result to fewer food waste in general. It is crucial for a company to eliminate its recalls, as it is proven that recalls cause an excessive damage to the company's image, status and wealth. According to a study in the US by the Food Marketing Institute and the Grocery Manufacturers Association, the average cost of a recall to a food company is $10M in direct costs, in addition to brand damage. The most important problem though is that these products may pose safety risk issues to the public (Dai et al., 2020).

Another benefit is that GFSI schemes provide to the supplier an attractive marketing policy as many retailers refuse to buy from suppliers without GFSI certification. Last but not least, consumer's health is protected from any kind of food related danger.

Image 2: The 5 benefits of the GFSI certification according to companies who have been GFSI certified at over 800 manufacturing locations across 21 countries ((Roop, 2016), *https://mygfsi.com/blog/gfsi-a-tide-that-raises-all-ships/)*

2.3 GFSI Schemes

Within the GFSI certification, there are many schemes to choose from. The right choice must be made according to the company's needs and philosophy. The GFSI umbrella includes all the platforms that are presented in Image 3. Many of those have been developed for certain food groups, such as fish and meat, while others concern specific countries or continents, like Canada, Japan and Asia. The standards that are going to be discussed in this study are those that apply to every food group and any country.

Image 3: The different GFSI certification schemes (Patil & Greenlee, 2019)

2.3.1 IFS standard (International Featured Standards)

The definition of IFS is the following: "IFS has been developed to ensure that the food safety and quality requirements (product specifications, customer focus, etc.), as well as applicable regulatory requirements in the products' country of destination are complied with" (IFS, 2020).

IFS certification applies when products are "processed" or when there is a hazard for product contamination during primary packing. Nonetheless, the standard is important for all food manufacturers, especially those with private labels.

The main objectives of the standard according to the company are:

- To create a common standard with a single evaluation system
- For companies to collaborate with accredited certification bodies and certified auditors
- To ensure comparability and transparency throughout the supply chain
- To reduce costs and time for both manufacturers and retailers

All the above aim to help the manufacturers to thrive in every aspect of the production.

2.3.2 BRC standard (British Retail Consortium)

The BRC standard provides a framework to manage product safety, integrity, legality and quality, and the operational controls for these criteria in the food and food ingredient manufacturing, processing and packing industry (BRCGS, 2020).

BRC was the first standard to be GFSI-benchmarked and tends to be the most used one in the United Kingdom and Western Europe. It is also the first one to define food fraud and offer a food safety culture assessment.

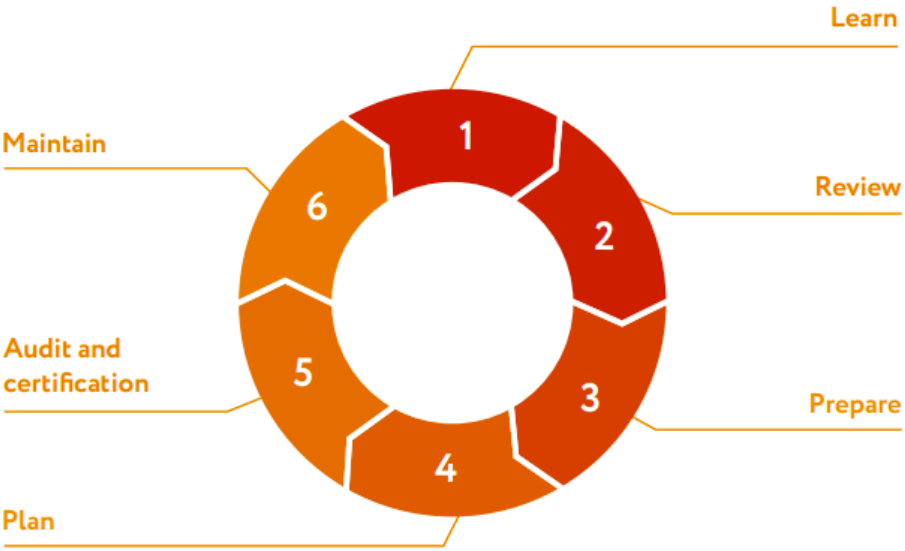


Image 4: The basic steps to get a BRC certification according to the company (BRCGS, 2019)

2.3.3 PrimusGFS (Global Food Safety)

PrimusGFS is another quality standard that concerns produce sector products, from growing operations to minimally-processed (fresh-cut) food. The principle of the standard is that quality and safety need to be a primary concern not only for processed goods, but also for the produce sector.

The GFSI recognition of the PrimusGFS Certification assists moving the produce industry one step closer to the desired goal of global food safety harmonization (primusGFS, 2020).

2.3.4 Global GAP (Good Agricultural Practices)

Global GAP is a certification regarding 3 scopes of production: crops, livestock and aquaculture. It includes more than 40 standards and is the world's leading farm assurance program.

Some of its objectives are sustainable agriculture, assurance of food safety, worker and animal welfare and responsible use of water and pesticides (Global GAP, 2020).

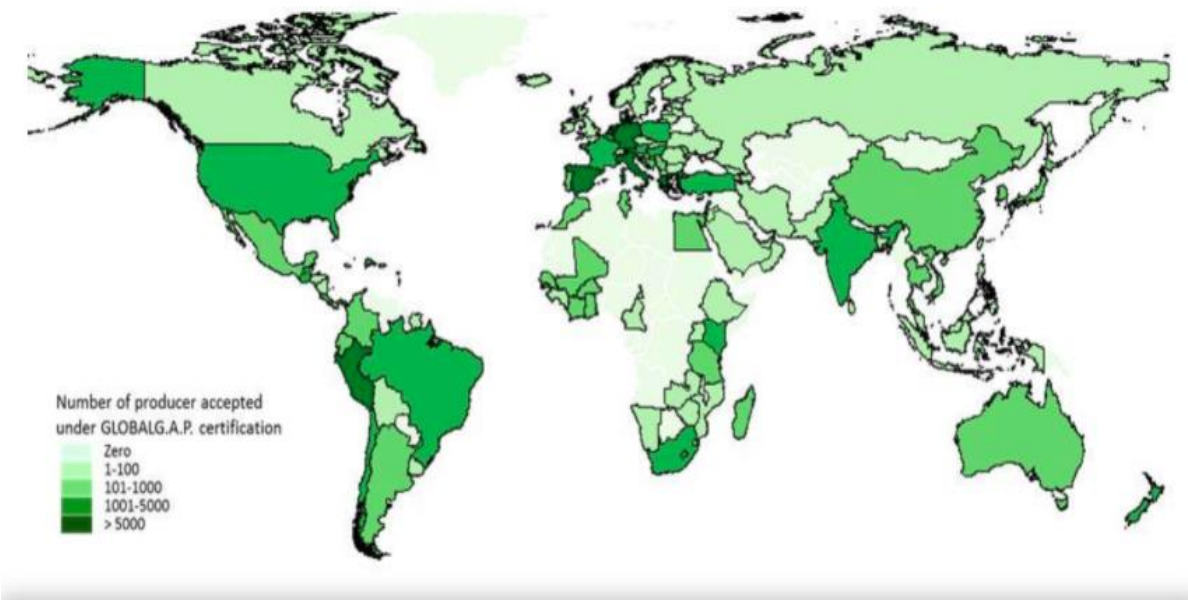


Image 5: Geographic variation in the diffusion of Global GAP (Masood, 2012)

2.3.5 SQF (Safe Quality Foods)

This standard was developed in Australia in 1994 and is a unique one, mostly because it consists of 2 modules. The one module is general and applicable to every manufacturer as it has to do with food quality and safety. The additional module is specific and has to do with the type of the food produced, for example dairy, meat, fish, etc. (Patil & Greenlee, 2019). It is essential that SQF is the only standard that applies to the entire supply chain (primary production to packaging) and also requires an on-site practitioner to implement and maintain the standard.

Image 6: Part of a marketing campaign for the SQF standard from 2016 (FMI, https://www.fmi.org/blog/view/fmi-blog/2016/04/07/why-seek-sqf-certification)

2.3.6 FSSC 22000 (Food Safety System Certification)

The last GFSI approved standard is FSSC 22000, which is a combination of ISO 22000, prerequisite programs (PRPs) and some additional requirements of its own. It is a standard that guarantees the safety of every food product and also services like catering and transport of food. According to the creators of the scheme, it offers: food safety, protection against food fraud and food risks, food defense and food traceability (FSSC 22000, 2020).

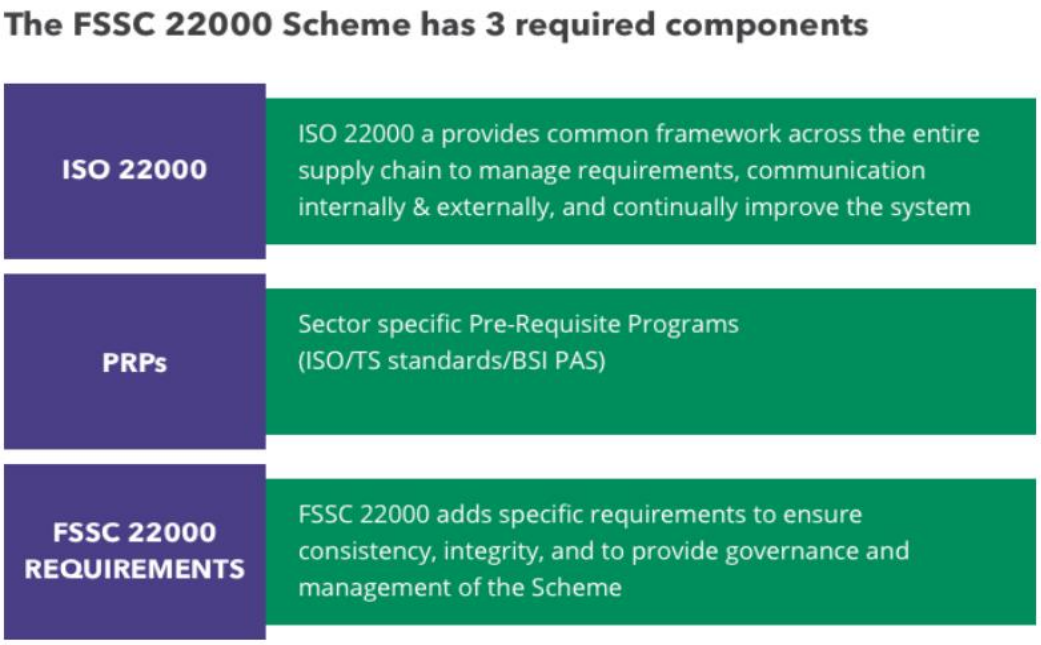


Image 7: The three key-components to the FSSC 22000 scheme (FSSC 22000, 2020, *https://www.fssc22000.com/scheme/)*

2.4 Achieving ongoing GFSI Schemes compliance

Choosing the correct scheme and becoming certified are only the two first steps in developing a robust GFSI program. Every company must ensure ongoing compliance through continuous audit preparedness, vendor management, scheduling and monitoring required activities, and performance trending for ongoing improvement. Each of these activities is essential for compliance, but performing them regularly can become time-consuming and resource-intensive.

To reduce the administrative burden, more and more companies are deploying technology to manage their GFSI certification requirements. Automated task scheduling and workflows can save a significant amount of time, while also verifying all tasks are completed. Additionally, online portals can simplify data retrieval, while companies can also use equipment data extraction to ensure efficiency and accuracy. All the above help to manage one of the major issues of companies, non-conformances and Corrective and Preventive Actions (CAPAs) (Sansawat & Muliyil, 2011).

2.5 ISO 22000 versus GFSI Schemes

ISO 22000 and GSFI schemes are all international standards and relate to the most important components for ensuring food safety and high-quality food products. But there are some important differences when comparing ISO 22000 to GFSI standards.

GFSI schemes and especially FSSC 22000 use ISO 22000 as a requirement for the management system. However, the GFSI standards contain additional requirements, including the Pre-Requisite Program (PRP), or universal procedures used to control the operating conditions in food factories and the specific requirements of the GFSI scheme to ensure consistency, integrity and management of the system itself. Another core difference is that GFSI schemes has unannounced audits, unlike ISO 22000. This helps to maintain the quality and safety system and keeps the quality team engaged with all the daily activities that have to do with the product's safety and quality. The main difference between these two certifications however, is that the ISO standard, is not recognized by the GFSI. GFSI recognition demonstrates that the scheme meets the highest standards globally leading to international food industry acceptance.

In conclusion, GFSI schemes are the next step for companies that are already ISO certified and want to achieve maximum certification.

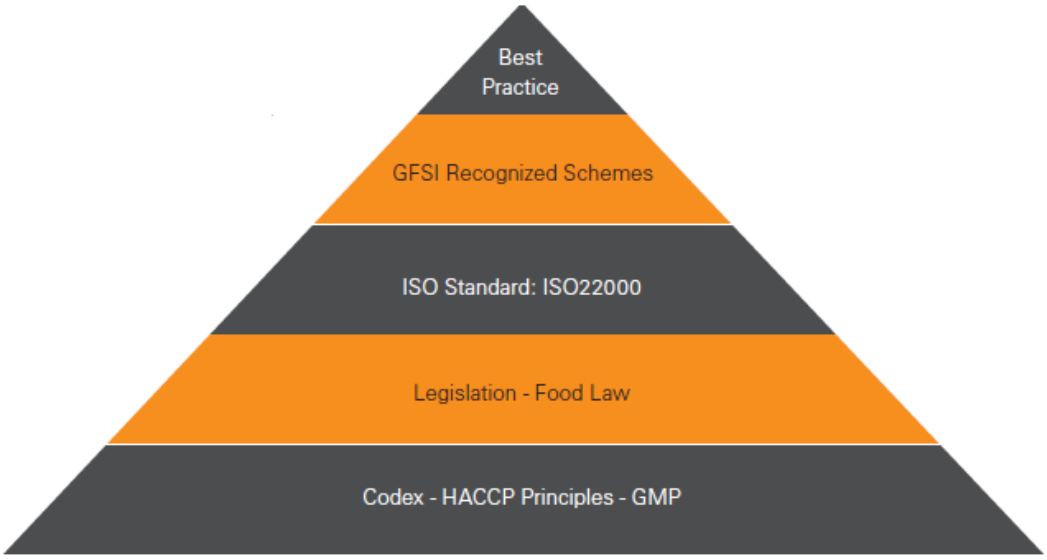


Image 8: The third-party certification pyramid (Sansawat & Muliyil, 2011)

2.6 Non-Conformances (NC)

There are 3 commonly recognized types of NCs when certified for a GFSI scheme, the same that appear in ISO 22000 standard:

1. Major NCs: A failure to fulfil one or more requirements of the management system of the standard, that raises doubt about the capability of the management system to achieve the expected food safety outcomes in the food chain or to effectively control the process for which it is intended. A major NC shall be issued when the finding affects the capability of the management system to achieve the intended results. Regarding NCs, companies must provide evidence of a root cause analysis and proposed corrective action plan within a specific number of days according to the standard they imply.
2. Minor NCs: A failure in a requirement of the management system which does not affect the capability of the management system to achieve the intended results. The handling of minor NCs is exactly the same with major NCs, except for the fact that they can be issued in a larger number of days.
3. Critical NCs: A critical nonconformity is issued when a direct food safety impact without appropriate action by the organization is observed, when legality and/or certification integrity are at stake. When a critical nonconformity is issued at a certified site the certificate shall be immediately suspended.

Non conformances can occur in every procedure the standards cover. Those are:

- Documentation
- Management system
- Communication with interested parties
- Internal-External audits
- Training
- Product traceability and recall procedures
- Supplier management
- Food defense – security
- Product Conformance
- Calibration and maintenance
- Facilities
- Pre-requisite GMPs-GHPs

3. Materials & Methods

In the present thesis 44 audit reports from various food companies and distributors (food industries, supermarkets, hotels, hospitals), which were conducted from 2015 to 2020, were analyzed, in order to analyze the number of non-conformances (NCs) and group them, depending on the type of each NC. None of the auditees were GFSI certified and the audits from which the reports were generated, were performed against the ISO 22000:2005 standard.

In each audit report the findings were grouped in 3 major categories:

- Prerequisite programs (PRPs) NCs
- Operational prerequisite programs (OPRPs) NCs
- Systemic NCs (NCs in Critical Control Points)

3.1 PRPs

According to ISO, PRPs are the basic conditions and activities necessary to maintain a hygienic environment throughout the food chain which are suitable for the production, handling and provision of safe end products and safe food for human consumption (International Organization for Standardization, 2005).

There is a wide variety of PRPs, depending on the type of the product and the process followed. They are usually described in the industry as Good Practices, for example Good Agricultural Practice (GAP), Good Veterinarian Practice (GVP), Good Manufacturing Practice (GMP), Good Hygienic Practice (GHP), etc. PRPs are often general to the process and not focused on any particular step in the process. They also have the character that their failure does not lead to an immediate and imminent food safety risk. The importance of PRPs is depicted in the fact that some of them are even included in Regulation (EC) No 852/2004 of the European Parliament, regarding the hygiene of foodstuffs (Commission, 2004).

Some examples of PRPs are shown in Image 9.

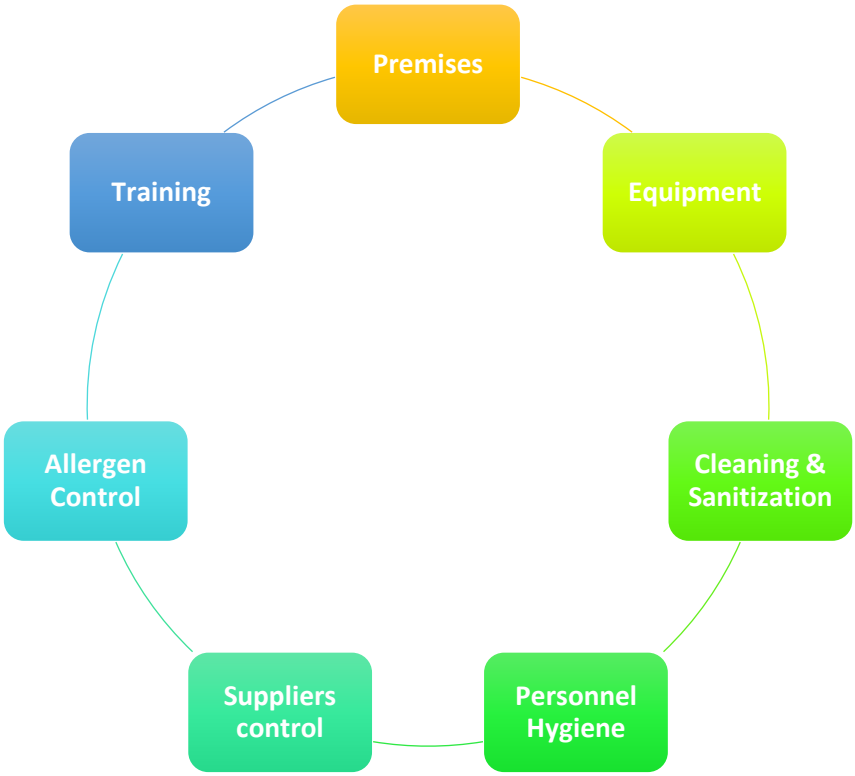


Image 9: Examples of PRPRs

3.2 OPRPs

OPRPs were firstly described by ISO 22000 as a control measure identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment (International Organization for Standardization, 2005).

OPRPs are often described as specific actions relating to the process that are not critical for food safety, but are essential in reducing the likelihood of specific hazard occurring. They are control measures that has been deemed crucial, but not considered a Critical Control Point (CCP). OPRPs are identified through risk assessment and should be treated just like a CCP. Some typical OPRP examples are:

- Temperature control
- Glass/metal control

3.3 CCPs

ISO defines CCP as any step of the process at which control measure(s) is (are) applied to prevent or reduce a significant food safety hazard to an acceptable level. Every CCP has

defined critical limits and measurements (International Organization for Standardization, 2005). Every NC that is observed in CCP is categorized as a systemic NC.

3.4 Codex Alimentarius decision tree

In order to decide if a step of a process is either PRP, OPRP or CCP, the food safety team of each facility, should follow a decision tree and answer to certain questions. The is a variety of decision trees on the market, but the most robust model build on the Codex decision tree. The tree is actually a risk assessment tool that helps to identify how significant every hazard is. Significance describes those hazards which present a real risk of impacting on the consumer. It may be said that significance is essentially an expression of risk. In food safety, risk is a measure of the combined severity of impact from a hazard and its probability of occurrence.

Overall, the tree allows for a solid and logical approach to determine control measures and will clearly show an auditor how the auditees arrived at their decisions.

3.5 ISO 22000 2018 Revision

The ISO certification 22000:2018 is quite distinct from its 2005 edition. Apart from filling the gaps, it is an ISO standard that has evolved unprecedented changes. It is of great interest that it took 13 years in order for the 2005 standard's weaknesses to be observed. The 2018 revision contains significant improvements and approaches the GSFI mindset and philosophy, through ISO perspective.

The key changes in the latest version of ISO certification 22000 are in respect of:

- **The High Level Structure (HLS)**: in order to make it easier for businesses using more than one management system standard, the new version of ISO 22000 will follow the same structure as all the other ISO management system standards, the High Level Structure (HLS). It makes it easier for organizations to obtain ISO certification of multiple ISO Standards.
- **Risk-based approach:** ISO certification 22000:2018 is now based on risk management and includes an innovative approach to trace and rule out potential risks.

The new management system standards include many novel aspects such as:

- **Animal food**
- **Control of externally provided processes, products or services**

- **Changes in definitions**: Significant modifications have been made to the terminology. Some important terms have been rephrased, such as:
  - '**Harm**' is replaced by '**adverse health effect**' to emphasize the degree of food safety hazard.
  - '**Assurance**' has been used to highlight the relationship between the consumer and health safety of the food products.

The new standard intends to cover all risks by having two separate principles working together- one is the PDCA (Plan, Do, Check, Act) approach and the other one is Hazard Analysis and Critical Control Points (HACCP). The standard emphasizes on the PDCA cycle for periodic assessment and removal of risks and also clearly expounds the HACCP strategy and clearly elaborates the differences between key terms like Critical Control Points (CCPs), the Operational Prerequisite Programs (OPRPs) and the Pre-requisite Programs (PRPs) (Chen et al., 2020). The changes are depicted in full analysis in Appendix 1.

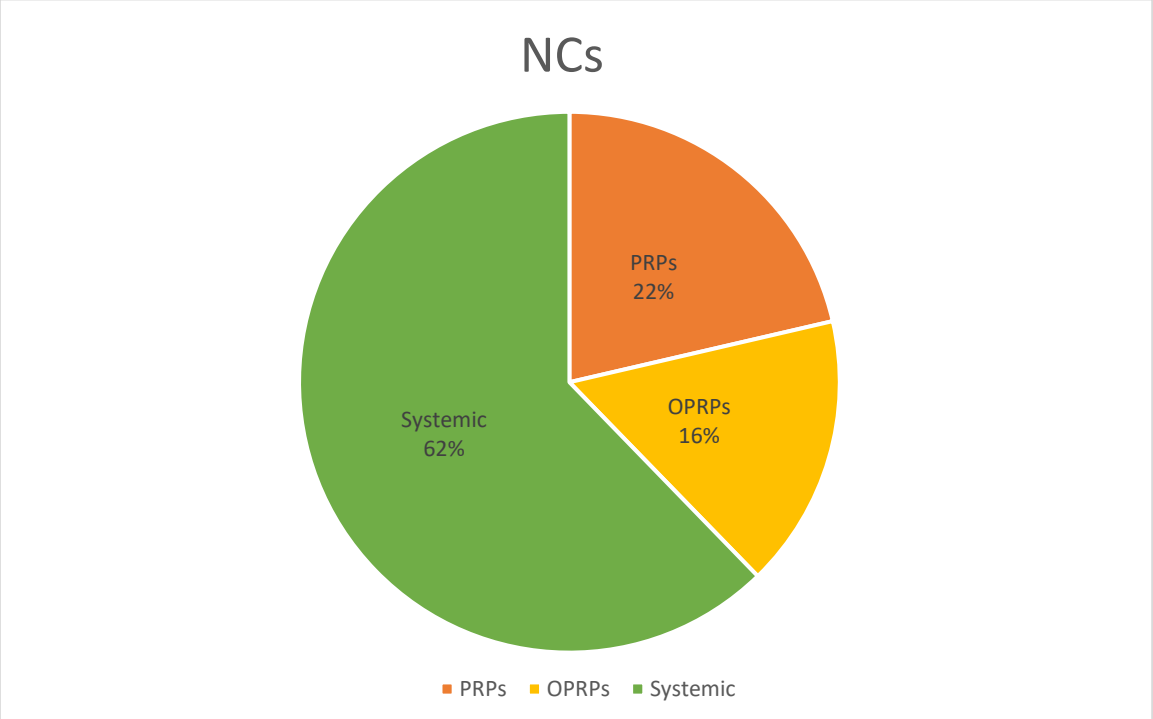
4. Results & Discussion

After analyzing the reports, there were 379 NCs in total. The results are divided among the three categories as follows:

- 81 NCs were about Prerequisite programs (PRPs)
- 62 NCs were about Operational prerequisite programs (OPRPs) and
- 236 NCs were Systemic, regarding CCPs

Out of the 44 audit reports, there was only 1 from an olive oil bottling company that had zero findings.

Figure 1: Percentage of NCs in every category



4.1 Audit reports results

In the present thesis the results will be presented and discussed grouped by the chapter of ISO 22000:2005 they belong to and not by their characterization as findings in PRPs, OPRPs or CCPs. This type of analysis is chosen due to the fact that each food industry or distributor had different PRPs, OPRs and CCPs, so the categorization according to these factors would not lead to any conclusion.

The ISO 22000:2015 chapters are:

- 4 Food safety management system
  - ➢ 4.1 General requirements

- 4.2 Documentation requirements
- 5 Management responsibility
  - 5.1 Management commitment
  - 5.2 Food safety policy
  - 5.3 Food safety management system planning
  - 5.4 Responsibility and authority
  - 5.5 Food safety team leader
  - 5.6 Communication
  - 5.7 Emergency preparedness and response
  - 5.8 Management review
- 6 Resource management
  - 6.1 Provision of resources
  - 6.2 Human resources
  - 6.3 Infrastructure
  - 6.4 Work environment
- 7 Planning and realization of safe products
  - 7.1 General
  - 7.2 Prerequisite programs (PRPs)
  - 7.3 Preliminary steps to enable hazard analysis
  - 7.4 Hazard analysis
  - 7.5 Establishing the operational prerequisite programs (OPRPs)
  - 7.6 Establishing the HACCP plan
  - 7.7 Updating of preliminary information and documents specifying the PRPs and the HACCP plan
  - 7.8 Verification planning
  - 7.9 Traceability system
  - 7.10 Control of nonconformity
- 8 Validation, verification and improvement of the food safety management system
  - 8.1 General
  - 8.2 Validation of control measure combinations
  - 8.3 Control of monitoring and measuring
  - 8.4 Food safety management system verification
  - 8.5 Improvement

(International Organization for Standardization, 2005)

4.1.1 Chapter 4 "Food safety management system''

There appeared 9 in total NCs regarding food management system. These NCs concerned bad documentation practices, like inadequate filled HACCP documents or non-updated procedures. This is a really important finding, as it is a sign that there is not daily engagement with the quality system.

4.1.2 Chapter 5.6 "Communication"

Both external and internal communication are common audit findings, as there are in total 58 NCs regarding the matter. Interestingly, 10 out of 58 NCs concern inadequate updated legislation files. It is a main responsibility of the quality team to keep up with the changes of the laws regarding food safety.

24 NCs concern the lack of specifications for raw and packaging materials, for example missing tests about migration of the packaging materials.

14 NCs concern mistakes on the finished product label. This finding is very important, as the label includes information critical to the consumers' health, like allergens presence.

Last but not least, 10 NCs were about inadequate or non-existent evaluation of vendors or services.

4.1.3 Chapter 7 "Planning and realization of safe products"

This is without any doubt the category with the most NCs. The first major issue is NCs regarding facilities. 61 NCs in total for various problems, like unsuitable equipment and doors and windows without covers. The interest of the above findings is that some issues were clearly caused by the management's and quality team's negligence, as they required very low cost in order to be fixed.

Another major issue in this category is pest control. The 31 total findings vary from deficiencies in pest control documentation to lack of hazard analysis for the pesticides used. For example, there was a major NC observed in 3 companies, where the rodent traps used were evaluated as toxic by legislation.

There also appeared 10 NCs concerning inadequate control in OPRPs. In most cases, the OPRPs were predefined, but there was not any control program established.

In addition, 7 NCs were found concerning product's traceability. The records kept in various steps of the process were inadequate and as a result the traceability of the product got lost. This a major NC, due to the fact that in any case of recovery or recall there would be a lack of information when searching for the products, or conducting a root cause analysis.

Lastly, there were 25 findings regarding finished product analysis and 9 regarding water analysis, that were inadequate according to legislation, or non-existent at all. There were 6 companies with zero final product analysis, 17 that did not check for chemical contaminants (Commission regulation (EC) No1881/2006), heavy metals, sodium nitride (Commission regulation (EC) No 1332/2008) and *Listeria monocytogenes* (Commission regulation (EC) No 2073/2005) and 2 that were selling olive oil as "extra virgin" without conducting the proper analysis to prove it.

4.1.4 Chapter 8 "Validation, verification and improvement of the food safety management system"

The analysis of the audit reports showed that there were 24 NCs regarding the calibration of instruments. This finding is very important when the instrument refers to the control of a CCP, especially for industries with ready-to-eat meals. In this analysis there were 2 findings regarding CCP control instruments.

4.2 Bibliography comparison

According to a study conducted in three western Balkan countries, Serbia, Bosnia and Herzegovina and North Macedonia, in 2011, where a total of 54 audit reports from HACCP audit (25 of them were from first stage audits, 17 from second stage audits and 12 from surveillance audits) and 15 audit reports from FSMS ISO 22000 audits (2 from first stage audits, 4 from second stage audits and 9 from surveillance audits). were analyzed, there were observed 394 NCs in total.

The majority of NCs discovered during the first stage audits are categorized under management, control, cleaning and sanitation, and cross contamination. Layout and premise structure, documentation, staff hygiene, storage, pest control, maintenance, waste management, and training were among the categories with less findings.

The major category of results in the second stage audits are in control, indicating that insufficient processes are present in managing typical food safety hazards as identified in the company's documentation. The top three categories with revealed findings are control, management, and documentation. Other categories yielded less than 10% of the total.

Control, management, maintenance and layout, and premise structure were the top four areas with the greatest findings in surveillance audits.

The majority of NCs were found in managing the HACCP-based system and different elements of food safety management, such as control of dangerous goods and recall, according to an analysis of the total number of NCs. These categories, when combined with discoveries in documentation and product specifications, account for almost 40% of all nonconformities.

PRPs and GHP requirements account for the majority of the findings (59.6%). Cleaning and sanitation are the most pressing concerns under GHP guidelines. NCs are commonly caused by insufficient procedures or a lack of verification that the chemicals employed in cleaning and sanitization procedures are acceptable for the manufacturing facility and technology. The primary concern listed under cross-contamination was allergen control.

Inadequate production plants (old buildings, bad interior structures – walls, floors, windows, doors, ceilings, lighting and ventilation, as well as old and repaired pieces of production equipment) are represented by layout and premises. Maintenance operations, including calibration, reveal that a lack of financial resources to adequately maintain the equipment is the primary cause of these findings.

In most small businesses, pest management concerns included insufficient monitoring of established pest control effectiveness or open/inadequate pest traps. Personal hygiene revealed that employers do not conduct all required medical screenings of employees and that employees do not wear appropriate protective gear. (Djekic et al., 2011).

Based on the above it is clear that the management system is one of the most common categories in which plenty of findings are observed. A trend is also visible in NCs in PRPs and facilities.

4.3 Discussion

The analysis of the audit reports shows no connection between the characteristics of the company or distributor and the findings.

Explaining the above statement, there were approximately the same NCs in companies producing sensitive products like ice cream and products with long shelf-life like olive oil. Also, there is not any connection between the size of the company and the findings. Smaller companies appear to have the same issues with larger companies.

The problem appears to be that in most cases the quality assurance team is understaffed or has inadequate knowledge on how to build a quality system tailored to the company's needs. There is also the unwillingness of the higher management to invest time and money on the quality system and make it a mindset rather than an obligation.

In 2014, a study conducted in Spain in order to understand the constraints to implement ISO 22000. The following statements were the primary barriers to ISO 22000 adoption and use: "not a necessity for doing business," "unfamiliarity," and "high expense", One of the most typical issue is the exorbitant cost of implementation and certification, especially when there is the need for hiring a certified specialist. "Not legally required" and "being unaware of its use" are two further explanations (Escanciano & Santos-Vijande, 2014).

5. Conclusion

The purpose of this thesis was to examine audit findings from certified food firms in Greece, in order to uncover quality and food safety concerns.

As the audit's reports showed, the primary concern is managing quality or food safety. As it has been proven in many studies, the top management is the main impediment to ISO implementation and certification (Withers & Ebrahimpour, 2000). Lack of management commitment, a lack of knowledge of management requirements, and a focus on certification rather than implementation instead of establishing quality and safety as mindsets, are the most common issues.

The majority of results in audits are categorized as PRPs and OPRPs requirements. This begs the issue of why some necessary initiatives were not completed prior to ISO adoption (layout and premise structure, maintenance and calibration, pest control and storage of hazardous materials). PRPs are procedures and circumstances that must be met before and while ISO is being implemented. Due to differing perspectives among industry workers, external consultants, and legal authorities, there is uncertainty between PRPs and ISO standards and their relationships, on how they should be maintained, and which obstacles should be addressed first (Ramrez Vela & Martn Fernández, 2003).

The above gaps would easily be filled in by the implementation of a GFSI system. GFSI systems tend to be more well-structured and require more actions in order to get certified. That is the reason that less companies choose GFSI certifications, as they require a bigger effort. As hard it may be to get certified by GFSI, the benefits are worth it, because the quality and safety systems that are built on GFSI standards are more stable and functional, than systems that are built on ISO 22000. After all, it is not random that ISO 22000:2018 revision tries to bring the ISO standard closer to the GFSI philosophy.

Lastly, it is recommended that further research should focus on the following:

- The maturity of the management systems and correlation between maturity and impact of findings related to managing food quality and safety
- The identification of possible patterns related to specific food industries
- The process according to which companies decide which food safety standard are going to implement

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APPENDIX 1

Clause	2005	2018	Nature of Change
		Overview of Main Changes	
Introduction			
0.1 General	One general section specifying application and aim of the standard	Benefits of the FSMS, reference to PDCA and clarification in verbal forms (shall, should, may, can) have been included	Alignment to HLS
0.2 FSMS Principles	New sub-section	Key elements moved from the Introduction section (2005) to a separate subsection. Principles common to ISO Management system standards have been included	Alignment to HLS
0.3 Process Approach	New sub-section	Process approach, PDCA cycle and risk-based thinking (including relationship with HACCP) explanations included	Alignment to HLS
0.4 Relationship with other MSS	New sub-section	Introduction to the relationship with the High Level Structure and document framework	Aligment to HLS
Food Safety Management Systems - Requirements for any organization in the food chain			
1 Scope	Existing section	General requirements are the same, but the wording had been changed for clarification or elimination of redundant terms (e.g. suppliers & customers are now all included under interested parties)	Clarification and improvement of the tekst
2 Normative references	Reference to ISO 9000:2000	Reference has been eliminated	-
3 Terms and definitions	Existing section: Definitions have been revised	Reference to ISO and IEC terminology databases has been included. Number of definitions has been increased from 17 to 45. The term **Significant food safety hazard** has been included and linked to the definition of control measures. **"Elimination"** of significant food safety hazards has been removed, leaving only reduction or prevention. Definitions of CCP's and	Revision/ improvement of the standard

		OPRP's have been enhanced with additional elements and linked to significant food safety hazards. Clarification between **validation, verification and monitoring** included. Food, Feed and animal food terms have also been included	
4. Context of the organization (New Title)			
4.1 Understanding the organization and its context	New clause	Requirements to determinte the external and internal issues relevant to the organization's purpose and ability to achieve intended results, have been included; as well as the review and update of the information	Alignment to HLS
4.2 Understanding the needs and exppectations of interested parties	New clause	Requirements to determine the needs and expectations of interested parties have been included, as well as the review and update of the information	Alignment to HLS
4.3 Determining the scope of the FSMS	Requirements for scope defintion already included in 4.1, however further requirements have been added	The term "services" has been added to the scope definition requirement, as well as "activities..... that can have an influence on the food safety of the end products of the organization". Link to requirements defined in 4.1 and 4.2 has been added when determining the scope.	Alignment to HLS
4.4 Food Safety Mgt. System	Already existing in 4.1 but more extensive than in the new version."The organization shall establish, document, implement and maintain an effective food safety management system and update it when necessary in accord-	General requirements related to the food safety management system, have been resumed in a single general clause. The word **"document"** has been removed giving an open decision how to manage the FSMS . "The organization shall establish, implement, maintain, update and continually improve a FSMS, including the processes needed and their interactions, in accordance with the requirements of this document.	Alignment to HLS

	ance with the requirements of this International Standard". Control of outsourced processes has been moved to clause 7.1		
The word d			
5.1 Leadership & Commitmment	Partially covered by clause 5.1 & 7.4.3	Responsibilites of top management have been extended, including demonstrable **leadership** and **supporting other elevant management roles**	Alignment to HLS
5.2 Policy	Partially covered by 5.2	The organization shall establish, implement, maintain, update and continually improve a FSMS, including the processes needed and their interactions, in accordance with the requirements of this document.	Alignment to HLS and Revision/ improvement of the standard
5.3 Organizational roles, responsibilities & authorities	Partially covered by 5.4, 5.5 and 7.3.2	Responsibilites and authorities for relevant roles shall also be "understood", not only defined and communicated (new requirement). Additional requirements have been assigned to top management, related to the assignation of specific responsibilities and authorities within the FSMS.	Alignment to HLS
6 Planning (New Title)			
6.1 Actions to address risks and opportunites	New clause	New requirements added related to determining risks and opportunities, actions to address them and their planning . **Important Note added** (6.1.1.) to clarify the concept of risks and opportunities in the context of the standard (events and their consequences relating to performance & effectiveness of the FSMS)	Alignment to HLS

6.2 Objectives of the FSMS and planning to achieve them	Partially covered by 5.3	Additional specific requirements for the definiton of objectives have been incorporated (SMART), as well as requirements related to the planning to achieve them. **New requirement**: Food safety, statutory, regulatory and customer requirements shall be taken into account when defining objectives.	Alignment to HLS
6.3 Planning of Changes	Partially covered by 5.3	The general requirement in clause 5.3 (V2005) has been extended to include additional considerations when planning and carring out changes within the FSMS	Alignment to HLS
7 Support (New Title)			
7.1.1 General	Partially covered by clause 6.1	**Consideration of capability & constraints of existing resources** as well as the need for external resources in the determination of resources needed, has been added as a requirement	Revision/ improvement of the standard
7.1.2 People	Partially covered by 6.2, 6.2.2.	Separated as a sub-clause under resources, requirements applicable to external experts have been included under this subclause. Definition of competency in the agreement/contracts with external experts has been added.	Revision/ improvement of the standard
7.1.3 Infrastructure	Partially covered by clause 6.3	Wording has been changed slightly and a note added	Revision/ improvement of the standard
7.1.4 Work Enviroment	Partially covered by clause 6.4	Wording has been changed slightly and a note added, in the note, the social part has been included	Revision/ improvement of the standard
7.1.5. Externally developed elements of the FSMS	Partially covered by 1	Specific requirements applicable to externally developed elements have been introduced under this clause	Revision/ improvement of the standard

7.1.6 Control of externally provided processes, products or services	Partially covered by 4.1	Version 2005 required the definition and documentation of the control of outsourced processes, however under version 2018 the requirements have been extended to also providers of products and services. Requirements have also been enhanced and made more specific. Requirements for **evaluation , selection, monitoring of performance/ re evauation of external providers** have been added as well as requirements for **adequate communicatio**n. **Performance of external providers** has also been added as an input for Management Review.	Revision/ improvement of the standard
7.2 Competence	Partially covered by clauses 6.2.1, 6.2.2, 7.3.2. No , all the information is in chapter 6.2.2 of the iso 22000-2005.	Food safety team competence has been included under this clause, scope of necessary competence includes now also specifically external providers. Requirement for personnel responsible of the operation of the hazard control plan has been changed from "trained" to "competent". Awareness requirements have been moved to clause 7.3. Requirements related to personnel understanding of effective communication has been moved to clause 7.4	Alignment to HLS and Revision/ improvement of the standard
7.3 Awareness	Partially covered by 6.2.2. No , all the information is in chapter 6.2.2 of the iso 22000-2005.	Awareness requirements previously mentioned in clause 6.2.2 e) have been moved to clause 7.3 and extended with specific awareness related to the food safety policy, objectives (relevant to their tasks), improved safety performance and implications of non-conforming with the FSMS requirements.	Alignment to HLS
7.4.1 Communication - General	Partially covered by 6.2.2	Additional requirements regarding the scope of the internal and external communications have	Alignment to HLS

		been added. Understanding of effective communication requirements have been included under this clause.	
7.4.2 External Communication	Partially covered by 5.6.1	Additional requirements have been added in regards to the external communication related to customers/consumers. The term "suppliers" has been subtituted by "external provider". The issues that need to be communicated are now to be defined in a previous step (clause 7.4.1) by the organization, thus they are not longer restricted only to issues concerning food safety, but all communication relevant to the FSMS.	Revision/ improvement of the standard
7.4.3 Internal Communication	5.6.2 All existing requirements have been maintained	"Personnel qualification" has been substituted by "competencies" g).	Revision/ improvement of the standard
7.5.1 Documented Information General	Partially covered by 4.2.1, 5.6.1,	Requirement for documented information required by statutory, regulatory authorities and customers has been added. Documented statements of the food safety policy and objectives are not longer mentioned separatedly under this clause, however the requirements for this documents are stated under 5.2.2. and 6.2.1	Alignment to HLS
7.5.2 Creating and Updating	Partially covered by 4.2.2	Requirement made applicable to all types of documented information (including records). Requirements for identification, description and format	Alignment to HLS
7.5.3 Control of documented information	Partially covered by 4.2.2, 4.2.3	Scope extended for all types of documented information	Alignment to HLS
8 Operation (New Title)			
8.1 Operational Planning and Control	Partially covered by 7.1a and covered in the chapter 8.3 and 8.5.2	The requirements originally included under 7.1 were extended to take into consideration the implementation of actions de-	Alignment to HLS

		fined to address risks and opportunities (6.1). Responsibiity of the organization to take under control the planned & unintended changes, as well as outsoruced processes has been added int his clause	
8.2 Pre-Requisite programs	Partially covered by 7.2	Wording has been changed slightly and appropriateness of the PRP linked to the context of the organization. Reference to consider ("should") the applicable ISO/TS document in the definition of PRP has been added. Supplier approval and product information/consumer awareness have been included in the list of minimal PRP needed by the organization. PRP's Documented information shall now also specify their selection, applicable monitoring and verification.	Revision/ improvement of the standard
8.3 Traceability system	Partially covered by 7.9	Wording has been changed, minimum requirements when establishing a traceability system have been added (including reworking). Requirement for verification and testing of the effectiveness of the traceability system has been added. A note has been added regarding the reconciliation of quantities of end products & ingredients.	Revision/ improvement of the standard
8.4 Emergency preparedness and response	Partially covered by 5.7	Responsibility is still assigned to top management. Word "accidents" has been changed to "incidents". A requirement for documented information regarding the management of these situations has been included. Procedures to respond to these situations are still required	Revision/ improvement of the standard

8.5.1 Preliminary steps to enable hazard analysis	Partially covered by 7.3 Description of process steps and control measures (7.3.5.2) has been replaced by Description of process and process environment, and the scope of the requirements has been extended to include additional descriptions such as: layout of premises and processing equipment among other things. Variations from expected seasonal changes & shift patterns shall also be included.	Requirements related to the competence of the Food Safety Team have been relocated to Clause 7.2 Competence. **General:** Minimum relevant information to be considered when conducting the HA has been added. **Characteristics Raw Material**: "Source (e.g. animal, mineral or vegetable)" has been included in the list of characteristics of raw materials and clarification given in regards to "place of origin". **Characteristics end product: wording such as Methods of distribution and delivery** has been added in the list of characteristics of the end product. **Flow Diagrams**: Inputs and Ouputs to be detailed in the flow diagrams have been extended and the on-site vertification requirements described separatedly in a sub-clause.	Revision/ improvement of the standard
8.5.2 Hazard analysis	Partially covered by , 7.4,	**Hazard identificacion & acceptable levels**: internal epidemiological/ scientific/ historical data shall also be used as an input in the identification of hazards, as well as statutory/regulatory/customer requirements. Clarification Notes have been added. Recommendation to consider hazards in sufficient detail has been added. Requirement to use the pre-defined flow diagram has been added(in alignment to the Codex). **Hazard Assessment:** The word "elimination"of food safety hazards has been removed. Requirement to identify significant food safety hazards has been included.	Revision/ improvement of the standard

		Selection of control measures: The word "elimination"of food safety hazards has been removed and the wording "significant food safety hazards"has been added to the scope of application of this sub-clause. Also clarification on control measures to be managed as OPRP(s) or as CCPs, (replacement of the words HACCP plan, CCP and OPRP to be managed via a Hazard Control Plan). Inputs for conducting the assessment & categorization of control measures have been extended to include also feasibility of establishing measuring Critical limits and applicability of timely corrections. External requirements that can impact the choice and strictness of control measures shall be documented.	
8.5.3 Validation	Partially covered by 8.2 and 7.6	Wording has been changed to clarify that validation applies to both: single control measures and combinations of control measures. Requirement to maintain the validation methodology and evidence of capability has been added.	Revision/ improvement of the standard
8.5.4 Hazard Control Plan	Partially covered by 7.5 and 7.6	The HACCP plan and OPRP document have been combined in a single document called Hazard Control Plan. Requirements for both OPRP and CCP (monitoring, critical limits/action criteria/ corrections/corrective actions) have been combined under this clause (8.5.4) "Action Criteria" definition has been included as a requirement for OPRP as well as specific requirements to define them. The input of "monitoring meth-	Revision/ improvement of the standard

		ods" has been added as an additional option next to monitoring devices. For OPRP's, equivalent methods of verification of reliable measurements are now permitted in place from calibration methods. Requirements for actions to be taken are not only applicable for when critical limits are not met but also when action criteria is not met.	
8.6 Updating the information specifying the PRP and Hazard control plan	Partially covered by 7.7	Change in wording to subsitute HACCP Plan & OPRP for Hazard Control Plan. Additional information has been added in the outputs of the update process	Revision/ improvement of the standard
8.7 Control of monitoring and measuring	Partially covered by 8.3	The scope of application of 8.7 has been clarified: methods and equipment related to PRP and hazard control plan. Frequency of calibration/verification has been modified to "specified intervals prior to use". Requirements for validation of software used in monitoring and measuring within the FSMS have been added, including documented information in validation activities. updates and management of changes of the software.	Revision/ improvement of the standard
8.8 Verification related to PRP and the hazard control plan	Partially covered by 7.8, 8.4.2	The activities to be covered by the verification activities have been extended: effectiveness of PRP's has been added and hazard control plan has been included in place of HACCP plan/ oprp. Requirement for impartiality of person conducting the verification has been added (not the same person that performs the monitoring). Application of corrective actions	Revision/ improvement of the standard

		has been included in case potentially unsafe product is detected via the verifcation activities	
8.9 Control of product and process nonconformities	Partially covered by 7.10	**Corrections/ Corrective Actions: Actions to review the NC** identified by regulatory inspections reports & consumer complaints have been added. The term "action criteria" has been defined as a trigger of corrections/ CA. The wording "evaluating the need for action to ensure that non conformities do not recur" has been replaced by "determining & implementing actions to ensure...". **Handling of potentially unsafe products:** Wording slightly changed. Requirement clarified for evaluating each lot of affected product. Requirement added for not releasing product affected by failure to meet critical limits at a CCP, leaving the evaluation for release only applicable to products that fail to comply with the audit criterion of an OPRP. Requirement added to retain as documented information the results of the evaluation of release. An additional potential disposition of NC product has been added (redirected for other use) & requirement to retain documented information. **Withdrawal/ recall**: Separation bewteen withdrawal and recall has been made, applicability for requirements under 8.9.5 is for both processes	Revision/ improvement of the standard
9. Performance Evaluation (new title)			

9.1 Monitoring, measuring, analysis and evaluation	Partially covered by 8.4.2, 8.4.4 + new subclause	**General:** New requirements introduced related to the organization responsibility to detemine the measuring & monitoring processes having as goal the evaluation of the performance & effectiveness of the FSMS.	Alignment to HLS
9.2 Internal Audits	Partially covered by 8.4.1	Inputs for generating the audit program have been extended: changes in the FSMS & results of monitoring and measurement shall be taken into account to develop the audit program. Requirement added to ensure that the results of the audit are reported to the FS Team & relevant management. Requirement added related to determining if the FSMS meets the intent of the food safety policy & objectives as part of the internal audit process.	Alignment to HLS and Revision/ improvement of the standard
9.3 Management Review	Partially covered by 5.2, 5.8	Mgt. Review inputs: The structure and number of inputs for the management review have been ammended. Additional inputs have been included and a number of inputs grouped under a general input of "information on the performance & effectiveness of the FSMS". Mgt. Review Outputs have also been ammended to include specific actions/decisions related to continual improvement opportunities and the need for updates & changes in the FSMS	Alignment to HLS and Revision/ improvement of the standard
10. Improvement			
10.1 Non conformity and corrective action	New	New clause specifying requirements to deal with Non Conformities within the organization, including the requirement to determine if similar non conformities could potentially occur (preventive actions)	Alignment to HLS

10.2 Continual Improvement	Partially covered by 8.1 , 8.5.1	Requirement extended to include the improvement of the suitability and adequacy of the FSMS, besides the effectiveness. Wording of inputs changes due to the inclusion of new titles of the clauses (e.g. analysis of resuts of verification activities)	Alignment to HLS and Revision/ improvement of the standard
10.3 Update of the FSMS	8.5.2	Wording changes slightly according to new terms & titles.	Revision/ improvement of the standard

Source: FSSC 22000 Foundation “ISO 22000 Gap Analysis”