Programa de Doctorado en Ciencias de la Alimentación

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FOODSIMPLEX – SEGURIDAD ALIMENTARIA EN PEQUEÑAS Y MEDIANAS EMPRESAS DE RESTAURACIÓN

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CERTIFICAN

La licenciada en Dietética y Master en Higiene y Seguridad en el Trabajo **Ana Lúcia Baltazar dos Santos** ha realizado bajo su dirección el trabajo que lleva por título

FOODSIMPLEX – SEGURIDAD ALIMENTARIA EN PEQUEÑAS Y MEDIANAS EMPRESAS DE RESTAURACÓN

y autorizan su presentación para optar al título de Doctor por la Universitat de València.

Y para que así conste, expiden y firman el siguiente certificado.

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RESUMEN

En la actualidad, los restaurantes ponen a disposición de la población trabajadora la principal fuente de alimentos listos para comer. En Portugal, los establecimientos de restauración son principalmente quioscos, pequeñas y medianas empresas con recursos insuficientes para cumplir con las normas de seguridad alimentaria. Estas empresas representan un punto de trasmisión de enfermedades infecciosas alimentarias y un problema de salud pública. Esta tesis tuvo como objetivo evaluar una metodología basada en el Análisis de Peligros y Puntos de Control Críticos (APPCC), denominada FoodSimplex, y aplicada en restaurantes durante un período de cuatro años. FoodSimplex es un conjunto de métodos implementados en cuatro etapas, con auditorías de seguridad alimentaria, capacitación del personal y análisis microbiológicos. Los resultados iniciales muestran una higiene y unas prácticas de manufactura deficientes en la auditoría, mala calidad microbiana de las superficies y de las manos de los trabajadores, y la contaminación de los alimentos con bacterias aeróbicas mesofílicas y Listeria monocytogenes. Al final del estudio, la metodología FoodSimplex demostró una mejoría estadísticamente significativa, hacia el cumplimiento de las normas de seguridad alimentaria en los parámetros de referencia. Lo que demuestra la efectividad del método, con el fin de promover la seguridad alimentaria en los restaurantes y paliar el problema de salud pública detectado.

PALABRAS CLAVE: salud pública, seguridad alimentaria, restaurantes, auditoría, calidad microbiológica

ABSTRACT

Actually, restaurants provide to a working population the leading source of ready-to-eat food. In Portugal, mass catering establishments are mainly micro, small and medium companies with insufficient resources to comply with food safety regulations. As so, these companies represent a foodborne disease focus and a public health issue. This investigation aimed to assess a Hazard Analysis Critical Control Point based methodology, FoodSimplex, applied in restaurants during a four year period. FoodSimplex is a combination of four stages methodology with technical-functional and food safety audits, training and microbial analysis. The initial results show inadequate hygiene and good manufacture practices in audit, poor microbial quality of surfaces and food handler hands' and food contamination with mesophilic aerobic bacteria and *Listeria monocytogenes.* At the end of the study, FoodSimplex application demonstrated a statistically significant improvement towards food safety compliance in the referenced parameters, attesting the effectiveness of the method in restaurants by providing food safety and a reducing the detected public health issue.

KEYWORDS: public health, food safety, restaurants, audit, microbial quality

Para ser grande, sê inteiro: nada

Teu exagera ou exclui.

Sê todo em cada coisa. Põe quanto és

No mínimo que fazes.

Assim em cada lago a lua toda

Brilha, porque alta vive.

"Odes de Ricardo Reis"

Fernando Pessoa

To my grandfather,
whom I will carry in my heart forever

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Abbreviations

American Public Health Association	**APHA**
Bacillus cereus	***B. cereus***
Bovine spongiform encephalopathy	**BSE**
Clostridium botulinum	***C. botulinum***
Clostridium perfringens	***C. perfringens***
Clostridium perfringes enterotoxin	***CPE***
Critical Point	**CP**
Critical Control Point	**CCP**
Department of Food safety, Zoonoses and Foodborne Diseases	**FOS**
Disability-adjusted life years	**DALYs**
Enteropathogenic *Escherichia coli*	**EPEC**
Enterotoxigenic *Escherichia coli*	**ETEC**
Escherichia coli	***E. coli***
Essential Public Health Operations	**EPHO**
European Action Plan	**EAP**
European Food Safety Authority	**EFSA**
European Member States	**EMS**
European Union	**EU**
Foodborne diseases	**FBD**

Foodborne Diseases and the Foodborne Disease Burden Epidemiology Reference Group	**FERG**
Food and Drug Administration	**FDA**
Food business operators	**FBO**
Food safety audit	**FSA**
Food safety management	**FSM**
Food safety management system	**FSMS**
General Food Law	**GFL**
Good Manufacturing Practice	**GMP**
Gross Domestic Product	**GDP**
Hazard Analysis and Critical Control Point	**HACCP**
Hemolytic uremic syndrome	**HUS**
Listeria monocytogenes	***L. monocytogenes***
Micro, small and medium enterprises	**SME**
National Advisory Committee on Microbiological Criteria for Foods	**NACMCF**
Pre-requisite program	**PRP**
Staphylococcus aureus	***S. aureus***
Shiga toxin-producing *Escherichia coli*	**STEC**

Technical/functional audit	**TFA**
United Kingdom	**UK**
United States of America	**USA**
World Health Organization	**WHO**

CHAPTER I – INTRODUCTION

1.1 BACKGROUND

The food offered outside of home increased, mass catering establishments such as restaurants, canteens, schools, hospitals and catering enterprises started throughout the years to have higher attendance (Regulation (EU) nº1169, 2011). This matter arises the concern about the safety of the meals that are served, do the food business operators (FBO) have the means to comply with the European Union regulation? Do micro, small and medium enterprises (SME) have the technical and scientific support ensure that the food they serve is safe?

Billions of meals are prepared each day safely throughout the world, but 22% outbreaks of foodborne diseases (FBD) were reported in Europe, all had their origin in processed foods and catering establishments (Powell *et al*., 2013; Garayoa *et al.*, 2011). FBD continue to be a significant public health concern in developed countries due to the number of people affected annually and the economic losses for the companies (Garayoa *et al.*, 2011). It is estimated that millions of people have had an FBD at least once. Health agencies associate these numbers with the consumption of meals in restaurants (Medeiros, Cavalli & Proença, 2012). The outbreaks in these cases cause emotional, physical and financially devastating results to all the intervenient, clients and business management (Powell *et al.,* 2013).

The mass caterer sector has grown in recent decades, and several factors have been identified, such as increased number of individuals living in urban areas, distance from home/work, increased percentage of women in the workplace, raised financial power and dietary concerns (Medeiros, Cavalli & Proença, 2012; Baptista & Linhares, 2005).

The economic activity of catering in Portugal embraces (I) the preparation and sale activities of food products for consumption, usually on site or in other establishments that do not produce those products; (II) the actions of preparation of meals or dishes delivered and/or served at the place determined by the customer for a specific event; (III) the supply activities and, where appropriate, the preparation of meals and drinks to well-defined groups of people, like public collectivities (hospitals, schools, elderly places, etc.). It includes canteens and military spaces; it also provides for the provision of meals based on a contract for a given period; (IV) the sales activities of drinks and small snacks for consumption on the premises with or without spectacle (Bank of Portugal, 2011).

To ensure food safety by the catering sector was introduce in the European food law a new concept in the food market, "from farm to

fork", by designing cross accountability to all stakeholders in the food chain (Garayoa *et al.*, 2011; Veiros *et al.,* 2009). The catering sector assigns a significant role to entrepreneurs, considering them primarily responsible for food safety (APHORT, 2008).
The European Union (EU) has created legal tools to ensure food hygiene in the sector, as well as official entities in charge of controlling and inspecting establishments to safeguard public health (Veiros *et al.,* 2007). European Regulations on the hygiene of foodstuffs were created to ensure restaurants must obey with general hygiene requirements (Regulation (EU) nº852/2004; *Codex Alimentarius*, 2003).

The need and obligation to produce safer food go to the inevitable implementation of efficient food safety systems along the entire food chain from production, to shipping and to distribution, namely a system based on the Hazard Analysis and Critical Control Points (HACCP) system (Sun & Ockerman, 2005).

This preventive system requires a strategic approach to the stages of production /serving, based on the identification of inherent hazards such as biological, chemical and physical (Regulation (EU) n. º 852/2004).

The HACCP system is a defensive system resulting from the application of scientific and technical principles. It is an essential tool for identification and analysis of critical points (CP) at different stages of the process while allowing the establishment of the necessary means to control these points and apply preventive monitoring. The HACCP system stands for proactivity instead of reactivity (Forsythe & Hayes, 1998). Although manufacturers have used the HACCP system successfully for many years, it has been less frequent in SME, especially those in the foodservice sector. There are considered to be some barriers which SME find particularly difficult to overcome (Charalambous *et al.*, 2015; Panisello & Quantick, 2001).

In Portugal, there are two kinds of situations that can increase food safety concerns. Namely, most of the small and medium restaurants management are from the family business, which means that old bad practices and premises keep going throughout the years. On the other hand, nowadays, like in other European countries, to reduce bureaucracy and facilitate the establishments of the new food business, the restaurant's premises only need registration, without pre-approval inspection, to start working (Haukijärvi & Lundén, 2017). As so, the restaurants' FBO is responsible for managing hygienic-sanitary quality and for providing safe food to clients, and most of the times they don't have the knowledge and the technical support to implement a food safety system or the financial ability to pay external professional care (Medeiros, Cavalli & Proença, 2012).

1.2 FOOD SAFETY

Food is vital for life, as so it must be safe to ingest. Food is characterized as edible substances whether in a natural or manufactured state which forms part of the human diet (Will & Guenther, 2007). Understanding the necessity of access to healthy and nutritionally foods is essential for all (Nyamari, 2013).

Food safety is a broader term, but it outlines the assurance that food will not cause any harm to the consumer when it's prepared and eaten according to its intended use (Nyamari, 2013). Safe food is defined as "a product which contains no physical, chemical or microbial organisms or by-products of those organisms which if consumed by man will result in illness, injury or dead" (Edelstein, 2011). It can be achieved through the utilisation of numerous resources and strategies to ensure that all types of foods are properly stored, prepared and preserved so that they are safe for consumption (WHO, 2015).

The history of food safety is as old as humanity (Baltazar, 2016; Griffith, 2006); all humans understood that some foods are naturally toxic (Griffith, 2006). Along the history probably by “trial and error” it became clear that food could be preserved by applying conservation techniques such as salting, drying, among others (Baltazar, 2016).

The human eating patterns, habits and foods changed, and food safety became more formalised. Throughout history, governments, have approved legislation to protect consumers and much of this early legislation was based on the need to prevent adulteration of food (Griffith, 2006). The link between food safety and microbiology only started to be seen, as a tip of the iceberg, in the 1800s when the heating process started with Appert, followed by Pasteur and by the combination of knowledge’s in medicine (Table 1). Food microbiology began linked to the development and shelf life of the products rather than concerning about food safety (Baltazar, 2016; Griffith, 2006).

After several years of experience in food safety combined with food microbiology and the latest molecular biology techniques, and it might be erroneously assumed that issues with food safety would have been resolved. However, the reports affirm that FBD cases had increased (Griffith, 2000; Redmond & Griffith, 2003).

Table 1. Food Microbiology timeline (adapted from Griffith, 2006).

1870-1890	Various	Food Processing
1890s	Various	Dairy Bacteriology
1892	Koch, Salmon and others	Veterinary Microbiology
1895	Russell	Food Processing/Microbiology
1900-1928	Russell	First textbook of Dairy Bacteriology
1930s/1940s	Various	Food Microbiology
1944-1958	Frazier	One of the first food microbiology textbooks
1957	Scott and others	Food Processing/Microbiology
1971-2006	Baumann and others	Molecular Approach to Food Microbiology and the dawn of the HACCP era Recognition of previously unknown foodborne pathogens – *Campylobacter*, *Listeria*, Norovirus, Prions and Mad Cow Disease

In the scientific review by Griffith, 2006 the main factors to this increase in developed countries are namely, changing patterns of food consumption; proper/incorrect use of new cooking equipment; more varied cuisine (e.i. ethnic foods); change in cooking/shopping practices (monthly rather than daily); decreased use of preservatives and less processing; more people eating out; reduced consumer immunity (higher number of children, pregnant, elderly, imunossuprimed individuals); more significant gap between the stage of production and the consumption; more massive FBD consumer awareness; changes in agricultural practices; evolution of existing and new food pathogens; failure to accept responsibility; government and food industry failures; consumer negligence/ignorance; failures in management practices and lack of multidisciplinary research approach (Baltazar, 2016 Redmond & Griffith, 2003; Griffith, 2000).

These many factors should have been the reinforce to adapt food safety throughout the times and to create a more dynamic system and food laws to ensure the primally request for food consumption, safety.

1.2.1 FOOD SAFETY: A PUBLIC HEALTH PRIORITY

Public health has been defined as “the art and science of preventing disease, prolonging life and promoting health through the organised efforts of society” by Acheson in 1988 (Royo-Bordonada & Román-Maestre, 2015). The state of Public Health is measured by morbidity and mortality by the rates at which illnesses and deaths occur in the population (Wagstaff, 1986).

To define public health, it should begin by examining what is the mean “public”. The “public” is usually thought of as a population or subgroup of people who share a profile, often identified by a geographic and temporal location (Fakruddin, Mannan & Andrews, 2013; Martinez *et al*., 2006; Miyagishma *et al.*, 1995). The target of preventive health care is usually the public since its methodology is based on the validity of individuals. In the other hand is the curative measures that deal with sick individuals. In other words, any public health-oriented approach should have in its scope the public as an object either suffering from the same pathology or subject to the same health risk inherent in their lifestyles, living conditions, or other conventional factors. As so, Public Health as two primary focus, one is the promotion of health and prevention of diseases and the other is the treatment of diseases and rehabilitation of disorders (Fakruddin, Mannan & Andrews, 2013; Martinez *et al*., 2006; Motarjemi *et al.*, 1996; Miyagishma *et al*., 1995). The original definition of public health is positioned food safety as a sub-domain, is one of the preventive approaches to health and cannot be free from trends regarding the changing nature of the public and the ever-growing health gaps between population groups (Fakruddin, Mannan & Andrews, 2013; Martinez *et al*., 2006; Miyagishma *et al.*, 1995). Food safety is distinctive among the various public health programs, it is multidisciplinary and multi-sectoral nature, it can be interpreted as both an advantage and a disadvantage, that results in a blend of voluntary and mandatory approaches which have no counterparts in other programs (Fakruddin, Mannan & Andrews, 2013; Martinez *et al*., 2006; Miyagishma *et al.*, 1995; Motarjemi *et al.*, 1996).

The accumulated advances in food safety can be seen in the control and prevention of communicable diseases. Over the past hundred years, better scientific understanding of food safety hazards and their power, including the application of the food technology has contributed to even safer food supply, at least in industrialised countries. Several FBD such as cholera, typhoid and paratyphoid fevers, have been virtually eliminated in the developed world (Miyagishma *et al.*, 1995). However, every year approximately 600million people become ill after consuming contaminated food, among these victims, an estimated number 420.000 die, including 125.000 children under the age of 5years (Zanin *et al.*, 2017).

Public health has improved markedly since the passage of the food safety laws. Some of the most significant gains have been in reduced mortality from infectious diseases transmitted through foods and beverages and from nutritional deficiencies. Various kinds of evidence may be cited to address the question concerning the relationship between food safety regulations and public health (Royo-Bordonada & Román-Maestre, 2015; Fakruddin, Mannan & Andrews, 2013; Martinez *et al*., 2006; Wagstaff, 1986):

- Time sequence. Improvements in public health notably decrease in reported death rates from food-transmitted diseases, followed the enactment of the food safety laws.
- The consistency of the relationship between different groups of people. Food-related diseases are higher among people of lower socioeconomic status in the USA who do not get the full benefit of the food safety laws.
- The absence of deleterious effects. There has been no indication that food safety regulatory activities have had any detrimental impact on public health.

The conclusion is that food safety regulatory activities have contributed to improved public health, in a broader sense, evaluation of public health data raises general points that can be applied to food safety activities (Royo-Bordonada & Román-Maestre, 2015; Wagstaff, 1986).

The World Health Organization (WHO) European Region recognise as the main challenges facing public health in the twenty-first century namely economic crisis; widening inequalities; an ageing population; increasing levels of chronic disease; migration and urbanisation; and environmental damage and climate change (WHO, 2018). As a result of these dares, the WHO Regional Office for Europe has adopted the European Action Plan (EAP) for Strengthening Public Health Capacities and Services. Of the ten essential public health operations (EPHO), is EPHO 3 that focuses on “Health protection including environmental, occupational, food safety and others” until 2020.

1.2.2 FOODBORNE DISEASES (FBD)

Safety and health problems have always occupied an obvious place in the concerns of human beings, as can be seen when looking at the Maslow human needs scale (Matias *et al*., 2013).

FBD are a commonly preventable burden of illness worldwide (Havelaar *et al.*, 2015; Jones & Angulo, 2006). Every human is susceptible to infections and intoxications, although some percentage of the population are at higher risk than others.

The more frequent types of FBD result from infections, when an individual eats food containing a viable organism that multiplies in the body, and intoxications, from eating food that contains a substance that poisons the body. However, other types affect only a select portion of the population, for example:

- Allergies that occur when food includes an element to which the consumer is hypersensitive (generally an adverse immune mechanism);

- Metabolic disorders (some called intolerances) that involve an individual's inability to process food components that are successfully digested by others;
- Idiosyncratic illnesses, events that may or not be caused by elements of food that affect some individuals in means that are not yet understood.

The concept of FBD may cause some confusion in the literature due to some identical terms, like food poisoning and foodborne illness (Griffith, 2006; O Cliver & Riemann, 2002). For this study, FBD will be used as defined by the WHO unless alternative terms are mentioned within the references. FBD, by WHO, refers to every food and waterborne illness regardless of the symptoms and includes "illness of an infectious or toxic nature caused by, or thought to be caused by the consumption of food or water" (WHO, 2015; Griffith, 2006;).

FBD are a burden globally to public health and every nation's economy (Hoelzer *et al*., 2017; Martins, Hogg & Otero, 2012; Moreb, Pryadarshini & Jaiswal, 2017; Copenhagen, 2015; Young & Wadell, 2016). They are a cause of morbidity and mortality worldwide but the full extent and cost of unsafe food, and especially the burden arising from chemical and parasitic contaminants in food, is still unknown (Havelaar *et al.*, 2015). The FBD caused by microbiological hazards are a large and growing public health

problem, most countries with systems for reporting foodborne disease have documented significant increases (EFSA, 2018; Hoelzer *et al*., 2017).
The epidemic outbreaks have alerted public health authorities to the looming problem of FBD; they are threatening any country, regardless of its stage of development, and affect mainly the risk populations (Hoelzer *et al*., 2017; Motarjemi & Käferstein, 1999).

A significant obstacle to adequately addressing food safety concerns is the lack of accurate data on the full extent and cost of FBD, which would enable policymakers to set public health priorities and allocate resources. Epidemiological data on FBD remain scarce, particularly in the developing world. Even the most visible foodborne outbreaks often go unrecognised, unreported or uninvestigated, and may only be visible if connected to primary public health or economic impact (Hoelzer *et al.*, 2017; Motarjemi & Käferstein, 1999).

The problem of FBD is not a new public health problem, but FBD had taken an original length at the end of the 20th century, both regarding the magnitude and regarding health consequence. Many factors related to the food style, the health system and demographic situation, lifestyle, the health system and infrastructure, and the environmental conditions of the country influence their prevalence, increase and health consequences (Table 2) (Motarjemi & Käferstein, 1999). The FBD depend from country to country as well, because of the food habits, food processing, preparation, handling, storage and population knowledge (ICMSF, 2006).

It represents a worldwide concern, across the WHO European Region, FBD are common, even in the most developed countries, and pose an essential burden for public health. Outbreaks of FBD have economic inferences, involving commercially produced food products. WHO/Europe supports nations in structure capacity to manage food safety challenges from food handling and production at any level, including those stemming from increased international trade (WHO, 2018).

Table 2. The incidence of FBD - influence factors (adapted from Park, Park & Bahk, 2018; Hussain & Dwason, 2013; Gould *et al*., 2013; Quinlan, 2013; Kirezieva *et al*., 2013; Kendrovski & Gjorgjev, 2012; Motarjemi & Käferstein, 1999)

The rate of FDB - influence factors	
Food Supply System	Intensive agriculture and animal husbandry practices leading to increased contamination of raw foodstuffs and increased use of pesticides and veterinary drugs
	International trade and import of potentially contaminated food
	A longer food chain as a result of urbanisation, leading to more significant opportunities for contamination survival and growth.

The rate of FDB - influence factors	
Food Supply System	Booming food service establishments where food handlers do not necessarily have any training in food hygiene.
Health and demographic situation	Population growth
	Increase in some vulnerable groups, e.g. the elderly, immunocompromised individuals and malnourished persons.
	Increase in some displaced persons and refugees often in a condition of poor health and nutrition as a result of human-made or natural disasters (e.g. wars, floods, earthquakes, etc.).
	Rapid urbanisation, in some areas without the necessary water supply and sanitation infrastructure
The social situation, behaviour and lifestyles	Increased consumption of food outside the home with a subsequent increase in the number of food service establishments.
	Increased travel and exposure to unsafe food.
	Changes in food preparation habits as a consequence of changes in family structure
	Poverty and lack of education
	Changed social and cultural behaviour leading to a preference for certain types of hazardous food
	Lack of time and striving for increased economic profits.
	Lack of training and education of food handlers and consumers in food safety
Health system and infrastructure	A decrease in resources with a simultaneous increase in the number of food businesses which require supervision guidance and control.
	Continued lack of water supply and sanitation as well as of fuel for cooking in some parts of the world, inadequate education and training of health workers in food safety, with the subsequent incapacity of the country to implement adequate and relevant health educational activities in the area of food safety

The rate of FDB - influence factors	
Health system and infrastructure	Weaknesses in the investigation and surveillance of foodborne diseases and monitoring of contaminants leading to a consequential chain of problems, such as lack of information about food safety problems and priorities, incapacity to evaluate the impact of food safety interventions, and lack of awareness of public health authorities of the magnitude and the consequences of foodborne diseases
	Availability and access to health technologies, including food technologies and telecommunication, etc.
Environmental conditions	Increase of environmental pollution
	Climatic conditions and changes

One of the biggest FBD challenges is their underestimation, precise information on the burden of FBD is needed to adequately inform policy-makers and allocate appropriate resources for food safety control and intervention efforts. In order to fill this data vacuum, in 2015, WHO - Department of Food Safety, Zoonoses and Foodborne Diseases, together with its partners launched the Initiative to Estimate the Global Burden of Foodborne Diseases and the Foodborne Disease Burden Epidemiology Reference Group (FERG) and published a first estimate of the global impact of foodborne illnesses (WHO, 2015), based on 2010 data (Hoelzer *et al*, 2017; WHO, 2015).

The data suggest that about 600 million cases of foodborne illnesses and 420000 associated deaths occur globally each year caused by 31 key known pathogens. Leading causes of foodborne deaths include infections with (i) non-typhoidal Salmonella (approx. 59,000 deaths), (ii) Salmonella Typhi (approx.52,000 deaths), (iii) Enteropathogenic E. coli (about 37,000 deaths), and (iv) Norovirus (approx. 35,000 deaths) (Hoelzer *et al*, 2017, WHO, 2015). This report used the case rates for these major pathogens to estimate the burden of FBD across world's population, measured regarding "healthy" life lost due to premature mortality and disability and express regarding "disability-adjusted life years" (DALYs) (WHO, 2015).

The data collected found considerable regional differences in the burden of FBD. The highest burden per 100000 population was witnessed in the African subregions, 2,500 DALYs. In the South-East Asian subregions the burden was 690 and 710 DALYs/100,000 population, correspondingly, and in the Eastern Mediterranean subregion, EMR D, 570 DALYs. The lowest burden was detected in the North American subregion AMR A (35 DALYs), trailed by the European subregions EUR A, EUR B and EUR C, and the Western Pacific subregion WPR A, which were all in the range of 40–50 DALYs. Other subregions (AMR B and AMR D, EMR B and WPR B) had intermediate burdens, all in the field of 140–360 DALYs (Hoelzer *et al*, 2017, WHO, 2015).

1.2.3 MICROBIOLOGICAL AGENTS

The majority of FBD have either a bacterial or viral aetiology (Linscott, 2011). Foodborne pathogens contaminate food during production and processing, but also during storage and transport. These pathogens are mostly bacteria and fungi, but also some viruses, prions and protozoa (Table 3) (Martinović *et al.*, 2016; Linscott, 2011). During their growth, these microorganisms can produce different components, including toxins, into the extracellular environment. Other harmful substances can also be liberating and can contaminate food after the disintegration of food pathogens. Some bacterial and fungal toxins can be resistant to inactivation and can survive harsh treatment during food processing (Martinović *et al.*, 2016).

Table 3. Common causative agents of FBD.

<table>
<tr><th>Organism</th><th>Incubation period</th><th>Signs and symptoms</th><th>Epidemiology</th><th>References</th></tr>
<tr><td>Bacillus cereus – preformed enterotoxin, emetic type</td><td>1 to 6 h</td><td>Sudden onset of nausea and vomiting, with or without diarrhoea</td><td>Cooked foods, like meat or fried rice that have not been adequately refrigerated</td><td rowspan="2">Osimani, Aquilanti & Clementi, 2018

Organji et al., 2015</td></tr>
<tr><td>Bacillus cereus - diarrheal type</td><td>8 to 16 h</td><td>Abdominal pain with diarrhoea</td><td>Variety of foods from meat, vegetables, pasta, desserts, cakes, sauces, milk</td></tr>
</table>

Organism	Incubation period	Signs and symptoms	Epidemiology	References
Campylobacter jejuni	2 to 5 days	Fever, abdominal cramping, diarrhoea with or without blood; Guillan-Barre syndrome can be seen in some individuals.	Raw and undercooked poultry, unpasteurized milk, contaminated water	Fiztgerald, 2015 Humphrey, O'Brien & Madsen, 2007
Clostridium botulinum – preformed toxin	12 to 72 h	Abdominal cramping, náusea, vomiting, diarrhoea, double vision; death or long-term nerve damage may be seen.	Improperly canned foods, herb-infused oils, baked potatoes in aluminium foil	Dahsten, Lindström & Korkeala, 2015 Membré *et al.*, 2015
Clostridium botulinum – infant	3 to 30 days	Floppy baby syndrome – lethargy, weakness, poor head control; constipation, poor feeding and sucking reflexes	Honey, home-canned vegetables and fruits, corn syrup	Dahsten, Lindström & Korkeala, 2015 Membré *et al.*, 2015
Clostridium perfringens – toxin	8 to 16 h	Diarrhoea, abdominal cramping and nausea	Meat, poultry, gravy, inadequately reheated food	Huang, Li & Hwang, 2018 Lindström *et al.*, 2011

Organism	Incubation period	Signs and symptoms	Epidemiology	References
Enterohemorrhagic *E. coli* – O157: H7 and other Shiga toxins	1 to 8 days	Bloody diarrhoea, abdominal pain and vomiting; fever may be absent; hemolytic uremic syndrome.	Undercooked beef, unpasteurized milk and fruit juices, raw fruits, and vegetables	Saedi *et al*., 2017 Vila *et al*., 2016
Listeria monocytogenes	9 to 48 h (gastrointestinal) 2 to 6 week (invasive disease)	Diarrhoea, fever, muscle ache, and nausea; pregnant women may have mild flu-like symptoms, and infection may lead to premature delivery or stillbirth. Meningitis and sepsis may be seen in elderly or immunocompromised individuals.	Unpasteurized milk, soft cheese made with unpasteurized milk, ready-to-eat deli meats and hot dogs.	Hamidiyan *et al*., 2018 Buchanan *et al*., 2017 Auvolat & Besse, 2016
Salmonella spp.	1 to 3 days (non-Typhi) 3 to 60 days (Typhi)	Non-Typhi: diarrhoea, fever and abdominal cramps Typhi: Fever, chills, anorexia, malaise, constipation and myalgia	Contaminated eggs; poultry; unpasteurized milk, dairy products, or juice; contaminated raw fruits and vegetables	Besser, 2018 Jarvis *et al*., 2016 Mukhopadhyay & Ramaswamy 2012 Silva & Gibbs, 2012

Organism	Incubation period	Signs and symptoms	Epidemiology	References
Shigella spp.	24 to 48 h	Diarrhoea (+/- blood and mucus), fever, and abdominal cramps	Food or water contaminated by faecal material; food contaminated by an infected person	Lee & Kang, 2016 Ahmed & Shimamoto, 2015
Staphylococcus aureus (preformed enterotoxin)	1 to 6 h	Sudden onset of nausea and vomiting and abdominal cramps; fever and diarrhoea may be present.	Unrefrigerated or improperly refrigerated meats, potato and egg salads or cream pastries	Rubad *et al.*, 2018

Symptoms of FBD may include nausea, vomiting, and diarrhoea, which typically last for 2 to 3 days in most individuals. However, severe complications can occur from FBD in individual patients may include stillbirths, hospitalisation due to sepsis, hemolytic uremic syndrome, Reiter's syndrome (reactive arthritis), Guillan-Barré syndrome (nerve paralysis), and death (Martinović *et al.*, 2016).

1.2.3.1 Bacillus cereus (*B. cereus*)

B. cereus is a facultative anaerobic, gram-positive, spore-forming bacterium, rod-shaped widely distributed in the environment due to its ability to resist hostile conditions (Osimani, Aquilanti &

Clementi, 2018; Organji *et al.*, 2015). *B. cereus* is considered a mesophilic microorganism, with a temperature range for growth between 10 and 50 °C (with an optimum between 28 and 37 °C). However, a few strains can multiply below 7 °C and above 45 °C. *B. cereus* spores are moderately heat-resistant and survive to freeze and dry. Some strains require heat activation for spores to germinate and outgrow (Forsythe, 2010; Tewari & Abdullah, 2015).

B. cereus is abundant; the living cells can be found in soil, water, vegetables, putrefying matter, animal's intestinal tract and insects. It is a common food contaminant present in different types of raw food such as rice, meat, vegetables, raw milk, dairy products as well as cooked dishes (Osimani, Aquilanti & Clementi, 2018; Organji *et al.*, 2015).

B. cereus sensu stricto is the causative agent of two types of gastrointestinal diseases: a) an intoxication (emetic syndrome) due to to a heat-stable and small molecular weight toxin (cerulide) performed in the food, and b) an infection (diarrheal syndrome) due to the ingestion of viable cells, which produce enterotoxins in the small intestine (Osimani, Aquilanti & Clementi, 2018; Organji *et al*, 2015).

B. cereus has been implicated in various foodborne outbreaks worldwide, the infections have a short duration and are self-limiting without recognised post-illness (Osimani, Aquilanti & Clementi, 2018; Schmid *et al*., 2013). Due to lack of sufficient surveillance, *B. cereus* food poisoning may be primarily underreported, and probably confused with Staphylococcus aureus and Clostridium perfringens food poisoning due to similar symptoms (Organji *et al.*, 2015).

The European Union summary report described a total of 287 outbreaks caused by B. cereus toxins, 3073 cases, with 8% hospitalisation cases, in European Member States (EMS), in 2014. Data from 2015 reported 291 outbreaks involving 3131 cases (with 3% hospitalisation) in nine EMS (EFSA, 2016). In 2017, EFSA reported 20 outbreaks caused by bacterial toxins including toxins produced by *Bacillus, Clostridium* other than *Clostridium botulinum* and *Staphylococcus* and other unspecified bacterial toxins (EFSA, 2018).

1.2.3.2 *Campylobacters*

The *Campylobacter* genus consists of a large and diverse group of bacteria currently comprising 26 species (Fitzgerald, 2015). The pathogenic species of man also have a slightly narrow temperature range for growth with a maximum temperature of ~46 °C and a minimum of 30 °C. Campylobacters are zoonotic pathogens. Most infections are caused by *Campylobacter jejuni* and *C. coli* although in the developing world *C. upsaliensis* is also essential (Humphrey, O'Brien &Madsen, 2007). *C. jejuni*, *C coli*, *Campylobacter lari,* and *Campylobacter upsaliensis* form a genetically close group and are known as the thermotolerant campylobacters because they grow optimally at 42°C (Fitzgerald, 2015).

C. jejuni and *C. coli* present an interesting dilemma. They can cause severe disease in infected people but are carried in the intestinal tracts of all types of domestic livestock and wild animals, almost always without any harmful effects. This carriage does have significant consequences for human health regarding FBD (Humphrey, O'Brien & Madsen, 2007).

Campylobacter species, in particular, *C. jejuni*, are the most common causes of human foodborne bacterial gastroenteritis in the industrialised world (Han *et al.*, 2016; Bronzwaer et al., 2009; Frost, 2001). It is accepted that chickens are natural hosts for *C. jejuni*, and colonised commercial broiler chickens are the primary vector for transmitting this pathogen to humans (Han *et al.*, 2016; Hermans *et al*., 2011).

For 2017, human campylobacteriosis data were reported by 27 EMS with 246,158 confirmed cases. The highest country-specific notification rates in 2017 were observed, as in previous years, in the Czech Republic (230.0 cases per 100,000), Slovakia (127.8), Sweden (106.1) and Luxembourg (103.8). The lowest rates in 2017 were observed in Bulgaria, Cyprus, Latvia, Poland, Portugal and Romania (≤ 5.8 per 100,000) (EFSA, 2018).

1.2.3.3 *Clostridium botulinum (C. botulinum)*

C. botulinum is a strictly anaerobic, Gram-positive, mesophilic, rod-shaped spore-forming bacterium, which can form endospores that are highly resistant to harsh environmental conditions (Peck & van Vliet, 2016; Dahsten, Lindsström & Korkeala, 2015). Various molecular and physiological approaches shown that *C. botulinum* strains are divided into four groups that produce the most potent biological toxin known to man, the botulinum neurotoxin. The foodborne botulism may be caused by consuming as little as 50 ng of neurotoxin (Peck & van Vliet, 2016; Smith, Hill and Raphael, 2015) formed by a strain of Group I or Group II, or more rarely by a strain of neurotoxigenic *C. baratii* or *C. butyricum* (Peck & van Vliet, 2016).

Group I *C. botulinum* strains are mesophilic, and their optimal growth temperature is commonly reported as 35-40°C. The minimum and maximum growth-limiting temperatures are classically reported to be 10 and 50°C, respectively. *C. botulinum* strains belonging to Group II differ substantially from those belonging to Group I in their physiological characteristics in contrast to the mesophilic Group I strains, Group II strains are psychrotrophic, their optimal growth temperature is reported as 26-30°C. These phenotypic characteristics present a considerable risk in minimally processed, ready-to-eat foods with extended shelf lives (Dahsten, Lindsström & Korkeala, 2014).

1.2.3.4 *Clostridium perfringens (C. perfringens)*

C. perfringens is a spore-forming, anaerobic, Gram-positive pathogen and can be considered as a significant pathogen. The main reasons are the most widely distributed pathogenic microorganism in nature, has spores that can be found in humans and animals intestinal tracts, soil, water, and many ingredients and raw materials used to make meat and poultry products; as a notorious for fast growth and it produces over 15 toxins to cause a range of different diseases in humans and animals (Huang, Li & Hwang, 2018; Lindström *et al.*, 2011).

C. perfringens spores are reasonably resistant to heat and can survive heating temperatures usually used to prepare and cook meat and poultry products. Once the spores are germinated, the vegetative cells can grow in a wide range of temperature between 10 and 52°C (Huang, Li & Hwang, 2018).

C. perfringens is a diverse species, with its strains being divided into five types, A-E, according to the significant toxins they produce. A and C strains have been associated with human diseases these include FBD, antibiotic-associated diarrhoea, sporadic diarrhoea, sudden infant death syndrome that are caused by *C. perfringens* enterotoxin (CPE), gas gangrene due to alpha toxin and human necrotic enteritis, also called pig bel, due to beta toxin (Lindström *et al.*, 2011).

CPE-mediated food poisoning is among the most common foodborne illnesses in the industrialised countries. Outbreaks typically involve a large number of victims and are associated with temperature-abused meat or poultry dishes. Optimal conditions for food poisonings arise when food contaminated with CPE-positive *C. perfringens* spores is slowly chilled or held or served at a temperature range of 10-54°C, allowing germination and rapid growth of *C. perfringens*. Upon ingestion of large numbers of vegetative *C. perfringens* cells, they sporulate in the intestinal lumen and produce CPE (Huang, Li & Hwang, 2018; Lindström *et al.*, 2011).

1.2.3.5 *Escherichia coli (E. coli)*

E. coli is the most-studied microorganism; it is both a common commensal inhabitant of the gastrointestinal tract and one of the most important pathogens in humans. E. coli are facultative anaerobic gram-negative bacteria naturally present in humans and animals as part of the intestinal microflora. Some strains can cause disease ranging from mild to chorela-like diarrhoea any lead to potentially fatal complications such as hemolytic uremic syndrome (HUS). The *E. coli* groups related to FBD are enteropathogenic *E. coli* (EPEC), enterotoxigenic *E. coli* (ETEC), enterohemorrhagic *E. coli* (EHEC) and enteroinvasive *E. coli* (EIEC) (Vila *et al.*, 2017; Saeedi *et al.*, 2017; Heredia, Wesley & García, 2009*)*. EHEC, also referred to as Shiga toxin-producing E. Coli (STEC), is responsible for severe human infections, the serotype 0157: H7 is the one that has been implicated most frequently in FBD outbreaks worldwide (Saeedi *et al.*, 2017).

E. coli has growth and survival characteristics very similar to those of other enteric organisms; it survives to freeze at -20°C and can survive cold storage, being able to grow at a minimum temperature of 6.5°C (Heredia, Wesley & García, 2009).

1.2.3.6 *Listeria monocytogenes (L. monocytogenes)*

The genus *Listeria spp*. Is gram-positive, non-sporulation, rod-shaped bacteria, facultatively anaerobic, comprises 17 species and are psychotropic bacteria widely distributed in the natural environment (Hamidiyan *et al.*, 2018; Phraephaisarn *et al.*, 2017). The ability to grow across a broad range of temperature (0 – 45°C) and external stress such as extreme pH (4.4 – 4.9), having water activity above 0.92, salt concentrations up to 14% osmotic stress tolerance, and survival under mild preservation treatment have introduced *Listeria spp*. As critical foodborne organisms (Hamidiyan *et al.*, 2018). Among the species, *L. monocytogenes* is widely associated with listeriosis in humans and one of the most critical FBD (Hamidiyan *et al.*, 2018; Phraephaisarn *et al.*, 2017). Clinical invasive infection by *L. monocytogenes*, listeriosis, is rare in healthy humans however, there are subgroups of the population that are more vulnerable to disease, the immuno-compromised (such as cancer, diabetes, chronic hepatic disorder, transplant recipients, immunosuppressive therapy, cirrhosis, and Acquired Immune Deficiency Syndrome), pregnant women, unborn or newly delivered infants and elderly, > 65 years old (Hamidiyan *et al*, 2018; CDC, 2016; Phraephaisarn *et al*, 2017).

Even though a wide variety of food may be contaminated with *L. monocytogenes*, outbreaks and sporadic cases of listeriosis are predominantly associated with ready-to-eat foods (Hamidiyan *et al.*, 2018; Phraephaisarn *et al.*, 2017; Preußel *et al*., 2015).

The number of cases of listeriosis reported in the EU has increased, in 2015, the number of confirmed human cases of listeriosis published in the EU was 2206 (0.46 cases per 100,000 population), which was similar to 2014. In 2015, nineteen-member states reported 270 deaths due to listeriosis, which was the highest annual number of deaths reported since 2008 (EFSA, 2016). In a systematic review of the literature, de Noordhout *et al*., 2014 estimated the case fatality rate was 23.5%. The susceptibility of older people is of concern in the UK due to its ageing population (Harper, 2016).

1.2.3.7 *Salmonella* spp.

Salmonella bacteria are gram-negative, rod-shaped bacilli that is one of the most common causes of food poisoning. Llow numbers of this microorganism in foods can cause illness (Silva & Gibbs, 2012; Mukhopadhyay & Ramaswamy, 2012). The bacterial genus Salmonella has only two species, *enterica* and *bongori*, but the *Salmonella* family includes more than 2300 serotypes. *Salmonella Enteritidis* and *Salmonella Typhimurium* are the most commonly identified serotypes in the incidence of Salmonellosis (Silva & Gibbs, 2012; Mukhopadhyay & Ramaswamy, 2012).

Animals used for human food consumption can be carriers of numerous serovars of *Salmonella*, some of which can cause disease in humans, although they may not cause illness in the carrier animals (Jarvis *et al.*, 2016). It can grow at temperatures within the range 8 °C to 45 °C, in foods of pH between 4 and 9, and water activity higher than 0.94 (Madden *et al*., 2018). The contaminated foods from animal origin such as undercooked/raw meat or poultry, fresh eggs, food products containing raw eggs, raw or under-pasteurized milk/dairy (e.g. butter, ice cream, cheese) and also a few vegetable based food products, can convey Salmonella and other pathogens from animals to humans, causing illness (FDA, 1992). Additionally, the ingestion of contaminated water, the use of contaminated water to irrigate crops or to wash fresh foods, can also cause human salmonellosis (Silva & Gibbs, 2012).

A higher proportion of *Salmonella* cases (52% of non-typhoidal and 37% of typhoidal *Salmonella* cases) than other enteric pathogens are thought to be foodborne, most of which are potentially preventable once vehicles are identified. *Salmonella* is responsible for 180 million, or 9% of the diarrheal illnesses that occur each year globally (Besser, 2018).

1.2.3.8 *Shigella* spp

Shigella is a gram-negative pathogenic bacterium belonging to the family *Enterobacteriaceae* responsible for illness outbreaks of shigellosis worldwide (Lee & Kang, 2016). *Shigella* is divided into four species by serogroup: *Shigella dysenteriae* (serogroup A), *Shigella flexneri* (serogroup B), *Shigella boydii* (serogroup C), and *Shigella sonnei* (serogroup D). All serogroups of *Shigella* are pathogenic, but each one shows different epidemiology (Lee & Kang, 2016; Ahmed & Shimamoto, 2015).

Shigellosis is an acute enteric infection caused by *Shigella spp,* is endemic in many developing countries and also occurs in epidemics causing considerable morbidity and mortality (Ahmed & Shimamoto, 2015). The global incidence of Shigellosis is estimated at 80– 165 million episodes annually, with 99% of events in the developing world. *S. flexneriis* the primary cause of endemic shigellosis in developing countries, and *S. sonnei* is commonly isolated in industrialised nations (Ahmed & Shimamoto, 2015).

1.2.3.9 *Staphylococcus aureus (S. aureus)*

The name *Staphylococcus* is originated from the two Greek words “Staphyle” and “cocci” that means “a bunch of grapes” and the name “aureus” from Latin meaning “gold” because it grows in large yellow colonies (Koydemir *et al*., 2011). *S. aureus* is a facultative, anaerobic, non-spore-forming, Gram-positive bacterium, ubiquitously found in the environment (Rubad *et al.*, 2018).

S. aureus is the fifth most common known pathogen caused foodborne illness, but still *S. aureus* is considered one of the most significant threats to public health. Therefore, its detection is a crucial element to reduce the risks associated with public health and food safety (Rubad *et al.*, 2018). It is naturally present in human skin, mucous membrane, and nose flora (Argudín *et al*., 2012). It has been reported in the literature that 30–50%of the general population is a carrier of *S. aureus*.

It is widely spread in the environment, capable of surviving in hot and dry conditions and can flourish in the saline environment too (Balasubramanian, *et al*., 2017; Chaibenjawong & Foster, 2011).

1.3 LEGISLATION

Reliable estimates of the global FBD burden are central to public health policy and can provide critical information for the allocation of resource and help measure the impact of food safety (Hoelzer *et al.*, 2017).

In recent times, food safety has become one of the most worrying issues and with the most significant impact on public opinion because consumers increasingly expect to be assured that the food they eat is safe (Hussain & Dawson, 2013). A series of food incidents, in the late 1990s, draw attention to the need to establish general principles and requirements concerning food and feed law at European Union level**.**

In Europe, risk assessment procedures were established when food legislation was reformed in response to various food scares such as bovine spongiform encephalopathy (BSE) crisis (Boer & Bast, 2018; Vos, 2000). The primary focus of European legislation on foodstuffs was to ensure that the legislation from the different state members would harmonise, to create one internal market without barriers to trade. The need to protect consumers from hazards and from being misled, provided a important role to the legislation to prevent food scandals, which resulted in the development of a new framework regulation for General Food Law (GFL) (Boer & Bast, 2018).
The public debate initiated with the Green Paper, in 1997, on the GFL in the EU. Its values the promotion of communication between suppliers and consumers, the need to improve law enforcement and communication between the unfair competition practices, the elimination of directives and adoption of regulations on the free competition to eliminating the legal and cultural diversities of the

various achieve full harmonisation. Where this is not possible, the principle of mutual recognition may be used, which flexibility in the most sensitive areas (Mariano & Cardo, 2007).

The Green Paper led to the publication of the "White Paper on Food Safety", in January 2000, that was a new step in the complete overhaul of legislation in this area. The Commission announces the development of a legal framework covering the whole food chain - from farm to table - by a comprehensive and integrated approach that includes all sectors, including feed production, primary production, food processing, storage, transport and retail sale. The White Paper, to uniform treatment throughout the Community, sets the need to harmonise national control systems, puts in permanent dialogue consumers and professionals in the sector and understands the need to provide citizens with clear and precise information on the quality, possible risks and composition of foods (Direção Regional de Agricultura e Pescas do Centro, nd).

In 2002, the European Parliament and the Council adopted Regulation (EC) No 178/2002. It positioned GFL, and it was formally established an independent agency responsible for scientific advice/support, the European Food Safety Authority (EFSA), and it's strengthened the rapid alert system for food and feed (EFSA, 2018; Osimani, Aquilanti & Clementi, 2018). The Regulation (EC) No 178/2002 establishes general principles:

1. reaffirms the integrated nature of the food chain;
2. emphases the essential foundation of food safety policy in the risk analysis (risk assessment through scientific advice, risk management through the intervention of public authorities and communication of risks to the public);
3. recognises the responsibility of all food business operators; establishes products traceability at all stages of the food chain and focuses the citizen's right to clear and accurate information from public authorities.

Within the regulatory framework draw from Regulation (EC) No 178/2002, in 2004, the European legislation on food safety was further expanded by issuing the "Hygiene Package". It is composed of four legislative acts, namely Regulation (EC) No 852/2004, Regulation (EC) No 853/2004, Regulation (EC) No 854/2004, and Regulation (EC) No 882/2004.

Regulation (EC) No 852/2004 is defined as the set of measures and conditions necessary to control hazards and to ensure that foodstuffs are fit for human consumption. Due to this growing concern, and working groups to address these issues, resulting in the publication of standards, recommendations and specific information, including the *Codex Alimentarius* or the food code. The *Codex Alimentarius* is a group of internationally adopted food standards, codes of practice, guidelines and other recommendations (FAO & WHO, 2016). It has become the global reference point for consumers, food producers and processors, national food control agencies and the international food trade. The publication of the *Codex Alimentarius* is planned to guide and promote the elaboration and creation of definitions and requirements for foods, to assist in their harmonisation and to facilitate international trade (Luber, 2011).

The chase of a high level of protection of human life and health is one of the fundamental objectives of Regulation (EC) No 852/2004 on the hygiene of foodstuffs. An integrated approach is required to ensure this safety, from primary production through to the consumer, across the food chain, from 'farm to fork'. The same Regulation stipulates that all food business operators throughout the production chain must ensure that food safety is not compromised by establishing and implementing safety programs based on Hazard Analysis and Critical Control Points (HACCP) (Osimani, Aquilanti & Clementi, 2018). The requirements of the HACCP system should, in turn, take into account the principles set out in the C*odex Alimentarius* and should be flexible enough to be applicable in all situations, but this flexibility does not compromise established hygiene objectives.

The Regulation (EC) nº 853/2004 lays down specific rules on the hygiene of food of animal origin for FBO, while Regulation (EC) nº 853/2004 writes particular regulations for the organisation of official controls on products of animal origin.

Regulation (EC) nº 882/2004 lays down general rules for the performance of official controls to verify compliance of regulations aiming the prevention, elimination or reduction to acceptable levels risks to humans/animals and guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information.

1.4 HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP)

Historically food safety management started in the early 1920s but those strategies were mostly unsuccessful. After there was a renewed emphasis, in the 1930s, on preventative food safety but it was only in the 1970s that this approach was adopted, leading to the use of HACCP system (Bauman, 1994). There was evidence that businesses taking a food safety management (FSM) approach based on HACCP and pre-requisite programs (PRP) produced food with better microbiological quality (Soriano *et al*., 2002a; Martínez-Tomé, Vera & Murcia, 2000).

Concomitant with the FBD increase, the HACCP system appears as a new method for food safety guarantee, and it made its appearance in the food safety management system (FSMS) as a regulatory tool in several countries, in particular in the industrialised ones. The attention that HACCP system has received in private and in the public sector was the acknowledgement of the increasing importance of food safety to public health and economic development (including promotion of food trade) (Motarjemi & Käferstein, 1999).

The public health and food control authorities all over the world have endorsed the concept of HACCP and included it in their country's legislation and European regulations as a mandatory requirement (Soriano *et al*., 2002a; Motarjemi & Käferstein, 1999).

Many large and medium-size food industries realise the importance of food safety for their businesses. They have therefore voluntarily adopted HACCP system in addition to complying with Good Manufacturing Practice (GMP). However, it is essential that small business including food service establishments recognise the importance of food safety and voluntarily introduce measures to prevent FBD. In this regard, a significant task for public health authorities was to promote food safety in society and, in particular, among consumers so that these adopt not only safe food handling practices in their homes but also be able to (a) recognize hazardous practices and foods, (b) demand hygienic practices, and (c) be appreciative of the efforts of those food businesses that practice it, even if their efforts may lead to justifiably higher prices (WHO, 2019).

HACCP was developed in the late 1950s by the Pillsbury Company, the Natick Research Laboratories, and the National Aeronautics and Space Administration team of scientists and engineers. They developed a system designed to build quality into the food products to ensure their safety for the man space program. The HACCP system was presented at the National Conference of Food Protection by their creators; the event was supported by the Food and Drug Administration (FDA) and by the American Public Health Association (APHA).

The initial version of HACCP consisted of three principles:

- Identification and assessment of hazards associated with all food chain;
- Determination of the critical control points to control any identified hazard;

- Establishment of a monitorization system of the critical control points (CCP).

Revisions have been made to simplify the HACCP concept, to make it easier to implement and maintain; however the initial idea of HACCP has never altered.

The FDA incorporated the HACCP concept into its low acid and acidified food regulations. These regulations were established in response to *C. botulinum* outbreaks in commercially canned food and had prevented efficiently such occurrences since their implementation. During the late 1970s, general interest in HACCP waned, and during this time, it was implemented and used by several large food processing companies. Toward the end of the 1980s, some publications made HACCP the essential food safety system. The use of HACCP, in the United States of America, was driven by the marketplace rather than by regulations. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) in print the first HACCP document and codified the practice of HACCP to date, including the seven principles, this was in 1989.

In 1993, the *Codex Alimentarius* Commission issued its first HACCP standard, which provided the first international definition for HACCP. This guide has been transposed into Community legislation by the Council Directive 93/43, of 14 June 1993, which pioneered the meaning of the general principles of hygiene and the obligation on operators to adopt measures for self-monitoring of critical points (Soriano *et al.*, 2002). Directive 93/43/EEC was later transposed into Portuguese legislation by Decree-Law no. 67/98 of 18 March, which lays down the general hygiene standards to which foodstuffs are subject, designated as self-monitoring (Baptista & Antunes, 2005). However, other directives were also adopted under the common agricultural policy, with the aim of which are a frequent basis for the safe production of all types of foodstuffs, including animal products. This approach should also cover food safety throughout the entire production chain (from the in production until the placing on the market or later shipment). Thus, all hygiene rules included in the various instruments are compiled in a single document, Regulation (EC) No 852/2004 of the Parliament and of the Council of 29 April 2004, to be in force since 1 January 2006. This Regulation repeals Council Directive 93/43/EEC of 14 June, which was previously mentioned (Gonçalves, 2006).

Despite many obstacles that companies face in the context of HACCP implementation this system provides many advantages for consumers and business operators alike, namely improved product safety, lower levels of biological hazards associated with the product itself, shelf life extension, improved consumer confidence, enhanced employee quality responsibility, reduced complaint rates and improved competitiveness (Trafiałek *et al.*, 2015).

1.4.1 HACCP pre-requisites

The production of safe food products requires that the HACCP system is built upon a solid foundation of prerequisite programs. The WHO published a definition for prerequisites (WHO, 1999) ''practices and conditions needed before and during the implementation of HACCP and which are essential for food safety''. The requirements are described in the *Codex Alimentarius* document "General Principles of Food Hygiene" and other Codes of Practice (Bas, Ersun & Kivanç, 2006).

The concepts of the PRP and how it will benefit HACCP had been reported by Wallace & Williams, 2001. It has been recommended that before HACCP is utilized, a PRP is needed (Seward, 2000). If the PRP is not used, there probably will be a waste of resources and might cause more resistance for future utilisation and HACCP system implementation (Bas, Ersun & Kivanç, 2006; Moran *et al*., 2017).

Prerequisite programs provide the necessary environmental and operating conditions that are necessary for the production of safe, wholesome food (Baş, Ersun & Kivanç, 2006). Examples of current PRP are:

- Facilities: The establishment should be located, constructed and maintained according to sanitary design principles. There should be linear product flow and traffic control to minimise cross-contamination from raw to cooked materials;
- Supplier Control: Each facility should assure that its suppliers have in place effective GMP and food safety programs. These may be the subject of a continuing supplier guarantee and supplier HACCP system verification;
- Specifications: There should be written specifications for all ingredients, products, and packaging materials;
- Production Equipment: All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented;
- Cleaning and Sanitation: All procedures for cleaning and sanitation of the equipment and the facility should be written and followed;
- Personal Hygiene: All employees and other persons who enter the manufacturing plant should support the requirements for personal hygiene;

- Training: All employees should receive documented training in personal hygiene, GMP, cleaning and sanitation procedures, personal safety, and their role in the HACCP program;
- Chemical Control: Documented procedures must be in place to assure the segregation and proper use of non-food chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in or around the plant;
- Traceability and Recall: All raw materials and products should be lot-coded and a recall system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary;
- Pest Control: Effective pest control programs should be in place (FDA, 1997).

The existence and effectiveness of PRP should be assessed during the design and implementation of each HACCP plan. All PRP should be documented and regularly audited. PRP are established and managed separately from the HACCP plan. However, certain aspects may be incorporated into a HACCP plan. For example, many establishments have preventive maintenance procedures for processing equipment to avoid unexpected equipment failure and loss of production (FDA, 1997).

The first step in achieving an effective HACCP system is to establish robust prerequisite programs, considered to be an indispensable tool for successful implementation of a self-control system (Garayoa *et al.*, 2017; Martins & Rocha, 2014; Henroid & Sneed, 2004).

To prevent, reduce or eliminate contamination of food during storage and preparation, every aspect of catering should be controlled using prerequisite procedures and a HACCP plan. The prerequisites provide the foundation for effective HACCP implementation and should be in operation before HACCP. Once this achieved, the HACCP plan may be developed and implemented. As a general rule, the prerequisites should be used to control hazards associated with the food service environment (premises and structures, services, personnel, plant and equipment), while HACCP should be to control risks associated directly with food processes. Therefore, prerequisites are an essential element in the task of developing simple, effective HACCP systems and it does not dilute the strength of HACCP (Wallace & Williams, 2001; Matias *et al.*, 2013).

1.4.2 HACCP Principles

HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles (*Codex Alimentarius*, 2003).

Principle 1: Conduct a hazard analysis

Hazard analysis requires identification at every stage of the process (from receipt of raw materials to the final consumer). In this hazard analysis, an assessment of the probability of occurrence and severity (impact to the consumer) of each of the identified hazards can be made, as well as the analysis of any preventive measures established for its control (Wallace *et al.*, 2014).

Principle 2: Determine the critical control points (CCP)

This principle is based on the determination of the CCP that must be controlled to eliminate the hazard or minimise the likelihood of its occurrence. A PCC is understood to mean a step, procedure or operation in which control is to be applied and is central to preventing, reducing to acceptable levels or eliminating a food safety hazard.

Principle 3: Establish critical limits.

The critical limit is the value or criterion that differentiates acceptability from the non-acceptability of the product. Thus, this third principle is to establish critical limits that must be ensured by ensuring that each CCP is controlled.

Principle 4: Establish monitoring procedures

This principle establishes a monitoring system to ensure control of each CCP. This monitoring system integrates the observation or measurement of the control parameters, to assess whether each CCP is within the previously established critical limits.

Principle 5: Establish corrective actions

It is understood that a CCP is not under control when there is a deviation from the established critical limits. In this way, corrective measures have to be determined if this situation is verified.

Principle 6: Establish verification procedures

It consists of establishing verification procedures to confirm the effectiveness of the HACCP System. The verification procedures include methods, procedures, tests and other assessments to verify compliance with the HACCP Plan and the effectiveness of the HACCP System (Regulation (EC) nº852/2004).

Principle 7: Establish record-keeping and documentation procedures

In the context of HACCP, the records are of paramount importance since they are evidence of the accomplishment of activities associated with the operation of the HACCP System (Matias *et al.*, 2013).

1.4.3 HACCP Monitoring Tools

The continued monitoring and verification of a HACCP system is at least as necessary as the initial development of a HACCP plan, perhaps even more critical. The development of a HACCP plan requires probably several months of effort by the HACCP team and the resulting HACCP system may be in place for several decades or even longer. Therefore, it is essential that monitorization and verification are done well (Sperber, 1998).

1.4.3.1 Audits

The term ‘audit’ refers to a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives (Regulation (EU) No. 882/2004).

The audit is a systematic, independent and documented process for obtaining factual records or statements or other information (audit evidence) that is valid and relevant to the set of policies, procedures or requirements (audit criteria). Thus, the audit criteria are based on the food safety system, company policies and legal requirements, which aim to determine to what extent their standards are met (Powel *et al.*, 2013; Lues & Tonder, 2007). Is a useful tool in monitoring and verifying the implemented HACCP system as it allows the head of a catering establishment to provide evidence that their food safety system ensures food safety. Auditing the quality system also ensures compliance of your products and services, customer satisfaction and continuous improvement.

The principles relating to auditing are independence (impartiality and objectivity) and the evidence-based approach (rational and reproducible method). Those who are related to the auditors are ethical conduct (trust, integrity, confidentiality and discretion), an impartial exposition (reporting truthfully and accurately) and due professional care (diligence and discernment) (NP EN ISO 19011).

The audit allows to maintain confidence in the food safety system as it provides an independent and objective view of the system's effectiveness, identifies areas of the system to be developed and improved, and continuously enhances knowledge of food safety management for implement the necessary adjustments (NP EN ISO 19011).

1.4.3.2 Microbiological analyses

The widespread implementation of HACCP programs, over the past decade, has led to many debates between experts and stakeholders on the benefits of HACCP regarding reducing microbial contamination at the processing level.

Some studies have demonstrated that the implementation of HACCP-based programs resulted in a lower microbial load of the final product, namely in fish, seafood and meat products (Yang, Wei & Pei, 2019; Djekic *et al.*, 2016; Frasier & Monteiro, 2009; Tsola, Drosinos & Zoiopoulos, 2008; Cormier *et al*., 2007).

Wilhelm *et al.*, 2011, through a scientific review, concluded that all studies analysed reflected a relationship between adherence to proactive safety management and the microbiological quality and safety of the end product, as measured by different microorganisms.

The microbiological control of the food production has met at last its purpose, give innocuous, nourishing and tasty products. The microbial analysis allows verifying that the food process is done correctly. It will enable the setting of appropriate corrective measures in case of non-conformities that exist and meets the critical limits established by current legislation and for the quality politics of the FBO (Pérez *et al*., 2011).

The microbiological analysis is a tool that can be used to evaluate whether an FSMS is providing control and if the microbial criteria were designed to determine adherence to GMP and HACCP (i.e., verification). In the application of HACCP, the use of microbiological testing is seldom an effective means of monitoring CCP. The continuous analysis of a sufficient number of samples, throughout time, allows obtaining valid information about the hazards associated with the food production flowchart (Pérez *et al*., 2011).

By the Regulation (EC) No 2073/2005, on the microbiological criteria for foodstuffs, FBO shall ensure that food complies with the established relevant microbial standards. In more detail, Annex I of this Regulation set a series of limits for microorganisms, their toxins or metabolites at either the production stage or shelf life of the products. Regulation (EU) No 1441/2007 amended Regulation (EC) No 2073/2005 by providing an additional hygiene and food safety processing criteria (Osimani, Aquilanti & Clementi, 2018; Pérez *et al*., 2011).

1.4.3.3 Training

FBD prevention requires favourable hygienic conditions during food preparation, a phase in which the handler plays an important role (Medeiros, Cavalli & Proença, 2012). Therefore appropriate handling practices are crucial for preventing FBD during food production and distribution (Campos *et al*., 2009; Lues & Van Tonder, 2007; WHO, 2012).

As stated by the WHO, in 2000, food safety education is an essential tool to assure that workers do not contaminate food products. It is also vital in eliminating or reducing food contaminants and preventing microorganism growth at levels causing disease (Medeiros, Cavalli & Proença, 2012).

Regular training is thus considered the most important way to prevent or mitigate food contamination risks by adjusting the practices of handlers and improving their skills. Such training should be accompanied by regular inspection of the activities of the workers involved (Gruenfeldova, Domijan & Walsh, 2019; Reynolds & Dolasinski, 2019; Campos *et al*., 2009; Acikel *et al*., 2008; Sousa, 2008; Capunzo *et al*., 2005).

Employee training is considered an essential component of a corporation's image and both its internal and external competitiveness. However, for a training programme to be successful, planning checks are required; and the methodology and approach adopted are equally important (Reynolds & Dolasinski, 2019; Medeiros, Cavalli & Proença, 2012).

The success of a HACCP system depends on training the FBO and employees in the importance of their role in producing safe foods, which includes information about the control of FBD hazards related to all stages of the food chain/process. It's important to recognise that employees must first understand what HACCP is and then learn the skills necessary to make it function properly. Specific training activities should include working instructions and procedures that outline the tasks of employees monitoring each CCP (Gruenfeldova, Domijan & Walsh, 2019; Reynolds & Dolasinski, 2019; Medeiros, Cavali & Proença, 2012).

The FBO must provide adequate time for education and training (Medeiros, Cavali & Proença, 2012). Thus effective training is an essential prerequisite to successful implementation of a HACCP plan (FDA, 1997) although it must be under supervision, to verify if the knowledge acquired is appropriate and being applied efficiently (Zanin *et al.*, 2017; Medeiros, Cavali & Proença, 2012).

The lack of professional training of employees and an insufficient provision of courses and training indicate a risk of the guarantee that safe food will be provided to consumers (Medeiros, Cavali & Proença, 2012).

1.5 FOOD SAFETY IN PORTUGUESE MASS CATERING

1.5.1 MICRO, SMALL AND MEDIUM ENTERPRISES (SME) - RESTAURANTS

SME play a central role in the European economy. They are a vital source of entrepreneurial skills, innovation and employment. In the enlarged European Union of 25 countries, approximately 23 million SME provide nearly 75 million jobs and account for 99% of total enterprises.

The category of SME is made up of companies employing less than 250 people and whose annual turnover does not exceed EUR 50 million or whose annual balance sheet total does not exceed EUR 43 million. In the SME category, a small enterprise is defined as a company employing less than 50 people and an annual turnover/total annual balance sheet does not exceed EUR 10 million (Commission Recommendation 2003/361/EU).

There are approximately 81 SME per 1000 inhabitants in Portugal, which is more than double the EU average (≤ 40) (European Commission, 2017). Portuguese SME account more than two-thirds of total added (compared with an average of 57% in the EU), and nearly four out five jobs (against two of three positions in the EU) depend on SME and the contribution to the overall economy (European Commission, 2017). In this context, a particular role is attributed to the micro businesses, accounting for 43% of all persons employed (EU-average less than 30%) (European Commission, 2017).

Figure 1. Value-added of SME (EU, 2017)

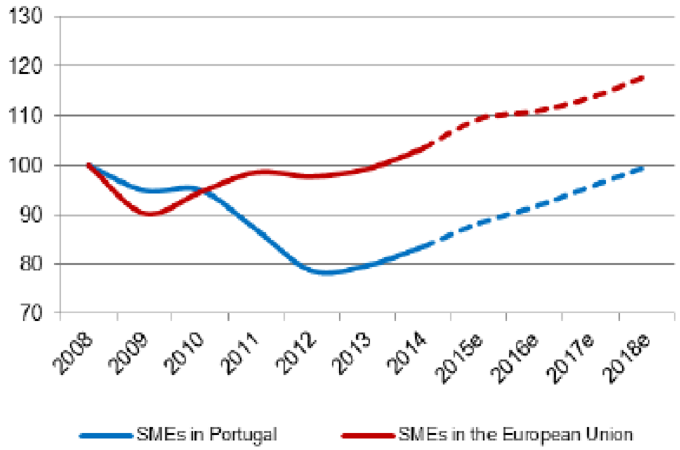
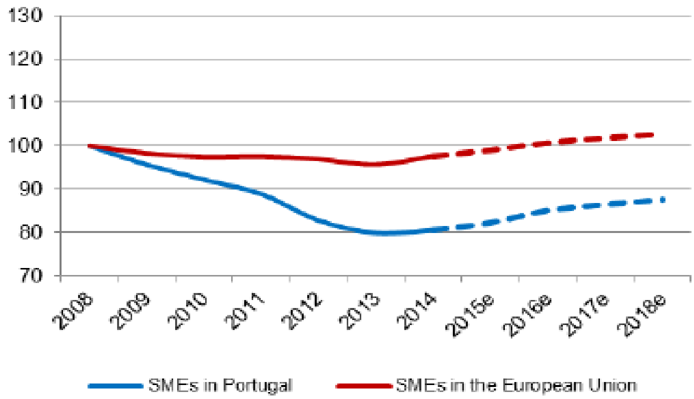


Figure 2. Number of persons employed in SME (EU, 2017)



The hospitality industry encompasses all aspects of catering businesses, the latter mainly referring to the provision of food. The so-called commercial sector of catering includes restaurants, hotels, bars, pubs and clubs, whereas schools and colleges, hospitals, prisons and the armed services are part of the so-called public sector. The catering system is characterised by very complex actions that lead to the production of finished food intended for many consumers (Osimani *et al.*, 2018). The catering establishments can exert a profound impact on public health, especially when vulnerable consumers, such as those eating at hospitals, nursing homes, childcare centres and schools, are involved (Garayoa *et al.*, 2014).

The economic activity of catering in Portugal embraces (I) the preparation and sale activities of food products for consumption, usually on site or in other establishments that do not produce those products; (II) the actions of preparation of meals or dishes delivered and/or served at the place determined by the customer for a specific event; (III) the supply activities and, where appropriate, the preparation of meals and drinks to well-defined groups of people, like public collectivities (hospitals, schools, elderly places, etc.). It includes canteens and military spaces; it also provides for the provision of meals based on a contract for a given period; (IV) the sales activities of drinks and small snacks for consumption on the premises with or without spectacle (Bank of Portugal, 2011).

The catering establishments can exert a profound impact on public health, especially when vulnerable consumers, such as those eating at hospitals, nursing homes, childcare centres and schools, are involved (Garayoa *et al*., 2014; Osimani & Clementi, 2016b).

The trend towards the rise of meals consumption outside of the home is found in many countries. Nevertheless, it should be considered that consumers are increasingly demanding about their choices and seek products that offer higher safety and quality (Medeiros, Cavali & Proença, 2012).

The improvement of quality and productivity in catering services can be a competitive advantage that leads the client to prefer one service over another, making quality a tool for sustaining proper management (Medeiros, Cavali & Proença, 2012; Figueiredo & Neto, 2001). In food service, quality is related to various factors such as raw materials, physical and functional structure, equipment, human resources, as well as the management of the establishment (Medeiros, Cavalli & Proença., 2012).

Evidence from numerous countries has shown that mass-catering and food service facilities are the most frequent cause of FBD outbreaks (Martins *et al*., 2012; Todd *et al*., 2007; Worsfold & Griffith, 1997). Data published by EFSA show that, in 2010, 48.7% of the verified foodborne outbreaks were associated with catering services or canteens.

Studies by health agencies of foodborne diseases associate these diseases with restaurants. People are the principal sources of food contamination of food employees in commercial establishments, with leading causes poor personal hygiene of employees, handlers contaminated by intestinal parasites, improper food preparations practices, preparation of food too long before consumption or insufficient cooking or reheating of food and cross contamination (Medeiros *et al.*, 2012; Hedberg *et al*., 2008; Kuo *et al*., 2009).

The quality assurance of food provided by the catering industry presents many critical issues because of its complexity and diversity. In this regard, the wide variety of food recipes and raw materials, together with the structural deficiencies of the settings (Osimani *et al*., 2016a) and the low motivation and training of the staff can lead to failures in the HACCP systems. Among the most frequently reported risk factors, poor hygiene, cross-contamination between raw and cooked foods, improper cooking and maintenance or storage of foods have been reported (Garayoa *et al*., 2014; Osimani *et al*., 2013, 2014, 2015a; Petruzzelli *et al*., 2014a, b).

In 2015, the housing, catering and similar sectors accounted for 10% of companies in Portugal (39 thousand companies), 8% of the number of people employed and 3% of turnover. Compared to 2011, the weight of the sector in the number of companies and the number of persons employed increased by 0.5 percentage points (pp), a more significant change than in turnover (0.3 pp). Between 2011 and 2015, the number of companies that initiated activity in the sector was higher than the number of closures, which implied an increase in the number of companies in business. This increase was increasing from 2012 onwards. In 2015, 1.3 companies were created for each one that ended operation. The rate of change in the number of companies in business in the sector amounted to 2.5%.

This value was higher than that observed for the total number of companies (differential of 1.4pp in 2015), a situation that was registered throughout the period under analysis (Fig. 1 and 2).

The sector "Restaurants and similar" was more relevant, given the breakdown by business segment (83%), turnover (64%) and some persons employed (74%) (Figure 4.).

Figure 3. Structure |Economic activity (adapted from PORDATA, 2017)

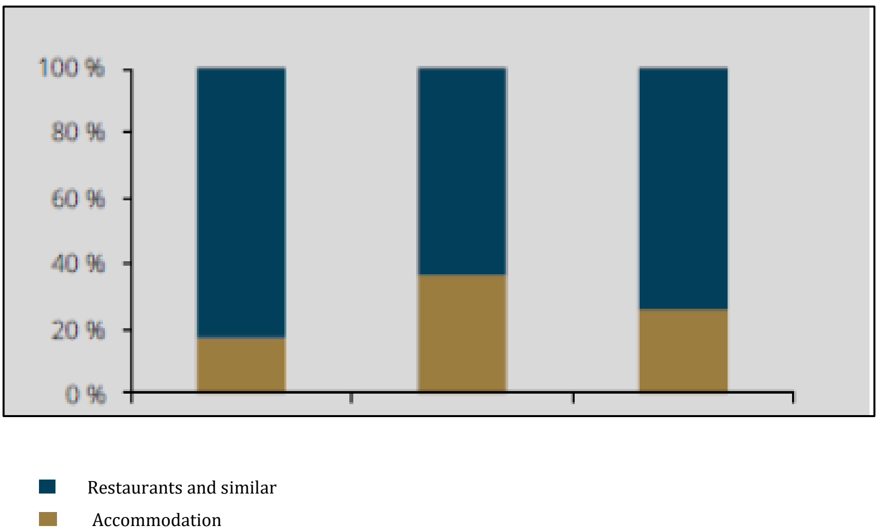
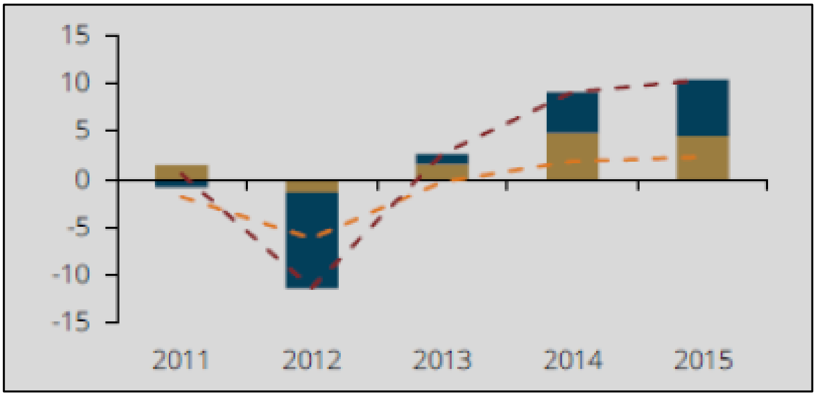


Figure 4. Business Volume | Economic activity by growth rate (adapted from PORDATA, 2017)



Total of companies (growth rate)

Accommodation and restaurants and similar (growth rate)

Restaurants and similar

Accomodation

1.5.2 FOOD BUSINESS OPERATORS (FBO)

Seeking improved quality in the sector Macausian, 2003 affirms that in the 21st century it's essential that restaurants have leadership, training, teamwork, cultural awareness, influence, oversight and evaluation combined with competent administration of food hygiene (Medeiros, Cavalli & Proença, 2012).

In the food sector, the activities of food handling and the quality of services are directly related to employees and owners, given that they are responsible for managing hygienic-sanitary quality and for providing safe food to clients (Medeiros et al., 2012; FDA, 2004). Proper practices by food handlers in restaurants are essential to providing safe food, as so FBO can contribute because there are responsible for the administration of the workers at the establishments and the quality of services. The administrative actions most important to food safety according to Szavo *et al*., 2008 are a commitment to administration, organisational structure, food safety policy, resources, documentation and communications (Medeiros, Cavalli & Proença, 2012). Cavalli & Salay (2004) identify the adoption or not of quality-control systems by companies and the professional qualification of the employees, noted the failure to apply HACCP and best practices, a lack of professional training of employees and an insufficient provision of courses and training. The results indicate a risk of the guarantee that safe food will be provided to consumers (Medeiros, Cavalli & Proença, 2012).

Food premises in the EU must be registered (notified) or pre-approved by the national food control authority depending on the type of premises (Regulation (EU) nº882/2004). Some EU member states, such as the United Kingdom, Germany, Sweden and Belgium register retail food premises and Portugal also began registering. The purpose of the amendment is to reduce bureaucracy and to facilitate the establishment of new food businesses (Haukijärvi & Lundén, 2017). Previusly, when an FBO applied for restaurant approval, an inspector conducted an on-site inspection before operations began, to ensure that the premises were suited to the intended activity. If the premises failed to meet the food safety requirements, either were denied for approval or were approved conditionally. Today, the shift from pre-control to post-control is a significant principal change, that may affect how food premises meet food safety requirements and assure food safety. To our knowledge, no studies have examined the effects of this shift from pre-to post-control of the compliance of food premises with food safety requirements (Haukijärvi & Lundén, 2017). The FBO must consider both infrastructure and operational prerequisites when establishing a food business before the FBO could provide guidance concerning the requirements during pre-inspection, but now no pre-inspections take place unless the FBO specifically request an inspection. This change has not only increased the importance of FBO's knowledge of food safety requirements but also emphasises the FBO responsibility for food safety, which is in line with the principle of EU food safety legislation (Regulation (EU) nº178/2002).

1.5.3 FOOD SAFETY CHALLENGES

Studies involving FBD outbreak investigations have suggested that poor food handling practices may be implicated in up to 97% in food service establishments and at home (Griffith, 2006; Howes *et al*., 1996; Zanin *et al.*, 2017).

Many raw foodstuffs that reach SME, homes and consumers are already contaminated as a result of the food production system, primarily due to problems at the primary industry level. It remains a fact which these problems are amplified because of the lack of training in food safety, including in good hygienic practice and HACCP system, of those preparing food in small food businesses and homes (Motarjemi & Käferstein, 1999).

Documented food systems explain how things “should be done” but what people “actually do” is a manifestation of the food safety organisational culture (Griffith, 2000). This is a complete integration of the individual food handlers’ knowledge, attitudes and practices with the culture or standards set by the manager/owner of the business (Figure 3). Food safety organisational culture is influenced by many things, including the facilities available (e.g. for hand-washing), as well as the time available to implement food safety practices. Within the food service context, this can be a more significant problem, where staff may need to supply food to order rather than from stock. Other studies based on self-report (Clayton et al., 2002), which is known to overestimate food safety behaviour, included an admission that in the United Kingdom (UK) 4% of food handlers “often did not carry out all known food safety behaviour at all appropriate times”. This should be viewed in the context of, for example in the UK, up to three million food handlers working for 365 days of the year, often implementing over 1,000 food handling actions a day. Observational studies using techniques, such as notational analysis (Clayton and Griffith, 2004), confirm that food handlers frequently do not use/implement appropriate known food safety practices. The role of training in improving food safety practices is not a simple linear one, and how, why and what training is delivered to improve food safety optimally needs to be carefully considered (Worsfold et al., 2004).

The emerging vision of the One Health concept (Centers for Disease Control and Prevention, 2017), recognizes that the health of humans, animals and the environment is connected, which illustrates the importance of multidisciplinary collaboration, local, national and global level, to achieve an optimal health outcomes for people, animals and the environment.

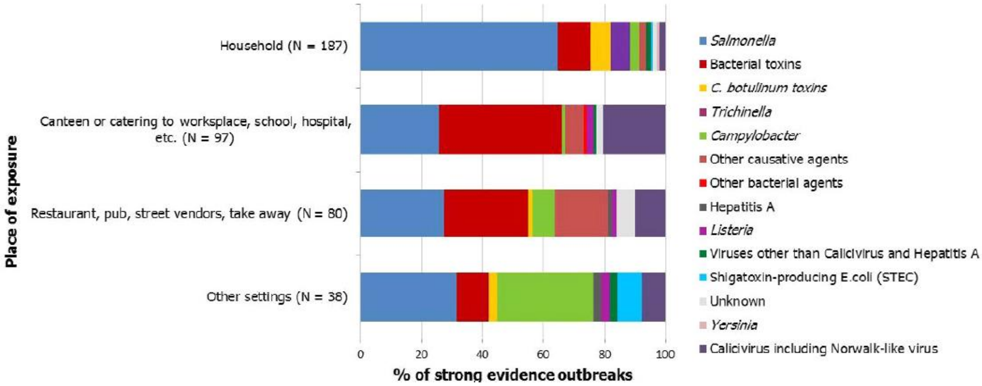
The development of new tools, which support the One Health concept, such as molecular-based surveillance systems, has significantly improved food safety surveillance around the globe. The tripartite nature (governmental-industrial-academic) of public-private partnerships to advance food safety is especially important. Involvement of academia provides access to specialised scientific skills and ensures the generation of a continuous pipeline of well-educated future industry employees with experience addressing fundamental food safety questions in an academically rigorous and evidence-based manner (Hoelzer *et al.*, 2017). This study was conducted a mean to achieve a link between academic research and the field in food safety matters.

As mentioned before, the increase FBD is not fully understood but may be linked to a combination of factors, including urbanisation, mass-production of food, changing lifestyles and diets, tourism and modern trade practices in food due to a longer distribution chain both in time and in the distance (Valero *et al.*, 2017; Miyagishma *et al*., 1995). The increase of the concern regarding this matter is also the Portuguese demographic information. A large percentage of the population in Portugal can be categorised as vulnerable, with older adults "65 years old and older" and younger children of "15 years old and younger" (20.9% and 14.1% respectively), which can increase the foodborne incidents (PORDATA, 2016).

The data published by EFSA show that, in 2010, 48.7% of the verified FBD outbreaks were associated with catering services or canteens. In Portugal, in the same period, from the eleven verified outbreaks, nine of them were associated with catering services (4) and cafeterias (5) (Martins *et al*., 2012). A massive outbreak, involving 120 people in a University, was also reported in Portugal as caused by non-O157 STEC and associated with 'mixed food' (cooked hamburger and cooked onions) (EFSA, 2016). Thus the relationship between FBD data in Portugal relates the incidents with the food supply provided by catering services. However, the data is scarce probably because little consideration is given to FBD in catering services, due to the symptoms that are often not linked to the food consume (Legnani *et al.*, 2004).

From previous data, we can understand that food safety problems are particularly significant and better risk control is needed in SME food business in the catering sector (Figure 5).

Figure 5. The causative agent of foodborne outbreaks in place of exposure (EFSA, 2016).



The HACCP system has still not made headway; there are a considered number of barriers which catering SME find particularly difficult to overcome (Charalambous *et al*., 2015; Panisello & Quantick, 2001). Not only in Portugal but worldwide, analysis of FBD outbreaks shows that the greatest majority of them result from malpractice during food practices and food preparation in the small food business, canteens, homes and other places where food is prepared for consumption (Legnani *et al.*, 2004; Motarjemi & Käferstein, 1999). For example, despite the legal requirement to implement a HACCP system, several deficiencies were identified in the production and distribution of safe food, which applies to both "new" and "old" EU member states. In 2010, Garayoa *et al*., 2011 assessed the implementation of HACCP system in 20 Spanish catering companies and found that, although HACCP manuals existed in 70% of the companies, the HACCP system did not work appropriately. Only 40% of these companies have provided adequate training in the principles of HACCP to their employees. As so, similar observations were made in a university food-service canteen in Portugal (Veiros *et al.*, 2009).

Therefore, the training of food safety professionals at all levels - including bachelor, master, and doctorate levels – is essential to ensure the availability of individuals who can appropriately utilize new tools to further address food safety challenges and to improve FBD diagnostics and surveillance, and thereby further enhance food safety (Hoelzer *et al*, 2017). This study provides a new methodologic food safety tool to apply in catering SME – restaurants, as a way to ensure the means to improve the general food safety conditions.

In Portugal, there are two kinds of situations that can increase food safety concerns. Namely, most of the small and medium restaurants management are from family business, which means that old improper practices and the establishment premises keep going throughout the years (Baltazar *et al.*, 2017). On the other hand, nowadays, like in other European countries, to reduce bureaucracy and facilitate the establishments of the new food business, the restaurant's premises only need registration, without inspection pre-approval, to start working (Haukijärvi & Lundén, 2017). As so, the restaurants' FBO is responsible for managing hygienic-sanitary quality and for providing safe food to the clients. Most of the times they don't have the knowledge and the technical support to implement an FSMS or the *financial* ability to pay specialised external care (Medeiros, Cavalli & Proença, 2012). As so, how can these companies provide safe meals without the support and the knowledge required? Could a defensive food safety plan avoid this public health problem?

Greater food safety requires enhancing local scientific and technical skills and the development of efficient tools and training programmes, considered a primary intervention for promoting food safety in food services (Mitchell, Fraser, & Bearon, 2007; WHO, 2002). This research was developed as a mean to find a solution to this public health problem by creating a food safety methodologic plan, FoodSimplex, to the catering SME, restaurants.

The development of this investigation allows a better understanding of the problem areas in HACCP system, specific shortcomings and misunderstandings within a HACCP analysis to help FBO, public health officers, as well as consultants to improve the effectiveness of HACCP systems in catering SME.

The present study intends to make a substantial contribution to the continuous improvement of the effectiveness of food safety management in SME (Trafiałek *et al*., 2015). As so, the study aims to create and assess the impact of a new food safety methodologic tool for small and medium restaurants, FoodSimplex, as public health instrument to be applied by food safety technicians.

CHAPTER II – OBJECTIVE

2.1 OBJECTIVES

This study aimed to develop and assess a food safety methodology created for SME - restaurants, named FoodSimplex, as a public health method to be applied by food safety technicians. As so, FoodSimplex provides a strategic methodologic tool with means to implement and monitor a food safety system in small and medium restaurants with little resources to ensure the safety of the meals they serve to the consumers.

To reach the general aim, the following specific objectives are proposed:

- To assess if SME restaurants have improved the global food safety status with the application of FoodSimplex;
- To assess if SME restaurants have improved sanitary conditions with the application of FoodSimplex;
- To assess if SME restaurants have improved Good Manufacturing Practices (GMP) with the application of FoodSimplex
- To evaluate microbiological conditions of the served food and its evolution towards the use of FoodSimplex;
- To evaluate microbiological conditions of the surfaces and food handlers' hands and its development towards the use of FoodSimplex.

2.2 OBJETIVOS

El objetivo del presente estudio es desarrollar y evaluar una metodología de seguridad alimentaria creada para restaurantes catalogados como pymes, llamada FoodSimplex, como un método destinado a promocionar la salud pública y que deben aplicar los técnicos de seguridad alimentaria. Como tal, FoodSimplex proporciona una herramienta metodológica estratégica para implementar y monitorear un sistema de seguridad alimentaria en restaurantes pequeños y medianos con pocos recursos, para garantizar la seguridad de las comidas que sirven a los consumidores.

Para alcanzar el objetivo general, se proponen los siguientes objetivos específicos:

- Valorar si los restaurantes han mejorado la seguridad alimentaria con la aplicación de FoodSimplex;
- Valorar si los restaurantes han mejorado las condiciones sanitarias con la aplicación de FoodSimplex;
- Evaluar si los restaurantes han mejorado las buenas prácitas de manufactura (BPM) y buenas prácticas de higiene (BPH) con la aplicación de FoodSimplex;
- Evaluar las condiciones microbiológicas de los alimentos servidos y su evolución con el uso de FoodSimplex;

- Evaluar las condiciones microbianas de las superficies y las manos de los manipuladores de alimentos y su evolución con el uso de FoodSimplex.

CHAPTER III – RESULTS

3.1 FoodSimplex in restaurants-how can it provide safer meals?

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FoodSimplex in restaurants-how can it provide safer meals?

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Abstract

The need and obligation to provide safe food to consumers leads to implement effective food safety systems along the entire chain production, shipping and distribution, as hazard analysis and critical control points (HAPPC) principles.

In Portugal, small and medium restaurants are family business that may lack the knowledge and the money for technical support to follow these principles.

The aim of this study is to assess a public health tool, FoodSimplex, in order to compare

food safety, good manufacturing practices (GMP) and HAPPC before, during and after its implementation in small and medium restaurants. Results show that, after systematic training and frequent audits,

FoodSimplex was linked to a change of habits: an increase of food safety and improvement of hygiene and GMP in small and medium restaurants.

Keywords: *food safety, FoodSimplex, restaurants, hygiene, good manufacturing practices*

Introduction

The offer increase in mass caterer establishments such as restaurants, canteens, schools, hospitals and catering enterprises [1], arises the concerns, are the meals prepared and ready for consumption by the final consumer safe? Do the food business operators (FBO) have the means and the technical support to respect the European Union regulation? Is there a preventive action plan effective to provide food safety in medium and small companies?

Billions of meals are prepared safely each day throughout the world but 22% outbreaks of food borne diseases were reported in Europe that had their origin in processed foods and/or by catering establishments [2,3].

It is estimated that millions of people have had a foodborne disease at least once. Health agencies associate these numbers with the consumption of meals in restaurants [4]. The outbreaks of this cases, the results are emotional, physical and financially devastating to all the intervenient, clients and the business management [2].

The mass caterer sector has grown in recent decades and several factors have been identified such as increased number of individuals living in urban areas, distance from home/work, increased percentage of women in the workplace, increased financial power and dietary concerns [4,5].

The economic activity of catering in Portugal embraces (I) the preparation and sale activities of food products for consumption, usually on site or in other establishments that do not produce those products; (II) the activities of preparation of meals or dishes delivered and/or served at the place determined by the customer for a specific event; (III) the supply activities and, where appropriate, the preparation of meals and drinks to well-defined groups of people, like public collectivities (hospitals, schools, elderly places, etc.). It includes canteens and military spaces; it also includes the provision of meals based on a contract for a given time period; (IV) the sales activities of drinks and small meals for consumption on the premises with or without spectacle. (Bank of Portugal, 2011) [6].

The European food laws introduced a new concept in the food market, “from farm to fork”, by designing a cross accountability to all stakeholders in the food chain [3,7]. The catering sector assigns a very important role to entrepreneurs, considering them primarily responsible for food safety [8].

The European Union (EU) has created legal tools to ensure food hygiene in the sector, as well as official entities in charge of controlling and inspecting establishments to ensure public health [7]. Council Regulations (EC) 852/2004 on hygiene of foodstuffs were created to ensure restaurants must obey with general hygiene requirements [9].

The need and obligation to produce safer food go to the inevitable implementation of effective food safety systems along the entire chain of production, shipping and distribution, namely a system based on the Hazard Analysis and Critical Control Points (HACCP) principles [10].

This preventive system requires a strategic approach to the stages of production /serving, based on the identification of inherent hazards such as biological, chemical and physical hazards [11].

The HACCP system is a preventive system resulting from the application of scientific and technical principles. It is an essential tool for identification and analysis of critical points (CP) at different stages of the process while allowing the establishment of the necessary means to control these points and apply preventive monitoring. The HACCP system stands for proactivity instead of reactivity (corrective approach) [12]. Although manufacturers have used HACCP system successfully for many years it has been less common in small and medium sized enterprises (SME), especially those in food service sector. There are considered to be a number of barriers which small businesses find particularly difficult to overcome [13,14].

In Portugal, we have two kinds of situations that can increase the food safety concerns, namely, most of the small and medium restaurantsmanagement are from family business, which means that old bad practices and the establishment premises keep going throughout the years. On the other hand, nowadays, like in other European countries, to reduce bureaucracy and facilitate the establishments of the new food business, the restaurant's premises only need registration, without inspection pre-approval, to start working [15]. As so, the restaurants' FBO are responsible for managing hygienic-sanitary quality and for providing safe food to clients and most of the times they don't have the knowledge and the technical support to implement a food safety system or the financial ability to pay external technical care [4].

This study aims to assess food safety action plan created for médium and small restaurants, named FoodSimplex, as public health tool to be applied by food safety technicians. Is compares food hygiene, good manufacturing practices (GMP) and HACCP documentation before, during and after implementation of FoodSimplex.

Material and methods

The small and medium restaurants have difficulties in complying the food safety regulations, mainly because of the lack of well-trained personnel, lack of motivation or adhesion to HACCP system on the part of the workers, and the lack of financial and economic resources to address the deficiencies in the facilities.

The small and medium restaurants were selected according to the following criteria:

- Portuguese economic activity code in Portugal for restaurante (financial Portuguese code)
- Turnover (up to 10 million euros)
- Geographic area (Leiria district)
- Restaurants interested in participating in the study

The project was a longitudinal study which took place between March 2010 and December 2014. Out of 42 restaurants eligible, 22 remained in the study for the four-year period.

The data collection instrument for the inspection was an audit checklist, created by food safety technicians after a pre-test applied to 31 restaurants, A checklist template was designed to collect data through visual inspection regarding food handlers and facilities hygiene and GMP as well as through interviewing the person responsible with regard to HACCP aspects (manual of procedures, records, etc.) and it's organized in three modules divided into specific topics (items).

After the pre-test, the food safety technicians reviewed some evaluation topics and insert others and the final checklist was the one applied in this study.

The final checklist consisted of 70 observations, each of which could be answered as "Compliance", "No Compliance" and "Not applicable". Every "Compliance" answer was allocated one point; every "No Compliance" was allocated 0. The final score for each premises was calculated by summing the points. The maximum score premises could achieve was 70, the minimum was 0. The audit required approximately 1.5h to complete, depending on the size of the premises. The outcome of the audit was a numeric score. The higher the score, the better premises complied with the requirements of the audit. For this study we only analyze the hygiene and GMP requirements.

The 352 audits were studied according to with the results and their evolution during the application of a FoodSimplex methodology (Table 1).

The FoodSimplex methodology, created for this study, includes four stages (Table 1).

The diagnosis audit focuses on gathering information about the food business to identify any areas of potential improvement in the business´s premises and to design the HACCP plan. The 2nd stage was meant to present the diagnosis audit report and the HACCP plan through training activities to the food handlers and the FBO. The training session intends to present the nonconformities, identify the areas of the business that have deficiencies, to appropriate action to correct any lacks and to reinforce food safety knowledge.

The 3rd step involved a systematic and independent assessment to determine whether food safety activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives [16].

The audits were supplemented with microbiological analyses towards hygiene and food quality standards. The audit reports are only useful if the food handlers and the FBO review the results, understands the risks addressed and makes risk-reduction decisions based on the results [2].

The 4th stage intended to present the reports in a training session and applicate a food safety improvement plan of the restaurant. The time schedule of the stages was: a month between the 1st and the 2nd stage and in between 2nd 3rd and the 4th stage is three months period. After the 4th stage the methodologic process continues repeating the order starting in the 3rd stage.

The audit results were structure and consider by 3 main groups, namely hygiene, GMP and HACCP documentation, however for this study we are only analyzing the 2 main groups Hygiene and GMP, to understand how effective the FoodSymplex is at the time, because the HACCP documentation was absent so the improvement is total (100%). As so only 52 checklist observations were used in this work.

Table 1. Food Simplex

Stage	Action Plan
1	Diagnosis audit (checklist) and HACCP data collection
2	Diagnosis report HACCP Plan Training Action "Hygiene & Food Safety – Restaurants"
3	Audit Microbiological analyses
4	Audit report
	Training Action "Treatment of non-compliance – audit and microbiological report"
	Improvement Plan Application

The results of the study were subject to statistical analysis, namely, McNemar test. For the statistical Inference, we took into account a 95% confidence level for a random error of up to 5%. The specialized software for treatment of analytical data was the IBM SPSS Statistics software, version 24.

The results were analyzed by score percentage (0-100) represented by the 2 selected groups. Since it was a continuous study, the data analyzed was based only on comparing the average scores provided between the diagnostic audit (1st) and the 4th audit, to have a summary knowledge of the change and improvement of the food safety status during the study.

Results and discussion

There were 42 restaurants eligible for the research, however only 22 maintained for the 4 years period of this study. The main reason for the decline of the companies was the economic crises in Portugal [17], which a big part of the SME didn't survive between 2012 and 2014 [18].

The results were analyzed taking into account the 1st and 4th audit, to assess the evolution in hygiene and GMP practices in this SME restaurants. The results were statistically treated by SPSS and the McNemar test was applied to a confidence of 95%.

Hygiene assessment

The results of the 24 items evaluated for hygiene were structured according to the checklist (Table 2).

In general, all the results between the two evaluation moments showed a maintenance or an improvement in the compliance with hygiene requirements. Compliance was maintained between the 1st and 4th evaluation on the following items: state of sanitation in the serving; personal hygiene (uniforms, gloves, adornments, state of health); general hygiene (obsolete material, non-food); disinfection (washing machine). On the remaining items, there was an improvement in the results for compliance. Positive results for hygiene compliance may be related to customer satisfaction, as

they attach an important role to the hygiene of catering establishments. The Sarter and Sarter study [19] also reinforces this aspect, noting that the lack of hygiene leads to economic sanctions, being the loss of customers is the most important one.
In the research done by Garayoa, *et al*. [3], 75% of the catering establishments were in conformity with the organization and cleaning, as in this study, in the 4th evaluation, all companies were in terms of overall hygiene value between 72.7% and 100 %. Utensils and containers are identified as not cleaned in Portuguese studies [20,21], but was not verified in this work. Also unlike the study by Garayoa, *et al*. [3], in which only 10% of the handlers presented the correct uniforms and absence of adornments, in this work 72.7% fulfilled the personal hygiene requirements and maintained them along the study.

There was a statistically significant change in the state of hygiene in the cooking stage between the first and fourth audits, with 63.6% non-conformities detected initially and after FoodSimplex application, a 27.3% reduction in non-conformities (p=0.021).

We can also mention that from the eight companies that have complied, there was an increase of 16 restaurants for compliance (72.8%). Also in this scope, of the 14 non-compliant companies for the hygiene in cooking, nine restaurants improved their condition.

Table 2. Data for hygiene and GMP in restaurants according with nonconformities (NC) and conformities (C) in audit

Audit Tool Premises – Hygiene	1st Audit		4th Audit		p
	NC	C	NC	C	
	% (n)	% (n)	% (n)	% (n)	
Reception-Hygiene of the facilities and equipment	4,5 (1)	95,5 (21)	,0 (0)	100,0 (22)	-
Room Temperature Storage-Hygiene of the facilities and equipment	40,9 (9)	59,1 (13)	18,2 (4)	81,8 (18)	0,125
Cold Storage- Hygiene of the facilities and equipment	77,3 (17)	22,7 (5)	54,5 (12)	45,5 (10)	0.180
Preparation-Hygiene of the facilities, equipment and utensils	40,9 (9)	59,1 (13)	18,2 (4)	81,8 (18)	0.125
Cooking-Hygiene of the facilities, equipment and utensils	63,6(14)	36,4 (8)	27,3 (6)	72,7 (16)	0.021
Serving-Hygiene of the facilities, equipment and utensils	9,1 (2)	90,9 (20)	9,1 (2)	90,9 (20)	0.500
Personal Hygiene-Uniforms	27,3 (6)	72,7 (16)	27,3 (6)	72,7 (16)	0.500
Personal Hygiene – Gloves	,0 (0)	100,0 (22)	,0 (0)	100,0 (22)	--
Personal Hygiene – Evidence of adornments and/or lack of personal hygiene	9,1(2)	90,9 (20)	9,1 (2)	90,9 (20)	0.500
Personal Hygiene – Visible diseases	,0 (0)	100,0 (22)	,0 (0)	100,0 (22)	--
General Sanitation-Dressing rooms	54,5 (12)	45,5 (10)	9,1 (2)	90,9 (20)	0.002
General Sanitation-Soap and disinfectant dispensers and towel rails	36,4 (8)	63,6 (14)	27,3 (6)	72,7 (16)	0.727
General Sanitation-No manual washbasin with hot and cold water	68,2 (15)	31,8 (7)	45,5 (10)	54,5 (12)	0.227
General Sanitation-First aid kit	59,1 (13)	40,9 (9)	22,7 (5)	77,3 (17)	0.039
General Sanitation – Cloths	31,8 (7)	68,2 (15)	27,3 (6)	72,7 (16)	0.500
General Sanitation – Obsolete material and equipment	27,3 (6)	72,7 (16)	27,3 (6)	72,7 (16)	0.500
General Sanitation – Use/conditions of non-food products	4,5 (1)	95,5 (21)	4,5 (1)	95,5 (21)	0.500
General Sanitation – Sanitary plan compliance	9,1 (2)	90,9 (20)	4,5 (1)	95,5 (21)	0.500
Cleaning & Disinfection-Dishwashing conditions	72,7 (16)	27,3 (6)	40,9 (9)	59,1 (13)	0.065
Cleaning & Disinfection-Operational dishwasher equipment	,0 (0)	100,0 (22)	,0 (0)	100,0 (22)	--
Cleaning & Disinfection-Waste containers	68,2 (15)	31,8 (7)	36,4 (8)	63,6 (14)	0.065
Cleaning & Disinfection – Pest Control	31,8 (7)	68,2 (15)	27,3 (6)	72,7 (16)	0.500
Cleaning & Disinfection- Waste Treatment	13,6 (3)	86,4 (19)	9,1 (2)	90,9 (20)	0.500
Cleaning & Disinfection – Chemical Products Storage	36,4 (8)	63,6 (14)	22,7 (5)	77,3 (17)	0.500
Audit Tool Premises-GMP					
Reception-Products inspection	54,5 (12)	45,5 (10)	18,2 (4)	81,8 (18)	0.021
Reception-Conditions of the products	4,5 (1)	95,5 (21)	4,5 (1)	95,5 (21)	0.500
Room Temperature Storage-Separation of food and non-food products	36,4 (8)	63,6 (14)	13,6 (3)	86,4 (19)	0.180
Room Temperature Storage-Organized Stock (FIFO / FEFO)	31,8 (7)	68,2 (15)	18,2 (4)	81,8 (18)	0.453
Room Temperature Storage-Labeling / Products identification	0,0 (0)	100,0 (22)	4,5 (1)	95,5 (21)	--
Room Temperature Storage-Non-according products and materials	86,4 (19)	13,6 (3)	36,4 (8)	63,6 (14)	0.003
Room Temperature Storage – Earth products	22,7 (5)	77,3 (17)	13,6 (3)	86,4 (19)	0.688
Cold Storage-Defrosting conditions	9,1 (2)	90,9 (20)	4,5 (1)	95,5 (21)	0.500
Cold Storage-Organized Stock (FIFO / FEFO)	13,6 (3)	86,4 (19)	9,1 (2)	90,9 (20)	0.500
Cold Storage-Freezing Procedure	45,5 (10)	54,5 (12)	27,3 (6)	72,7 (16)	0.344
Cold Storage-Labeling / Products identification	90,9 (20)	9,1 (2)	45,5 (10)	54,5 (12)	0.006
Cold Storage-Packaging	68,2 (15)	31,8 (7)	40,9 (9)	59,1 (13)	0.146
Cold Storage-Non-according products and materials	13,6 (3)	86,4 (19)	18,2 (4)	81,8 (18)	0.500
Cold Storage-Temperatures	13,6 (3)	86,4 (19)	9,1 (2)	90,9 (20)	0.500
Cold Storage-Refreezing conditions	4,5 (1)	95,5 (21)	0,0 (0)	100,0 (22)	--
Preparation-Preparation conditions	9,1 (2)	90,9 (20)	4,5 (1)	95,5 (21)	0.500
Preparation-Correct handling of prepared foods	9,1 (2)	90,9 (20)	9,1 (2)	90,9 (20)	0.500
Preparation-Proper disinfection of food to consume in raw	22,7 (5)	77,3 (17)	18,2 (4)	81,8 (18)	0.500
Cooking-Handling cooked food	0,0% (0)	100,0 (22)	0,0 (0)	100,0 (22)	--
Cooking-Absence of food at room temperature	36,4 (8)	63,6 (14)	18,2 (4)	81,8 (18)	0.388
Cooking-Frying oils conditions	0,0 (0)	100,0 (22)	0,0 (0)	100,0 (22)	--
Cooking-Presence of leftovers and scraps	31,8 (7)	68,2 (15)	13,6 (3)	86,4 (19)	0.289
Cooking-Sampling	0,0 (0)	100,0 (22)	0,0 (0)	100,0 (22)	--
Cooking-Eve cooking	13,6 (3)	86,4 (19)	9,1 (2)	90,9 (20)	0.500
Serving-Food exposure conditions	13,6 (3)	86,4 (19)	9,1 (2)	90,9 (20)	0.500
Serving-Exposure temperature	9,1 (2)	90,9 (20)	4,5 (1)	95,5 (21)	0.500
Serving-Plating procedure	0,0 (0)	100,0 (22)	0,0 (0)	100,0 (22)	--
Serving-Existence of non-compliant products	0,0 (0)	100,0 (22)	0,0 (0)	100,0 (22)	--

In “General hygiene for the locker rooms there was also a statistically significant change. It was verified that in an initial phase 12 companies (54.5%) presented non-conformities and of these, 83.3% passed to conform (n=10). Of the restaurants that in the 1st evaluation phase were in agreement, none regressed. At the end of the 4th audit it was found that 9.1% of the establishments maintained non-conformity.

Also, in the large group of “General hygiene” for the first aid box, it was found that in the first evaluation 59.1% failed the compliance and that after applying the methodology of this study, 76.9% (n=10) comply. That means, of the 40.9% of restaurants that initially had compliance, at the end of the fourth phase 77.3% were satisfied and 22.2% maintained non-conformity. These results were also statistically significant (p=0.039).

GMP assessment

The results evaluated were based on the 28 assumptions selected for the evaluation of the GMP. Compliance was maintained between the evaluations on the following items: reception of the raw material (95.5%); handling in preparation (90.9%) and cooking stages (100%); treatment of leftovers (100%) and food sampling (100%) and in serving dishes and the conformity of food products served, both maintaining 100%. Veiros, *et al*. [7] named that the

equipment and materials are suitable for the areas or tasks, but they were not clearly identified for the area by colors or sanitized following the contact with raw foods during the work shift. In the present study, this as was verified in the preparation stage, and the restaurants that didn't comply (n=2) maintained along the study.
The preservation of the noncompliance in these items was not a concern for the researchers since the values for compliance are in the order of 90 to 100%.

In this evaluation group, there was a decline in compliance, namely: in the storage of tubers, in the 1st stage with 100% and in the 4th phase with 95.5% and in cold storage for nonconforming products of 86.4% (1st stage) for 81.8% (4th phase).

As for the weakening of the room temperature storage of tubers, the researchers took into account the fact that the orders of raw material are made in high quantities, there is no stock rotation for their storage time to be reduced. A further justification for the retrogression is the facilities conditions, that don't have the settings for storage of these products and are often in closets close to non-food products (detergents, napkins, etc.).
For storage under cold conditions the increase in the number of nonconformities is due to poor packaging of the products in the cold (ice burns), the break in the cold chain (ice crystals in

packages) and the high number of products in the cold equipment, reducing the capacity of temperature distribution in the equipment.

The study by Garayoa, *et al*. [3] also detected as major deviations in the compliance of the storage stage (70% in refrigeration, 35% in freezing and 40% at room temperature), justifying insufficient space areas, inadequate lighting, and unprotected shelves. Mostly nonconformities for the storage at the room temperature of the nonperishable products were related to the direct contact of the food products with the floor or by the nonphysical separation with cleaning products. All these factors coincide with those detected in this study for the regression of conformities for these points.

There were also statistically significant changes, notably in receiving of products for control ($p= 0.021$). In the first audit 54.5% (n=12) of the companies did not comply and after intervention only 18.2% (n=4) maintained non-conformity. As eight restaurants passed compliance throughout the study. In the 1st audit the nonconformities detected were related to no verification of quantity, temperature, the integrity of containers and expiry date and no records kept for control and tracking, like in Veiros, *et al.* [7] but with the FoodSimplex there was a major evolution towards food safety.

In storage at room temperature, changes in product identification and labeling for compliance were also statistically significant (p=0.003). Initially, only 13.6% were satisfied with the item and after the intervention, 14 companies came to fulfill the requirements (63.6%). Of the 19 non-compliant restaurants (86.4%), only 8 maintained noncompliance in the fourth phase (36.4%).
The same happened for the labeling and identification of products in cold storage under conditions (p-value=0.006), with 90.9% noncompliances in the first evaluation and at the end of the 4th audit there was a decrease to 54.5% restaurants.

In Veiros, *et al.* [7] the cold storage presented nonconformities as well, also with visible labeling. The remaining items evaluated through the audit tool evolved to conformance between the first and last audit. In Garayoa, *et al.* [3], deficiencies were detected, namely: in the treatment of leftovers, which was not verified in this study, with compliance being complied with in 100%; in thawing of products, which also did not occur in this work since compliance in the first phase was 90.9% with an increase in compliance to 95.5% (n=21); and disinfection of vegetables (95%), which in this investigation started with 77.3% compliance and ended with an increase of 81.8% (n=18).

Restaurants – hygiene and GMP

The results of the 1st audit highlighted significant gaps in knowledge, attitudes and practices of safe food handling in restaurants. The areas of high concern were: the poor hygiene of cold storage, cooking, locker rooms, handwashing sinks, 1st aid kit, dishwashers and waste treatment.

In GMP were receiving inspection, labeling in room temperature and cold storage, freezing procedures and cold packaging of food. All these items presented nonconformities in more than 50% of the restaurants.

After the application of FoodSimplex, the restaurants (n=22) showed an evolution in compliance both in hygiene and GMP.
In Figure 1, we found that for Hygiene, there was a statistically significant change for compliance for all companies (p=0.01). Reiterating that the FoodSimplex application has positive results for all hygiene items.

In Figure 2, there was also a statistically significant change to the compliance for all GMP companies (p=0.005), with the Food Simplex method also suitable for this group of items.

The reasons some restaurants still find struggle to comply the food safety requirements is the reduced number of foodservice workers and the time constraints in the restaurants.
FoodSimplex was designed to address all the technical barriers that small and medium-sized catering companies faced in preimplementation, implementation and after the implementation of the HACCP system [14].

One of the differentiating factors in the methodology is that it communicates the audit's results and corrective measures through training to all food handlers as well as to the restaurants FBO. Which proved to be a methodological step of high importance, also according to the study of Powel, *et al.* [2] "*Audit reports are only useful if the purchaser who requires them to review the results, understands the risks addressed by the standards and makes risk-reduction decisions based on the results*".

FoodSimplex also defines time for handling the audit nonconformities detected and sets the time for their correction, knowing the team will be re-evaluated in the next audit. The study by Läikkö-Roto, *et al.* [22], also defends the significance of time limit for corrective measures on the efficacy of the controls.

One of the limitations that we can point out to the study is that the audit tool (or audit checklist) is not valid since there is no scientific basis for certification/validation in audits. There is high variability in the quality and reliability of audits and many different types of audit tools that vary in length, complexity, and style [2]. In the study, the researchers try to develop a checklist according to the stages of the meals production, as well as assess the main 3 groups (hygiene, GMP, and HACCP documentation), with a quantitative evaluation and allowing a periodic application to monitoring the restaurants.

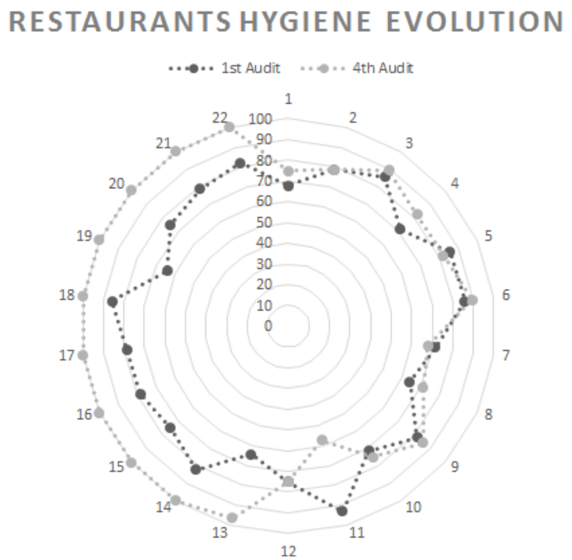

*Figure 1.*Restaurants hygiene evolution

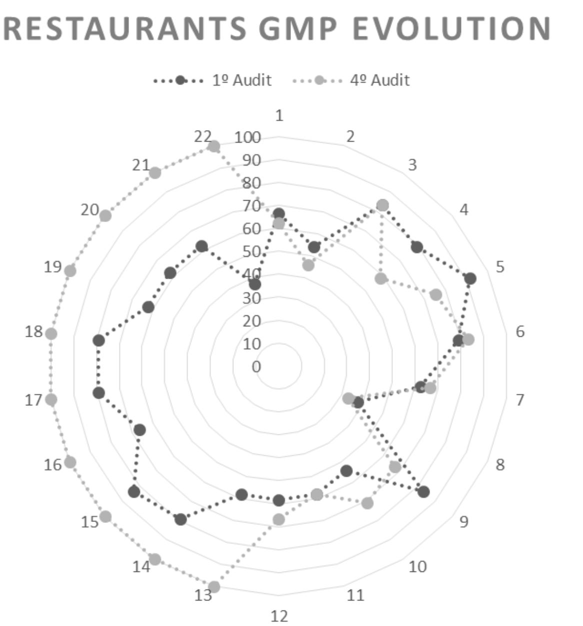

Figure 2. Restaurants GMP evolution

Conclusions

The primary causes of food poisoning in restaurants are cross contamination between raw and cooked foods; insufficient heating; keeping food at room temperature for extended periods of time; contamination by infected food handlers and contamination by inadequately cleaned equipment [23].

The FoodSimplex method allowed us the possibility of assessing food handlers and of exploring how the action plan was useful in changing behaviors towards food safety.

These gaps were resolved with risk-based training of food handlers in the facilities, using appropriate training aids to encourage understanding and assurance in the application of food safety principles in their day-to-day operations.

In this work, the FoodSimplex was linked to a change of habits to obtain a sustained improvement in food safety. It is important to refer that, after continuous and systematic training, with frequent audits, the hygiene and the GMP in these restaurants has improved. As so, this methodology proved to be efficient in public health matters, namely in the production of safer meals in SME restaurants.

References

1. Regulation (EC) No. 1169/2011. The European Parliament and the Council of 25th.

2. Powell DA, Erdozain S, Dodd C, Costa R, Morley K, et al. (2013) Audits and inspections are never enough: A critique to anhance food safety. *Food Control* 30: 686-691.

3. Garayoa R, Vitas AI, Díez-Leturia M, García-Jalón I (2011) Food Safety and the contract catering companies: Food handlers, facilities and HACCP evaluation. *Food Control* 22: 2006-2012.

4. Medeiros CO, Cavalli SB, Proença RPC (2012) Human resources administration processes in commercial restaurants and Food Safety: the action of administrators. *Int J Hosp Manag* 31: 661-674.

5. Baptista P, Linhares M (2005) Hygiene and Food Safety in Catering: Volume I – Initiation. Forvisão. Guimarães, Portugal.

6. Bank of Portugal (2011) Sector Analysis of accommodation, catering and alike. Studies of central balances. Lisbon, Portugal.

7. Veiros MB, Proença RPC, Santos MCT, Rocha A, Kent-Smith L (2007) Proposta de check-list hígio-sanitária para unidades de restauração. *Alimentação Humana* 13: 51-61.

8. APHORT (2008) Code of Good Practices in Food Safety. Portuguese Association of Hotels, Restaurants and Tourism, Portugal.

9. *Codex Alimentarius* (2003) Recommended International code of practice – General Principles of Food Hygiene. CAC/RCP 1-1969 Rev 4.

10. Sun Y, Ockerman HW (2005) A review of the needs and current applications of hazards analysis and critical control point (HACCP) system. *Food Control* 16: 325-332.
11. Regulation (EC) No. 852/2004. The European Parliament and the Council of 29th April 2004.

12. Forsythe SJ, Hayes PR (1998) Food Poisoning and other foodborne hazards. In: Forsythe SJ, Hayes, PR (eds). Food hygiene, microbiology and HACCP. Third edition. Gaithersburg, MD: Aspen Publication, pp: 21-85.

13. Charalambous M, Fryer PJ, Panayides S, Smith M (2015) Implementation of Food Safety Management Systems in small food businesses in Cyprus. *Food Control* 57: 70-75.

14. Panisello PJ, Quantick PC (2001) Technical barriers to Hazard Analysis Critical Control Point (HACCP). *Food Control* 12: 165-173.

15. Haukijärvi V, Lundén J (2017) Does waiving preventive food control inspections in Filand weaken the prerequisites for safe food handling in restaurants? *Food Control* 71: 187-192.

16. ANZFA (2001) Food Safety: an audit system. Australian New Zealand Food Authority. www.info@anzfa.gov.eu

17. Nunes JL, Curto H, Varela M (2016) Gestão de Tesouraria: O impacto da atual crise económica e financeira nas PME portuguesas. Business and Economics School, Lisbon.
18. http://hdl.handle.net/10400.26/15250

19. PORDATA (2017) Pequenas e médias empresas: total e por sector de atividade económica. Base de Dados Portugal Contemporâneo. https://www.pordata.pt

20. Sarter G, Sarter S (2012) Promoting a culture of food safety to improve hygiene in small restaurants in Madagascar. *Food Control* 25: 165-171.

21. Veiros MB, Proença RPC, Santos MCT, Kent-Smith L, Rocha A (2009) Food safety practices in a Portuguese canteen. *Food Control* 20: 936-941.

22. Santos MC (2005) Segurança alimentar Porto/EURO 2004. Universidade Técnica de Lisboa, Lisboa.

23. Läikkö-Roto T, Mäkelä S, Lundén J, Heikkilä J, Nevas M (2015) Consistency in inspection processes of food control officials and efficacy of official controls in restaurants in Finland. Food Control 57: 341-350

24. Ko W (2015) Food suppliers' perceptions and practical implementation of food safety regulations in Taiwan. *J Food Drug Anal* 23: 778–787.

3.2 FoodSimplex as a mean to improve Portuguese restaurants good manufacturing practices - audit and microbial assessment

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FoodSimplex as a mean to improve portuguese restaurants good manufacturing practices - audit and microbial assessment

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A R T I C L E H I S T O R Y

The consumption of meals outside of home increased towards mass catering establishments. The food services may present several risk factors towards foodborne diseases which have a substantial negative impact on public health. The smallest business struggle to comply with food safety European regulation without technical or financial support. The aim of this four years study was to assess Good Manufacture Practices (GMP) in Portuguese restaurants applying a designed food safety methodology, FoodSimplex, through audit data and microbiological sampling of the meals. The audit's results for GMP parameters showed a general improvement with a total of 80% compliance. The ready-to-eat food samples presented regarding the total mesophilic aerobes a statistics significative change to acceptable and satisfactory condition (p-value <0.029); *Listeria monocytogenes* a favorable evolution with 100% compliance and for *E. coli*, *Coagulase-positive staphylococci* and *Salmonella spp.* all the food samples presented satisfactory results. At the end of the investigation period, was observed a decrease in food samples microbial populations and an improvement of the GMP audit data which indicated that the FoodSimplex methodology improved the food safety status of these establishments.

Keywords: public health; food safety; mass catering; restaurants; good manifacture pratices

1. INTRODUCTION

Foodborne diseases (FBD) represent a large group of diseases with a substantial negative impact on health due to their widespread nature. Little consideration is given to such because the symptoms are often moderate and self-limiting (Garayoa *et al.*, 2017; Legnani *et al.*, 2004).

FBD are an urgent problem that threatens the health of people and generates significant economic losses (Guchait *et al.*, 2016). Approximately 48 million people get sick annually because of FBD (Scallan *et al*. 2011). The European Union (EU) reported 355 thousand foodborne diseasrd in 2017 caused by *Campylobacter*, *Salmonella*, bacterial toxins and viruses (EFSA, 2018).

In foodservice environments, various risk factors may be related to FBD, like unsafe food sources, inadequate cooking, improper holding temperatures, contaminated equipment and poor personal hygiene. The general underestimation of FBD importance leads, consequently, to incorrect practices during the preparation and preservation of food, resulting in the frequent occurrence of outbreaks involving groups of varying numbers of consumers (Marzano & Balzaretti, 2011).

EU Regulations on food hygiene focuses on controls needed for public health protection and clarifies the obligation of food business operators (FBO) to produce food safely (Petruzzelli *et al.*, 2018; Marzano & Balzaretti, 2011).

Regulation (CE) nº852/2004 imposes catering businesses to apply a food safety management system (FSMS) based on the 7 principles of hazard analysis and critical control points (HACCP) (Petruzzelli *et al.*, 2018; Lahou *et al.*, 2014). The system aimed at the improvement of employee hygiene practices, cleaning and sanitation programs, proper facility-design practices, equipment-maintenance, supplier selection and specification programs (Santana *et al.*, 2009). In restaurants, due to the complexity of the recipes, menus, food varieties and varies types of foodservice operations, the efficiency of implementing and monitoring HACCP is imperative (Marzano & Balzaretti, 2011; Veiros *et al.*, 2009).

In Portugal, the foodservice system is traditional "cook-serve", a daily basis preparation of food from a raw state to a meal. This type of service brings advantages; consumers associate it with fresh, homemade meals, with sensorial and nutritional quality. However, food safety matters have some constraints, the intensive labour due to the reduced time gap between preparation, cooking and serving; the faulty premises dimensions and the staff number that leads to an increase of food safety risks (Petruzzelli *et al.*, 2018; Marzano & Balzaretti, 2011).

Safer meals are produced by adhering to proper cleaning and sanitation, good manufacturing practices (GMP), good agricultural practices (GAP), etc. and implementation of FSMS such as HACCP (Schothorst *et al*., 2009; Walker & Jones, 2002). As to the FBO should adopt the following specific hygiene measures: (i) compliance with microbiological criteria for foodstuffs; (ii) procedures necessary to meet the objectives of the Regulations (CE); (iii) compliance with temperature control requirements for foods; (iv) maintenance of the cold chain; and (v) sampling and analysis (Regulation (CE) nº852/2004; Petruzzelli *et al.*, 2018).

Catering establishments must control that FSMS can diminish the hazards and to provide evidence that monitoring measures can meet the targets. To assess compliance, companies rely on audit procedures (for example, physical examination of manufacturing facilities, review of HACCP monitoring and verification records, analysis of samples) to verify the adequacy of control measures adopted (Schothorst *et al*., 2009).

The microbiological contamination of foods prepared by catering systems is one of the main parameters that must be assessed to ensure the safety of prepared foods. Indeed, meals can be contaminated by saprophytic microorganisms (total mesophilic aerobes), as well as by spoilage and pathogens (e.g. *Salmonella spp., Listeria monocytogenes, Escherichia coli* and *Staphylococcus* *aureus*). Such contamination depends on the quality of the raw materials and on the application of GMP by the staff (Petruzzelli *et al.*, 2018).

Various documents and guidelines have been developed to facilitate the implementation of prerequisites programs and HACCP in catering services according to the characteristics and needs of small establishments. However, difficulties in the implementation of these FSMS in catering micro, small and medium enterprises (SME) have been reported (Garayoa *et al.*, 2017). As mean to achieve an effectively FSMS in catering SME in Portugal, namely restaurants, a public health tool FoodSimplex was developed.

The purpose of this study is to assess the FoodSimplex in SME restaurants in Portugal, through GMP audit data and microbiological food sampling.

2. MATERIALS AND METHOD

One of the seven principles of the HACCP system is verifying whether the FMFS is functioning correctly. Such verification can be elaborated with a microbiological sampling plan (Lahou *et al.*, 2014). However, no strict requirements related to the sampling plan have been set at a European level. Neither are any sampling guidelines for verification of the system taken up in the food service operation's self-checking guide (Lahou *et al.*, 2014). Quality managers in food service operations mostly select food products and sampling frequencies without a well-described scientifically (Lahou *et al.*, 2014).

The study was designed to cover restaurants SME between 2010-2014, out of 42 restaurants, 24 remained in the study for the four-year period. The sample selection criteria were; Economic Activity Code (EAC) for the restaurant sector (Portuguese financial code), geographic area, belong to SME Portuguese category and availability of the restaurants to participate in the study. The exclusion criteria were, not complying with the duration of the study, bankruptcy and change in economic activity or geographic area.

In the 4 years period of this study, 24 restaurants remained in the study during the period of the investigation.

The results were analyzed considering the GMP audit data and were statistically treated by SPSS version 24 and Excel (Q de Cochran test).

2.1 AUDITS AND CHECKLIST-APPLICATION

The data collection instrument for the food safety audits was a checklist explicitly created for this investigation, regarding Cleaning and Sanitation and GMP, as well as through interviewing the person responsible regarding HACCP aspects (manual of procedures, records, etc.). The checklist was organized into three modules, divided 12 items with a total of 70 subitems for specific topics (Baltazar *et al.* 2017).

For the study, was applied the FoodSimplex methodology based on 28 subitems referred to GMP, according to Table 1 (Baltazar *et al*, 2017).

2.2 FOOD SAMPLE COLLECTION AND MICROBIOLOGICAL ANALYSIS

The food samples were chosen according to an Analytical Sample Plan (Table 2.). All meals were sampled with a casual frequency and with no prior notice. A 150g sample of each tested meal was aseptically collected at each catering plant using sterile instruments and sterile bags (Nasco Whirl-Pak Easy-To-Close Bags, Fisher Scientific Italia, Rodano, Italy) after they were transported in a refrigerated box to the laboratory. The laboratory protocols were made according to Table 3 (Osimani *et al.*, 2018a).

Table 1. FoodSimplex Methodology (adapted from Baltazar *et al*, 2017)

Stage	Actions
1	Diagnosis audit (Assessment of technical/functional premises conditions and HACCP prerequisites)
	HACCP documentation (HACCP plan; Layout; Flowchart; Products; e.g.)
2	Diagnosis audit report
	HACCP Dossier
	Training Action "Hygiene & Food Safety – Restaurants"
3	Microbiological samples
	Food safety audit
4	Audit and microbiological analysis reports
	Training Action "Treatment of non-compliance – audit and microbiological report."
	Restaurant Improvement Plan

The analysis of the data obtained in the microbiological to ready-to-eat foodstuffs was carried out within the FoodSimplex framework and interpreted according to the INSA Guideline Values (Santos *et al.*, 2005) which is more demanding that the European Regulation (CE) nº1441/2007.

The Food Groups were specified according to the "Guideline Values for the Evaluation of the Microbiological Quality of Ready-to-Eat Foods in Restaurant Establishments" of Health National Institute Dr Ricardo Jorge (INSA) (Table 4).

Table 2. Analytical Food Sample Plan

Food Sample	Microbiological parameters	Food Groups (INSA, 2005)
Starters	Microorganisms 30°C Escherichia coli Coagulase-positive staphylococci	Group 1 and 2
Meat Dish	Microorganisms 30°C Escherichia coli Coagulase-positive staphylococci Listeria monocytogenes Salmonella spp	Group 1
Fish Dish	Microorganisms 30°C Escherichia coli Coagulase-positive staphylococci Salmonella	
Soup	Microorganisms 30°C Escherichia coli Coagulase-positive staphylococci Salmonella spp	
Deserts	Microorganisms 30°C Escherichia coli Coagulase-positive staphylococci Salmonella spp	Group 1 and 2
Salads	Microorganisms 30°C Escherichia coli Coagulase-positive staphylococci Listeria monocytogenes	Group 3

Table 3. Reference procedures - microbiological laboratory techniques

Microorganism	Desert	Plate (meat/fish dish)	Salad
Microorganisms 30°C	ISO 4833:2003	ISO 4833:2003	TEMPO TVC (AFNOR - BIO 12/16-09/05)
E coli	ISO 16649-2:2001	ISO 16649-2:2001	TEMPO EC (AFNOR - BIO 12/13-02/05)
Coagulase-positive staphylococci	ISO 6888-1:1999; AOAC OMA	ISO 6888-1:1999	TEMPO STA (AFNOR - BIO 12/28 -04/10)
Salmonella spp	VIDAS SLM (AFNOR - BIO 12/16-09/05)		
	ISO 6579:2002		
Listeria monocytogenes	VIDAS LM02 (AFNOR - BIO 12/11 -03/04)		

Table 4. Food Groups (Santos *et al.,* 2015)

Group 1	Meals / Sandwiches / Cakes /Sweet desserts with ingredients fully cooked, or added spices, herbs aromatic, dried, dehydrated or treated by ionizing radiation, of UHT and mayonnaise products industrialized.
Group 2	Meals / Sandwiches / Cakes / Cooked sweet desserts added with raw ingredients and / or with specific flora
Group 3	Salads / Vegetables / Raw fruits

3. RESULTS

3.1 GMP AUDIT RESULTS

For the GMP assessment, in general, all the results during the study showed an improvement in compliance with statistical significance in some subitems (Table 5).

Table 5. GMP Audit Results

Items	Subitens	Conformity (%)				Q de Cochran	
		Aud. 1	Aud. 2	Aud. 3	Aud. 4	Q	p
Reception	Products inspection	33.3	46.2	40.0	58.3	0.257	0.968
	Conditions of the products	95.7	100.0	95.8	100.0	2.000	0.572
Room Temperature Storage	Separation of food and non-food products	65.2	75.0	75.0	83.3	2.684	0.433
	Organized Stock (FIFO / FEFO)	65.2	87.5	73.9	70.8	4.385	0.233
	Earth products (tubers)	100.0	100.0	95.5	95.7	7.826	0.051
	Labeling / Products identification	16.7	13.0	13.0	17.4	0.375	0.945
	Non-according Food products	53.3	73.9	83.3	83.3	17.328	0.001
Cold Storage	Defrosting conditions	80.0	77.8	71.4	90.9	10.518	0.015
	Organized Stock (FIFO / FEFO)	75.0	75.0	75.0	70.8	0.231	0.972
	Freezing Procedure	47.8	41.7	54.2	60.9	2.222	0.528
	Labeling / Products identification	16.7	8.3	8.3	17.4	1.600	0.659
	Packaging	25.0	29.2	54.2	43.5	5.625	0.131
	Non-according Food products	76.9	85.7	77.3	87.5	11.470	0.009
	Temperatures	75.0	81.8	76.2	100.0	8.143	0.043
	Refreezing conditions	90.5	91.3	95.8	100.0	6.600	0.086

Items	Subitens	Conformity (%)				Q de Cochran	
		Aud. 1	Aud. 2	Aud. 3	Aud. 4	Q	p
Preparation	Preparation conditions	93.8	85.7	93.8	100.0	6.319	0.097
	Correct handling of prepared foods	100.0	77.8	100.0	100.0	9.273	0.026
	Disinfection of food to consume in raw	61.1	61.9	52.4	84.6	0.643	0.887
Cooking	Handling cooked food	80.0	50.0	80.0	100.0	----	----
	Absence of food at room temperature	61.9	45.5	63.6	72.7	3.169	0.366
	Presence of leftovers and scraps	87.5	94.4	94.4	94.1	1.636	0.651
	Frying oils conditions	57.9	78.9	75.0	69.6	5.571	0.134
	Food Sampling	100.0	100.0	100.0	100.0	----	-----
	Eve cooking	68.4	85.0	83.3	81.8	6.240	0.100
Serving	Food exposure conditions	72.7	90.5	69.6	72.7	2.189	0.534
	Exposure temperature	88.2	90.0	70.6	88.2	4.154	0.245
	Plating procedure	100.0	100.0	100.0	100.0	----	-----
	Existence of non-compliant products	91.7	100.0	100.0	94.7	16.176	0.001

Statistical significance in the improvement was shown in the following subitems: Room Temperature Storage – “Non-according Food products” (p value = 0.001); Cold storage – “defrosting” (p value = 0.015); “Non-according Food products” (p value = 0.009);

and “Temperatures” (p value = 0.043); Preparation – “Correct handling of prepared foods” (p value = 0.026); Serving – “Existence of non-compliant products” (p value = 0.001).

3.2 FOOD MICROBIOLOGICAL ANALYSIS RESULTS

The researchers considered 68 food samples from the 24 companies that were available along all the timeline of the study. The microbiological quality of the samples was analyzed according to parameters shown in Table 6.

Table 6. Microbiological Quality Parameters of Food Samples (Santos *et al.*, 2015)

Microorganisms	**Food Groups (INSA, 2005)**	**Microbiological Quality (CFU / g when not indicated)**			
		Satisfactory (S)	**Acceptable (A)**	**Unsatisfactory (US)**	**Unacceptable / potentially dangerous**
Microorganisms 30°C	1	$\leq 10^2$	$>10^2 \leq 10^4$	$>10^4$	NA
	2	$\leq 10^3$	$>10^3 \leq 10^5$	$>10^5$	NA
	3	$\leq 10^4$	$>10^4 \leq 10^6$	$>10^6$	NA
E. coli	1, 2	<10	NA	≥ 10	NA
	3	≤ 10	$>10 <10^2$	$\geq 10^2$	NA
Coagulase-positive staphylococci	1,2,3	$<10^2$	NA	$\geq 10^2 \leq 10^4$	$>10^4$
Salmonella spp.	1,2,3	absent in 25g			present in 25g
Listeria monocytogenes	1,2,3	absent in 25g	present in 25g		$\geq 10^2$

The samples were analyzed by food group (Table 7, 8, 9 and 10.) for all the microbial parameters throughout the investigation and considered 68 food samples from the 24 companies that were in the study for all the timeline, for the evaluation assessment was taken into account the 1st sampling results and the last.

The results were subjected to an integrated interpretation through the analysis between the GMP audit compliance and the results of the food microbiological analyzes. The intention is to verify if the FoodSimplex, as a food safety methodological, is useful for SME restaurants in terms of GMP.

This analysis was only made considering the Microorganisms 30º (mesophiles count) and *L. monocytogenes*, since the other parameters presented a "Satisfactory" classification at all times, validating the FoodSimplex methodology in 100%.

Table 7. Food Group 1 – Microbial Results (Unsatisfactory (US), Acceptable (A), Satisfactory (S))

Nº samples	**Parameters**	**1st evaluation (%)**			**2nd evaluation (%)**			**P**
		US	**A**	**S**	**US**	**A**	**S**	
38	MO 30º	5.3	26.3	68.4	5.3	15.8	78.9	0.527
	L. monocytogenes	0	5.3	94.7	0	5.3	94.7	1
	E. coli	0	0	100	0	0	100	1
	Coagulase-positive staphylococci	0	0	100	0	0	100	1
	Salmonella spp	0	0	100	0	0	100	1

Table 8. Food Group 2 – Microbial Results (Unsatisfactory (US), Acceptable (A), Satisfactory (S))

Nº samples	Parameters	1st evaluation (%)			2nd evaluation (%)			P
		US	A	S	US	A	S	
18	*MO 30º*	0	22,2	77,8	0	0	100	0,157
	L. monocytogenes	0	0	100	0	0	100	1
	E. coli	0	0	100	0	0	100	1
	Coagulase-positive staphylococci	0	0	100	0	0	100	1
	Salmonella spp	0	0	100	0	0	100	1

Table 9. Food Group 3 – Microbial Results (Unsatisfactory (US), Acceptable (A), Satisfactory (S))

Nº samples	Parameters	1st evaluation (%)			2nd evaluation(%)			P
		US	A	S	US	A	S	
12	*MO 30º*	16,7	66,7	16,7	0	16,7	83,3	0,025
	L. monocytogenes	16,7	16,7	66,7	0	0	100	0,180
	E. coli	0	0	100	0	0	100	1
	Coagulase-positive staphylococci	0	0	100	0	0	100	1
	Salmonella spp	0	0	100	0	0	100	1

Table 10. Food Groups 1,2 and 3 – Microbial Results (Unsatisfactory (US), Acceptable (A), Satsifactory (S)

Nº samples	Parameters	1st evaluation (%)			2nd evaluation (%)			P
		US	A	S	US	A	S	
68	*MO 30º*	5,9	32,4	61,8	2,9	11,8	85,3	0,029
	L. monocytogenes	2,9	5,9	91,2	0	2,9	97,1	0,180
	E. coli	0	0	100	0	0	100	1
	Coagulase-positive staphylococci	0	0	100	0	0	100	1
	Salmonella spp	0	0	100	0	0	100	1

4. DISCUSSION

In the 4 years period of this study, 24 restaurants remained in the investigation. The main factor for the decline in the number of companies is due to the Portuguese economic crises which had a significant amount of the SME bankrupted, between 2012 and 2014 (Nunes, Curto & Varela, 2016).

4.1 GMP AUDITS

The results were based on the 28 subitems selected from the audit checklist for the GMP assessment. For a global analysis, the GMP audit results were evaluated in three categories (Table 11.).

Table 11. Categories of GMP audit results

Poor GMP	Compliance <50%
Acceptable GMP	Compliance 50%≤80%
Satisfactory GMP	Compliance >80%

As the most relevant results in food safety matters, there was an improvement from 1st to 4th audit from "Poor GMP" to "Acceptable" in the following subitems: "Reception – products inspection" and "Cold storage – freezing procedure". Veiros *et al.*, 2009 in their study also identified in the "Reception", that there was also a non-compliance towards the verification of quantity, temperature, integrity of containers and expiry date of the food, and no records for control and tracking, and in "Cold Storage", problems with the actual storage of foods, visible labelling and lack of an alert system for the temperatures in the refrigerators. Although, in this investigation, the initial assessment provides “Poor GMP” with FoodSimplex it improved.

The items that improved from “Acceptable GMP” to “Satisfactory” condition were the subitems: “Room temperature - Separation of food and non-food products and non-according food products”; “Cold storage - Non-according Food products and temperatures“; “Preparation - Disinfection of food to consume in raw”; “Cooking - Eve cooking”. The remain subitems maintain compliance towards the categories.

The “Poor GMP” compliance was maintained in “Room Temperature”, and “Cold Storage” subitem “Labeling / Products identification”. Food handlers only at the end of the service make the identification of the products, as so when the audits were in the service period, there was a lack of labelling and identification of the products, like products open date. In "Cold Storage" subitem "Packaging" maintained the "Poor GMP" compliance, with products often presenting ice burns and signs of cold chain break (ice crystals in packages). This fact is due to the high number of products in the cold equipment, which reduces the capacity of temperature distribution in the equipment. The study by Garayoa, *et al*. also detected as significant deviations in the compliance the storage stage (70% in refrigeration, 35% in freezing and 40% at room temperature), justifying insufficient space areas, inadequate lighting, and unprotected shelvesVeiros *et al*., 2009 also support that the existence of sufficient and adequate equipment does not in itself ensure that foods will be stored correctly and taking into account the delivery time, making into the scene the importance role fo the food handlers knowledge.

4.2 FOOD MICROBIOLOGICAL ANALYSIS

A wide range of foods is involved as a source of FBD in restaurants due to incorrect food handling and processing operations (Soriano et al., 2000).

Microbiological analyses are one of the potential tools that can be used to evaluate whether a food safety risk management system is providing the level of control it was designed to deliver (Schothorst *et al*., 2009). Microbiological criteria are developed to determine adherence to cleaning and sanitation and GMP when more effective and efficient means are not available (Schothorst *et al*., 2009).

This study showed no contamination in any Food Group towards *Salmonella spp*., *Coagulase-positive staphylococci* and *E. coli* in concordance with some authors (Tables 7,8,9, and 10) (Petruzzelli *et al.*, 2018). However, studies showed higher microbial values than recommended, for *E. coli* in meat samples (Arranz, Gómez & Peña, 1995; Ferrer, Simón & Tarragó, 1992) and for *Coagulase-positive Staphylococci* in eggs based dishes (Soriano *et al*., 2002), which the presence of *S. aureus* indicates improper handling and possible cross-contamination. According to Santana *et al*., 2009, the implementation of GMP reduces the amount of aerobic plate count, *staphylococci coagulase-positive* and thermotolerant coliforms in meals, and in this study, the FoodSimplex methodology may contribute to these satisfactory results through the firsts stages.

The WHO considers that the primary mechanism of transmission of *L. monocytogenes* to humans is through foodstuffs contaminated during production and/or processing. In this investigation, *L. monocytogenes* was detected in unsatisfactory (US) values in the first evaluation mainly in Food Group 3 which is primarily constituted by salads (Table 9.), unlike other studies where was also found in meat, fish and seafood dishes (Soriano *et al.*, 2001; Santana *et al*., 2009). In the first microbial evaluation, some restaurants showed incorrect disinfection procedures, with no sodium hypochlorite to sanitize the vegetables or with wrong doses or time application (Martínez-Tomé, Vera & Murcia, 2000; Soriano *et al.*, 2001; Sospedra *et al.*, 2013). Due to the non-compliance in the microbial analysis, FoodSimplex methodology specifies the development of training activity to the food handlers to assess the possible causes of the high microbial deviation, and in the final microbial evaluation, the results were within the recommended values (Table 9).

The Microorganisms 30º found in food have been microbiological indicators of the quality of the most commonly used food, indicating if there were flaws in the cleaning and sanitation processes, temperature control, thawing, transportation and storage. As so, mesophyll microbiota is the primary indicator of general hygiene because it requires the same growth conditions as most pathogenic species in the meals (Lacasse, 1995).

In this study, Microorganisms 30º in Food Group 2 (Table 8.), first evaluation, had values in an acceptable (A) and satisfactory (S) class and had an improvement to 100% to "S" results in the final evaluation. However, in Food Groups 1 and 3 that was not the case (Table 7 and 9).

In Food Group 1 (Table 7.), in the first and final evaluation, the percentage of "US" results maintain, which may indicate poor handling of meals after cooking. The speed of service in meal hours may be one of the reasons for these values. However, there was also an improvement for some restaurants which had "A" values and improved them into a satisfactory condition. In Food Group 3 (Table 9), in the first evaluation, existed "US" results, but after the non-compliance treatment procedure, through training, the results all improved to "A" and "S" in the final evaluation. These results support the GMP audit results for the improvement of the subitem “Preparation - Disinfection of food to consume in raw”.

After application of FoodSimplex methodology, the microbiological quality of food has generally improved, with an equally important point that was the contribution of this results to the identification of weak spots in the general management of the food production process. The knowledge of these problems was essential for the improvement of the control system of restaurants and to adjust the staff training contents, in order to obtain more excellent safety in mass catering services (Legnani *et al*., 2004). The presence of some of the microorganisms studied showed that there are some handling practices that require more attention, in the “cook-serve” system, like keeping the meals warmed or refrigerated after cooking, in proper containers to avoid the occurrence of microbiological contamination and proliferation (Soriano *et al.,* 2002).

Article 9 of the Regulation (EC) nº 2073/2005 on microbiological criteria for foodstuffs expressly states that to prevent the occurrence of a microbial risk, FBO shall analyze trends in the test results to take appropriate action when they observe a bias towards unsatisfactory results. Indeed, different authors state that the microbiological monitoring of end products has been effectively used to evaluate the HACCP plan and to discover persistent problems related to microbial contamination in catering premises (Petruzzelli *et al.*, 2018). In fact, through FoodSimplex methodology was possible to apply and certified better results in audit and microbial data towards GMP.

CONCLUSION

New literature reviews have highlighted the contribution of mass catering to the spread of FBD. Specifically, inadequate hygiene during food preparation and storage was the primary risk factor with staff members directly involved in most documented outbreaks.

At the end of the investigation period, with the application of FoodSimplex methodology, was observed an improvement in GMP, through audit data, and decrease in microbial populations of examined food samples, which indicated that the 4^{th} stage of FoodSimplex, that addresses the training and the presentation of the audit and microbial reports to the food handlers represents an added value to food safety in restaurants.

REFERENCES

Arranz, AS; Gómez, DPM & Peña, CE (1995). Sanitary quality from snacks in bars in the summertime. Alimentaria 265:73-77.

Baltazar, A; Figueiredo, JP; Ferreira, A; Manyes, L; Mañes, J (2017). *FoodSimplex in restaurants - how can it provide safer meals?* Integr Food Nutr Metab 4(5): 1-6.

Comissão Europeia. Regulamento nº 2073/2005 de 15 de novembro, relativo a critérios microbiológicos aplicáveis aos géneros alimentícios e subsequentes alterações. Jornal Oficial da União Europeia. 22.12.2005. L 338/1-26.

Comissão Europeia. Regulamento nº 852/2004 do Parlamento Europeu e do Conselho de 29 de abril, relativo à higiene dos géneros alimentícios. Jornal Oficial da União Europeia. 30.4.2004. L 139/1-[54].

Codex Alimentarius Commission. General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 4-2003. Rome: FAO/OMS, 2003.

Codex Alimentarius Commission. Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering, CAC/RCP 39-1993. Rome: FAO/OMS, 1993.

Codex Alimentarius Commission. Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Foods, CAC/GL 61-2007. Rome: FAO/OMS, 2007.

EFSA (2018). *The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2017*. EFSA journal 2018, 16 (12): 5500.

Ferrer, MD; Simón, M & Tarragó, C (1992). Presence of microorganisms in prepared cooked foods. Alimentaria 299: 69-70.

Garayoa, R; Abundancia, C; Díez-Leturia, M; Vitas, AI (2017). *Essential tools for Food Safety surveillance in catering services: on-site inspections and control of high-risk cross-contamination surfaces*. Food Control 75, 48-54.

Guchait, P; Neal, JA; Simons, T. (2016). *Reducing food safety errors in the United States: Leader behavioural integrity for food safety, error reporting and error management*. International Journal of Hospitality Management 5, 11-18.

Lacasse, D. (1995) Introdução à Microbiologia Alimentar.Instituto Piaget, Lisboa, p:421-424.

Lahou, E; Jacxsens, L; Van Landeghem, F; Uyttendaele, M. (2014). *Microbiological sampling plan based on risk classification to* *verify supplier selection and production of served meals in food service operation.* Food Microbiology 41, 60-75.

Legnani, P; Leoni, E; Berveglieri, M; Mirolo, G; Alvaro, N. (2004). *Hygienic control of mass catering establishments microbiological monitoring of food and equipment.* Food Control 15, 205-211.

Martínez-Tomé, M; Vera, AM; Murcia, MA. (2000). *Improving the control of Food production in catering establishments with particular reference to the safety of salads*. Food Control 11, 437-445.

Marzano, MA & Balzaretti, CM (2011). *Cook-serve method in mass catering establishments: Is it still appropriate to ensure a high level of microbiological quality and safety?* Food Control 22, 1844-1850.

Nunes JL, Curto H, Varela M (2016) Gestão de Tesouraria: O impacto da atual crise económica e financeira nas PME portuguesas. Business and Economics School, Lisbon. Available in http://hdl.handle.net/10400.26/15250.

Osimani, A; Aquilanti, L & Clementi, F (2018). *Bacillus cereus foodborne outbreaks in mass catering*. International Journal of Hospitality Management 72, 145–153.

Osimani, A; Milanovic, V; Polverigiani, S; Garafalo, C; Clementi, F (2018). Hygiene auditing in mass catering: a 4-year in a university canteen. Public Health I59, 17-20.

Petruzzelli, A; Osimani, A; Tavoletti, S; Clementi, F; Vetrano, V; Di Lullo, S; Paolini, F; Foglini, M; Micci, E; Orazietti, N; Luchetti, T; Tonucci, F (2018). *Microbiological quality assessment of meals and work surfaces in a school-deferred catering system.* International Journal of Hospitality Management 68, 105-114.

Santana, NG; Almeida, RCC; Ferreira, JS; Almeida, PF (2009). *Microbiological quality and safety of meals served to children and adoption of good manufacturing practices in public school catering Brazil.* Food Control 20, 255-261.

Santos, MI; Correia, C; Cunha, (2005). *Valores Guia para Avaliação da Qualidade Microbiológica de Alimentos Prontos a Comer Preparados em Estabelecimentos de Restauração*. Revista da Ordem dos Farmacêuticos 64, 66-68.

Scallan, E; Griffin, PM Angulo, FJ; Tauxe, RV; Hoekstra, RM. (2011). *Foodborne illness acquired in the United States – unspecified agents*. Emerg. Infect. Dis. 17, 16-22.

Schothorst, M; Zwietering, MH; Ross, T; Buchanan, RL; Cole, MB; International Commission on Microbiological Specifications for Foods (2009). *Relating microbiological criteria to food safety objectives and performance objectives.* Food Control 20, 967-979.

Sospedra, I; Rubert, J; Soriano, JM & Mañes, J (2013). Survey of microbial quality of plant-based foods served in restaurants. Food Control 30, 418-422.

Soriano, JM; Rico, H; Mólto, JC; Mañes, J (2002). *Effect of introduction of HACCP on the microbiological quality of some restaurant meals.* Food Control 13, 253–261

Regulation (EC) No. 852/2004. The European Parliament and the Council of 29th April 2004.

Veiros, MB; Proença, RPC; Santos, MCT; Kent-Smith, L; Rocha, A (2009). Food safety practices in a Portuguese canteen. Food Control 20, 936-941.

Walker, E & Jones, N (2002). *An assessment of the value of documenting food safety in small and less developed catering businesses*. Food Control 13, 307-314.

3.3. FoodSimplex - a public health tool to improve restaurants cleaning and sanitation status

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FoodSimplex - a public health tool to improve restaurants cleaning and sanitation status

FoodSimplex - una herramienta de salud pública para mejorar el estado de sanitario de los restaurantes

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Abstract

Foodborne diseases have a negative impact on health, and little consideration has been given to such because the symptoms are often moderate and self-limiting. The microbiological contamination of meals by catering systems is one of the main issues, and it must be assessed to ensure safer meals. The aim of this study is to evaluate the hygienic quality in portuguese micro, small and medium restaurants through audit data and microbial sampling through the application of new food safety methodology – FoodSimplex. This four-year longitudinal study revealed maintenance or an improvement in the compliance with hygiene requirements according to the FoodSimplex checklist, and with statistical significance evolution in food handlers hands microbial analyses (p=0,003), which confirms that FoodSimplex contributed for a general food safety status uplift.

Keywords: public health, food safety, foodsimplex, restaurants, hygiene status

Resumen

Las enfermedades transmitidas por los alimentos tienen un impacto negativo en la salud y se les ha prestado poca atención porque los síntomas suelen ser moderados y autolimitados. La contaminación microbiológica de las comidas por los sistemas de restauración es uno de los principales problemas, y debe evaluarse para garantizar comidas más seguras. El objetivo de este estudio es evaluar la calidad higiénica en micro, pequeños y medianos restaurantes portugueses a través de datos de auditoría y muestreo microbiano mediante la aplicación de una nueva metodología de seguridad alimentaria: FoodSimplex. Este estudio longitudinal de cuatro años reveló un mantenimiento o una mejora en el cumplimiento de los requisitos de higiene de acuerdo con la lista de verificación de FoodSimplex, y con una evolución estadísticamente significativa en los análisis microbianos ($p = 0{,}003$), que confirma que FoodSimplex contribuyó para aumentar la seguridad general de los alimentos.

Palabras clave: salud pública, seguridad alimentaria, foodsimplex, restaurantes, higiene.

1. Introduction

The trend towards consuming meals outside of the home is found in many countries. The continued improvement of quality and productivity in restaurants can be a competitive advantage that leads the client to prefer one service over another, making quality a tool for proper sustainable management. The employees and owners food handling activities are directly related to managing hygienic-sanitary quality and for providing safe meals to the clients (Medeiros, Cavalli & Proença, 2012). Severe shortcomings have been noted in food safety knowledge of restaurant head chefs, catering managers, and other persons in charge of hygiene (Läikkö-Roto & Nevas, 2014).

Hygienic food preparation and the education of those involved in preparing, processing and service of meals are essential lines of defence in the prevention of most types of foodborne illness the infectious agent may be transferred to food directly or by cross-contamination (Veiros *et al.*, 2009).

A common outcome of poor knowledge is a recommendation for training. According to some authors, regular training programs for the safe production of food and effective handwashing practices should be introduced. Recently, combined theoretical and practical training of food safety was shown to lead to a lower level of hand contamination (Soares *et al.*, 2013).

There are limitations relating to finances, technical, information and human resources existing in micro, small and medium enterprizes (SME) of the mass catering sector (Charalambous *et al*., 2015). This fact takes to a severe hindrance to the implementation of the food safety systems, like Hazard Analyse Critical Control Point (HACCP), in this group of food businesses (FAO/WHO, 2006). There are many barriers hindering the implementation of the HACCP system in SME that involves a lack of understanding of the need for system documentation (Holt & Henson, 2000), a lack of qualified staff for the system implementation, insufficient skills for the assessment of the qualifications of an external consultant who is employed for the HACCP implementation (Karipidis *et al*., 2009), limitations relating to qualified and experienced staff, as well as a low level of knowledge of food safety relating to the control of microbiological hazards (Walker, Pritchard & Forsythe, 2003).

The consumption of contaminated food by pathogenic microorganisms and their toxins are the main responsible for foodborne diseases (FBD), in particular, gastrointestinal infections which have a severe negative impact in public health (Marzano & Balzaretti, 2011). In foodservice environments, various factors are related to FBD, like unsafe sources of food, inadequate cooking, improper holding temperatures, contaminated equipment and poor personal hygiene. Hygienic food preparation and training of food handlers are essential lines of prevention of FBD (Marzano & Balzaretti, 2011).

FoodSimplex is a food safety methodologic tool to SME restaurants that have the constraints mentioned above in the implementation of HACCP. It's a defined combination of stages that includes diagnostic audits, HACCP documentation preparation, training, food safety audits, microbial analyses and plan for non-compliance treatment. FoodSimplex was designed as a public health tool to be applied by Food safety technicians (Baltazar *et al*., 2017). This study results from an investigation regarding FoodSimplex, in order to compare food safety status towards cleaning and sanitation, good manufacturing practices (GMP), HAPPCs documentation and microbial analyses before, during and after its implementation. The aim of this particular study was to assess the hygienic quality of the restaurants based on audit and microbial analyses results with the application of FoodSimplex.

2. Methodology

The sample group was SME – restaurants in Portugal, in total forty-two volunteer SME's were recruited to participate in the study. The sample selection criteria were: Economic Activity Code (EAC) for the restaurant sector (Portuguese financial code); Geographic area (Leiria district); belong to SME Portuguese category (undertakings employing fewer than 250 persons and the annual turnover of which shall not exceed EUR 50 million or whose annual balance sheet total does not exceed EUR 43 million) and availability of the restaurants to participate in the study. The exclusion criteria were, not complying with the duration of the study, bankruptcy and change in economic activity or geographic area.
During the study in each business was applied FoodSimplex methodology (Table 1.)

In stage 1 was performed a diagnosis audit and gathering of information about the food business premises, on identifying any areas of potential improvement, and to design the HACCP plan. Stage 2, participants received introductory training in food hygiene, and HACCP was presented the diagnostic audit results and assistance to implement the pre-requisite programmes. After stage 2, the sampling plan for microbial analyses began as the Food safety audits, for every assessment, by this two means, was developed training regarding the correction of the non-compliance items and to design an improvement plan (Charalambous *et al.*, 2015).

Table 1. FoodSimplex Methodology (adapted from Baltazar *et al*, 2017)

Stage	Actions
1	Diagnosis audit (Assessment of technical/functional premises conditions and HACCP prerequisites)
	HACCP documentation (HACCP plan; Layout; Flowchart; Products; e.g.)
2	Diagnosis audit report
	HACCP Dossier
	Training Action "Hygiene & Food Safety – Restaurants"
3	Microbiological samples
	Food safety audit
4	Audit and microbiological analysis reports
	Training Action "Treatment of non-compliance – audit and microbiological report."
	Restaurant Improvement Plan

2.1 Audit

Hygiene was assessed using an audit tool, developed for the purpose, after consideration of standard hygiene criteria such as those listed in official control audits and scientific literature.

The contents of the audit checklist were evaluated by Food safety experts, consisted of 70 observations and three modules (Table 2.), each of which could be answered as 'compliance', 'non-compliance' or "Not applicable". In this study for the assessment of the restaurants' hygiene has analysed the results of module "Cleaning and sanitation" and the subitem "hygiene of the facilities and equipment" in the GMP module for each item (Reception, Room Temperature and Cold Storage, Preparation, Cooking and Serving) and the "Facilities" module during the timeline of the investigation.

Table 2. Audit Checklist structure

Module	Main Item	Nº subitems
Good Manufacture Practices (GMP)	A. Reception	3
	B. Room Temperature Storage	6
	C. Cold Storage	9
	D. Preparation	4
	E. Cooking	7
	F. Serving	5
Cleaning and Sanitation	G. Personal Hygiene	4
	H. General Sanitation	8
	I. Cleaning & Disinfection	6
Prerequisites HACCP and documentation	J. Records	2
	K. Documentation	11
	L. Facilities	5

2.2 Microbiologic Analyses

Swabs were taken from the hands of food handlers prior to food contact in the pre-preparation, preparation and cooking areas and were collected by the swab method (Santana *et al*., 2009). Samples of the hands were collected during the work of randomly selected food handlers from the SME restaurants, after washed the hands, according to the established procedure, before the harvest.

Sampling was performed using swabs, test and cap tubes, sterile disposable gloves, Styrofoam box, adhesive label and pen. The test tubes contained 10 mL of diluent (sterile buffered water) each, which were stored in styropor and the transportation was carried out under refrigeration (between 0 and 4º C) to the laboratory. The procedure was according to ISO 18593: 2004 – "Horizontal methods for sampling techniques from surfaces using contact plates and swabs" (point 8 and 9) and the microbial analysis of the hands of the workers, total aerobic microorganisms were counted at 30°C, was according to ISO 4833:2003 – "Horizontal method for the enumeration of microorganisms -- Colony-count technique at 30 degrees C".

The establishment of microbiological criteria is a risk management measure, which will allow an increase in consumer protection and competitiveness among food business operators through the definition of fair and precise rules in the European Union (Gomes, 2007). When establishing microbiological limits, the risks related to microorganisms and the conditions for food handling and consumption should be considered, as well as the likelihood of the microorganisms being distributed unequally in the food and the variability inherent in the analysis procedure (*Codex Alimentarius*, 2003). However, the criteria stipulated by Regulation (EC) Nº 2073/2005 relate only to microorganisms in food, and no limits are established for the hands of manipulators. Due to the lack of microbiological criteria for the hands of handlers with food during meal confectionery, microbiological limits should be set on the basis of guides and standards of legislation, literature, practical experience, prior data and internal rules of each. Thus, each company must define the criteria that best fit its operating system. For this investigation, was considered the microbial criteria of laboratory responsable for the analyses.

The samples examined are divided into three categories: *satisfactory, acceptable and unsatisfactory.* A three-class sampling plan is used if it is acceptable that some samples exceed the lower limit (m), as long as a risk contamination level (M) is not exceeded (Table 3.).

Table 3. Laboratory Microbial Criteria (CFU/cm^2)

Microorganisms	**Microbial Criteria (CFU/cm^2)**		
	Unsatisfactory	***Acceptable***	***Satisfactory***
Microorganisms 30°C	> 10^2	≥ 4 ≤10^2	<4

3. Results

3.1 Hygiene Audit Data

The results in table 4. represent the percentages of conformities in the items and in the global hygiene assessment domain observed in the four audit moments. The Percentages of higher conformities are found in items "Facilities - Drinking Water", "Facilities - Gas and electricity", "Reception - Hygiene of the facilities and equipment", "Personal Hygiene – Visible diseases", "Cleaning & Disinfection - Operational dishwasher equipment", "General Sanitation – Use/conditions of non-food products" and "Facilities – Suitability".

Table 4. Hygiene Audit Data

Items	Subitens	Conformity (%)				p-value
		Aud. 1	Aud. 2	Aud. 3	Aud. 4	
Reception	Hygiene of the facilities and equipment	91,3	100,0	87,0	100,0	0,475
Room Temperature Storage		52,2	62,5	58,3	83,3	0,085
Cold Storage		20,8	25,0	8,3	4,2	0,112
Preparation		60,9	58,3	50,0	82,6	0,088
Cooking		45,8	39,1	54,2	65,2	0,157
Serving		81,0	95,7	78,3	83,3	0,249
Personal Hygiene	Uniforms	73,9	47,6	65,2	75,0	0,028
	Gloves	80,0	83,3	90,0	100,0	a)
	Evidence of adornments and/or lack of personal hygiene	81,0	95,5	90,9	95,0	0,417
	Visible diseases	100,0	100,0	100,0	100,0	0,468

Items	Subitens	Conformity (%)				p-value
		Aud. 1	Aud. 2	Aud. 3	Aud. 4	
General Sanitation	Dressing rooms	33,3	47,8	56,5	77,3	0,013
	Soap and disinfectant dispensers and towel rails	52,2	58,3	54,2	78,3	0,210
	No manual washbasin with hot and cold water	38,5	26,1	27,3	28,6	0,981
	First aid kit	55,0	38,9	57,9	47,4	0,585
	Cloths	60,9	78,3	70,8	75,0	0,487
	Obsolete material and equipment	70,8	73,9	63,6	79,2	0,474
	Use/conditions of non-food products	95,8	95,7	77,3	94,7	0,042
	Sanitary plan compliance	80,0	83,3	83,3	100,0	a)
Cleaning & Disinfection	Dishwashing conditions	41,7	20,8	25,0	54,5	0,046
	Operational dishwasher equipment	95,8	95,7	95,8	95,8	0,801
	Waste containers	17,4	25,0	25,0	36,4	0,420
	Pest Control	59,1	57,1	42,9	57,1	0,392
	Waste Treatment	83,3	90,5	85,0	95,2	0,595
	Chemical Products Storage	54,2	69,6	45,5	73,9	0,093
Facilities	General conditions	45,8	62,5	58,3	58,3	0,440
	Suitability	100,0	83,3	79,2	91,7	0,069
	Drinking Water	100,0	100,0	100,0	100,0	0,392
	Gas and electricity	100,0	100,0	100,0	100,0	1,000
	March in Front	75,0	83,3	66,7	100,0	0,004
Global assessment		66,0	66,9	63,8	76,1	0,004

a) not a reliable number of observations in audit

The items in which lower percentages of conformities were observed were “Cleaning & Disinfection - Waste containers”, “Cold Storage - Hygiene of the facilities and equipment”, “General

Sanitation - No manual washbasin with hot and cold water", "Cleaning & Disinfection - Dishwashing conditions", "Facilities - General conditions", "Cooking - Hygiene of the facilities, equipment and utensils" and "General Sanitation - Dressing rooms".

The Cochran's Q test revealed the existence of statistically significant differences (p-value < 0,05) in the items "Personal Hygiene – Uniforms", "General Sanitation - Dressing rooms", "General Sanitation – Use/conditions of non-food products", "Cleaning & Disinfection - Dishwashing conditions" and "Facilities - March in Front".

The Friedman test, used to compare the overall percentages of conformities in the four audit moments, revealed the existence of significant differences (p-value = 0.004), and it was found that the hygiene conditions improved at the fourth audit time.

3.2 Microbiologic Analyses – Food Handlers

The results in Table 5 verify that the percentage of microbiological analyzes done to food handlers with the satisfactory result was much higher in the last evaluation compared to the result observed in the first evaluation. The Wilcoxon signed ranks test revealed that the differences were statistically significant (p-value = 0.003).

4. Discussion

4.1 Audit

All sections of the audit score show the sample group made improvements in hygiene during the study by comparison with their score at the beginning. These results are similar to the study of Charalambous *et al*., 2015.

Regarding the items concerning the meal production stages (reception, storage, preparation, cooking and distribution) the subitem "Hygiene of the facilities and equipment" presented a general improvement towards compliance, except in the cold storage. For this matter, the results might be due to the few numbers of equipment in the kitchens, that lead to ice accumulation, which compromises the hygiene status.

In the module "Personal Hygiene", there was a statistical significant improvement in the use of uniforms ($p = 0{,}028$), regarding the "gloves" subitem there was not enough data to provide statistical analyse, because not always the food handlers tasks require their utilization as so it was not a reliable number of observations in audit moment. For the subitem "Evidence of adornments and/or lack of personal hygiene" there was a definite change unlike the investigation of Rodríguez *et al*., 2011 which verified noncompliant behaviours of handlers, as the and change of gloves, use of aprons for cleaning hands, and wearing jewellery. Rodríguez *et al*., 2011, Campos *et al*.., 2009 and Veiros *et al*.., 2009 detected the proper use of hair nets in only 23%, 33%, 24% respectively, in this investigation, 75% comply. Also, in Osimani *et al*., 2018 food handlers of a canteen were found to wear earrings and necklaces during food preparation, and the required cap was not always correctly worn.

Through the study, this kind of behaviour has received considerable attention through FoodSimplex training and procedures because it represents a concern as jewellery could inadvertently fall in the preparations, thus constituting a risk for the consumer.

In the audit assessment for "General Sanitation", subitems like "Soap and disinfectant dispensers and towel rails", "First aid kit", "Cloths", "Obsolete material and equipment" had improve towards compliance, with statistical significance in subitems "Dressing rooms" (p=0.013) and "Use/conditions of non-food products" (p=0.042).

The use of cloths, which can favour the bacterial spread, also had an improvement (Bergen *et al*., 2009).

For the item “Cleaning and Disinfection”, Osimani *et al*., 2018 found negative compliance in general conditions of cleanliness, concerning food preparation areas, low level of inadequacy for the cleanliness of tools and tableware. In this study, dishwashing conditions have improved some restaurants initially didn’t have dishwashing machines or with no pre-washing procedures (p-value = 0.046), restaurants with dishwashing machines presented some times problems in drying procedure. Waste containers were recommended to be in washable material with plastic bags in the interior and with waste separation for reclining.
Pest control fulfilled the designation, but there was some inadequate management in the file sheets archive, map of baits and identification of the placement of the same in the kitchen.

Regarding the item “Facilities” there was a generally positive change to compliance in all subitems. Initially like Haukijärvi & Lundén, 2017 mainly noncompliance was concerning infrastructure with cleaning facilities missing, adverse conditions of ceilings, walls and floors and with small spaces for their intended purpose. The terms of potable water, gas and electricity supply were adequate and remained in that condition through the study (p-value=1). Facilities “general conditions” improved with hygiene practices but the suitability of the facilities and a small decline in compliance, due to adulteration of the use of some areas in service time (e.g. preparation zone with unclean crockery). The “march in front” practice, had an improvement through the design of flow diagrams in each kitchen layout, no improvement with statistical significance (p-value= 0.004).

The correction of noncompliance related to infrastructure can be difficult due to economic reasons and especially difficult when operations have started. Proper facilities enabling GMP are essential at all types of food premises, especially in restaurants, which are the most common sites of foodborne outbreaks (Haukijärvi & Lundén, 2017; Zoonosis Center, 2015). The FoodSimplex methodology allowed an evolution towards compliance in this item in SME restaurants.

At the end of the investigation and according to cleaning and sanitation assessment in audit data, there was a statistical significant improvement towards compliance (p-value=0.004).

4.2 Microbiologic Analyses – Food Handlers

Rodríguez *et al*. (2011) verified regarding the use of gloves, that the general trend observed was that food handlers did not use gloves regularly, and hand washing was not always done correctly. These inappropriate behaviours can lead to the presence of pathogens, that can survive for a relatively long time and could also be transmitted through the food chain. In this investigation, there was an improvement with statistical significance in food handlers hands microbial analyses (p=0.003), which confirms that the FoodSimplex methodology contributed for the uplift.

Unhygienic handling of food causes a critical risk for food safety. Poor hygiene has been shown to lead to the detection of pathogens like *Salmonella Enteritidis* on hand towel samples and *Staphylococcus aureus* and *Escherichia coli* O157:H7 in the working equipment (Sheth, Gupta, & Ambegaonkar, 2011). Among food handlers, a lack of knowledge has been reported regarding food allergens, temperatures in food handling, hand hygiene, and other microbiological risks for food contamination.

The primer identification of deficient practices leads to the implementation of effective training methods for food handlers in food service systems. The results of several studies by Bergen *et al*. 2009, Santana *et al*, 2009 and Veiros *et al*., 2009 have confirmed that training of food handlers can be useful. However, training should be repeated over time to overcome the reluctance of food handlers to apply the acquired knowledge, which it looked on with FoodSimplex.

FoodSimplex had in account other factors that influence the hygiene of food handlers like the number of meals served, the socioeconomic status of the geographical area, and the number and qualifications of the staff members (Bering, 2008; Griffith, 2002) and relies in recommended periodic microbiological assessment of highrisk food service operations, in addition to visual inspection, for minimizing the risk of foodborne disease outbreaks.

5. Conclusion

Studies have associated foodborne disease outbreaks with poor personal hygiene than with unsafe food sources. This investigation performed a 4-year intervention in SME restaurants with the application of FoodSimplex methodology regarding hygiene status. Based on the results, the improvement towards compliance were statistical significant not only in audit data but also in food handlers hands microbial analyses. The scores on attributes evaluated in the checklist were correlated with microbial counts in food handlers hands, initially with a relation between audit and microbial data to improper hygienic measures, but along the study the improvement was notorious. As so, FoodSimplex is shown to be an essential public health tool, with effective contribute to the safety uplift of the meals served.

6. References

Baltazar, A; Figueiredo, J; Ferreira, A; Manyes, L; Mañes, J (2017). *FoodSimplex in restaurants – how can it provide safer meals?*. Integr Food Nutr Metab, Volume 4(5), 1-6.

Bergen, LK; Meyer, M; Høg, M; Rubenhagen, B; Andersen, LP (2009). *Spread of bacteria on surfaces when cleaning with microfibre cloths*. J. Hosp. Infect. 71:132–137.

Bering, CC (2008). *Condicões higiénico-sanitárias no preparo de refeicões em creches comunitárias de Belo Horizonte, Minas Gerais*. Tese de Mestre em Ciência de Alimentos, Facultade de Farmácia da UFMG, Belo Horizonte, Minas Gerais, Brazil.

Campos, C. A. K., S. A. M. Cardonha, L. B. Galva˜o-Pinheiro, R. N. Ferreira, P. R. Medeiros de Azevedo, and M. T. L. Stamford. 2009. Assessment of personal hygiene and practices of food handlers in municipal public schools of Natal, Brazil. Food Control 20:807–810.

Charalambous, M; Fryer, PJ; Panayides, S; Smith, M (2015). *Implementation of Food Safety Management Systems in small food businesses in Cyprus*. Food Control 57: 70-75.

Codex Alimentarius Commission (2003). *Code of practice - general principles of food hygiene*. CAC/RCP 1-1969, Rev. 4-2003. Rome.

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. Retrieved in https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32005R2073

Gomes-Neves, E., Araújo, A.C., Ramos, E. and Cardoso, C.S. (2007) Food Handling: Comparative Analysis of General Knowledge and Practice in Three Relevant Groups in Portugal. Food Control, 18, 707-712.

Griffith, C (2000). *Food safety in catering establishments*. Safe handling of foods, p 235–256. J. M. Farber and E. C. D. Todd (ed.), Marcel Dekker, New York.

FAO/WHO. Second FAO/WHO global forum of food safety regulators. Building effective food safety systems, Bangkok, Thailand, 12e14 October. 2004. Issued by the Joint Secretariat of the FAO/WHO Global Food of Food Safety Regulators, FAO, Rome. Available online: ftp://ftp.fao.org/docrep/fao/meeting/008/y5871e/y5871e00.pdf

Haukijärvi, V & Lundén, J (2017). *Does waiving preventive food control inspections in Finland weaken the prerequisites for safe food handling in restaurants?*. Food Control 71, 187-192.

Holt, G & Henson, SP (2000). *Information for good hygiene practice in small businesses.* British Food Journal, Vol. 102 Issue: 4, pp.320-337

Karipidis, P; Athanassiadis, K; Aggelopoulos, S; Giompliakis, E (2009). *Factors affecting the adoption of quality assurance systems in small food enterprises*. *Food Control, 20(2), 93-98*

Läikkö-Roto, T & Nevas, M (2014). *Restaurant business operators' knowledge of food hygiene and their attitudes toward official food control affect hygiene in their restaurants*. Food Control 43, 65-73.

Marzano, MA & Balzaretti, CM (2011). *Cook-serve method is mass catering establishments: Is it still appropriate to ensure a high level of micobiological quality and safety*. Food Control 22, 1844-1850.

Medeiros, CO; Cavalli, SB; Proença, RPC (2012). *Human resources administration processes in commercial restaurants and Food Safety: The actions of administrators.* International Journal of Hospitality Management 31, 667-674.

Osimani, A; Milanovic, V; Aquilanti, L; Polverigiani, S; Garofalo, C; Clementi, F (2018). *Hygiene auditing inm mass catering: a 4-year study in a university canteen*. Public Health I59, 17-20.

Rodríguez, M; Valero, A; Posada-Izquierdo, GD; Carrasco, E; Zurera, G (2011). *Evaluation of Food handler practives and microbiological status of ready-to-eat foods in long-term facilities in the Andalusia region of Spain*. Journal of Food Protection 74, No. 9, 1504–1512.

Santana, NG; Almeida, RCC; Ferreira, JS; Almeida, PF (2009). *Microbiological quality and safety of meals served to children and adoption of good manufacturing practices in public school catering in Brazil*. Food Control 20:255–261.

Sheth, M; Gupta, A; Ambegaonkar, T (2011). *Handlers' hygiene practices in small restaurants of Vadodara*. Nutrition & Food Science, Vol. 41 Issue: 6, 386-392.

Soares, K; Garcia-Diez, J; Esteves, A; Oliveira, I; Saraiva, C (2013*). Evaluation of food safety training on hygienic conditions in food establishments.* Food Control 34 (2), 613-618.

Veiros, M B; Proença, RPC; Santos, MCT; Kent-Smith, L; Rocha A (2009). *Food safety practices in a Portuguese canteen*. Food Control 20, 936–941.

Walker, E; Pritchard, C; Forsythe, S (2003). *Food Handlers' Hygiene Knowledge in Small Food Businesses*. Food Control, 14, 339-343.

Zoonosis Center (2015). Food poisonings. Finnish Food Safety Authority Evira and National Institution for Welfare and Health. Accessed 10.04.19 http://www. zoonoosikeskus.fi/portal/fi/ruokamyrkytykset.

CHAPTER IV – METODOLOGIA Y DISCUSION

Los restaurantes pequeños y medianos tienen dificultades para cumplir con las normas de seguridad alimentaria, principalmente debido a la falta de personal bien capacitado, la falta de motivación o adhesión al sistema de Análisis de Peligros y Puntos Críticos de Control (APPCC) por parte de los trabajadores y la falta de recursos financieros y económicos para abordar las deficiencias en las instalaciones.

AUDITORIA

El instrumento de recopilación de datos para la inspección es una lista de verificación de auditoría, creada por técnicos de seguridad alimentaria después de una prueba preliminar aplicada a 31 restaurantes. Para lo cual se diseñó una plantilla en que figuran los datos a recopilar durante la inspección visual de los manipuladores de alimentos, la higiene de las instalaciones y el material y métodos empleados, así como de entrevistar a la persona responsable del APPCC (manual de procedimientos, registros, etc.). Todo ello se organiza en tres módulos divididos en temas específicos (elementos).

Después de la prueba preliminar, los técnicos de seguridad alimentaria revisaron algunos temas de evaluación e incluyeron algunos elementos nuevos, hasta confeccionar la lista que se aplicó en este estudio.

La lista de verificación final consiste en 70 observaciones, cada una de las cuales puede responderse como “Cumplimiento”, “No cumplimiento” y “No aplicable”. A cada respuesta de "Cumplimiento" se le asigna un valor de punto; a cada "No cumplimiento" se le asigna 0. La puntuación final para cada local se calcula sumando los puntos. El puntaje máximo que puede alcanzarse es de 70, el mínimo de 0. La auditoría requiere aproximadamente 1,5 horas para completarse, dependiendo del tamaño del restaurante auditado. El resultado de la auditoría fue un puntaje numérico. Cuanto más alto sea la puntuación, mejor cumple el local con los requisitos de la auditoría. Para el primer estudio solo analizamos los requisitos de higiene y buenas prácticas de manipulación.

Los restaurantes para realizar el presente estudio fueron seleccionados de acuerdo con los siguientes criterios:

• Código de actividad económica en Portugal para restaurante (código financiero portugués).

• Rotación (hasta 10 millones de euros).

• Área geográfica (distrito de Leiria).

• Restaurantes interesados en participar en el estudio.

El proyecto fue un estudio longitudinal que tuvo lugar entre marzo de 2010 y diciembre de 2014. De los 42 restaurantes elegibles, 22-24 permanecieron en el estudio durante el período de cuatro años. Y en total 352 auditorías han sido realizadas.

El objetivo de las auditorias técnicas y de manipulación es identificar los puntos críticos y elaborar un plan de APPCC específico para cada establecimiento teniendo en cuenta su influencia en los peligros, pero también proporcionar información para el seguimiento y beneficio de la infraestructura, para que puedan cumplir con los requisitos y reducir el riesgo.

EVALUACIÓN DE LA HIGIENE

Todas las secciones de los datos proporcionados por la auditoría muestran una mejora general en la higiene durante el estudio en comparación con los datos iniciales (Apéndice 2 - tabla 1). Estos resultados son similares a otros estudios (Charalambous et al., 2015; Santana et al., 2009).

Con respecto a los ítems relacionados con las etapas de producción de la comida (recepción, almacenamiento, preparación, cocción y distribución), el subtema “Higiene de las instalaciones y equipos” presentó una mejora general hacia el cumplimiento, excepto en el almacenamiento en frío (p = 0,112). Para esta cuestión, los resultados podrían deberse a la poca cantidad de equipos de refrigeración existentes en las cocinas, que llevan a la acumulación de hielo, lo que compromete el mantenimiento de la temperatura programada y su estado de higiene.

En el módulo "Higiene personal", hubo una mejora estadísticamente significativa en el uso de uniformes (p = 0., 028). Con respecto al subítem de "guantes" no había datos suficientes para proporcionar análisis estadístico, porque no siempre las tareas de los manipuladores de alimentos requieren su utilización, ya que no se hizo un número suficiente de observaciones durante las auditorías.

Para el subítem "Evidencia de adornos y / o falta de higiene personal" hubo un cambio definitivo, a diferencia de la investigación de Rodríguez et al. (2011), que verificó comportamientos no conformes de los manipuladores, hacia el uso y cambio de guantes, uso de delantales para secarse las manos y llevar joyas. Los estudios de Rodríguez et al. (2011), Campos et al. (2009) y Veiros et al. (2009) detectaron el uso adecuado de las redes para el cabello en solo el 23, 33, 24% respectivamente; en esta tesis, el 75% cumple. Asimismo, Osimani et al. (2018a) y Santana et al. (2009) detectaron que los manipuladores de alimentos llevaban pendientes y collares durante la preparación de los alimentos, y el gorro requerido no siempre se llevaba correctamente. Durante el presente estudio, este tipo de comportamiento deficiente ha recibido una atención considerable a través del curso de entrenamiento de FoodSimplex. Estas prácticas representan una atención preponderante, ya que las joyas o los cabellos podrían caer inadvertidamente en los alimentos preparados y constituir un riesgo para el consumidor.

Para el subítem "Enfermedades visibles" se mantuvo el cumplimiento (100%). En los "Vestidores" hubo una mejora estadísticamente significativa (p = 0.0013), los restaurantes que no tenían casilleros los adquirieron y los establecimientos que comenzaron a usarlos correctamente (todos los artículos personales debían depositarse en el armario).

En la auditoría para “Saneamiento general”, los subpuntos “Dispensadores de jabón y desinfectantes y toalleros” (p = 0.210), “Paños” (p = 0.487), “Material y equipo obsoleto” (p = 0.474) y “plan sanitario" presentaron una mejora apreciable. En el estudio de Bergen et al. (2009) también hubo una mejora en el uso de los paños. En Santana et al. (2009) los problemas se identificaron en el jabón y las toallas desechables, tanto en las cocinas como en los baños. Algunas de estas situaciones también se observaron en la parte inicial de esta investigación, pero se mejoraron.

En los subítems "Sin lavabo con agua caliente y fría" hubo una disminución en el cumplimiento (p = 0.981) porque no todos los lavamanos tenían acceso al agua caliente, principalmente por falta de conexión. El "Botiquín de primeros auxilios" también presenta una disminución en el cumplimiento (p = 0.585), porque el uso de algunos artículos no fue reemplazado o para algunos productos se alcanzó la fecha de caducidad.

El "uso / condiciones de los productos no alimenticios" tuvo una disminución significativa (p = 0.042), y las razones de este asunto podrían considerarse por carecer de un equipo de seguridad individual adecuado para el uso, no poseer hojas de seguridad, sin espacio de almacenamiento adecuado para los utensilios de limpieza.

Para el suítem “Limpieza y desinfección”, Osimani et al. (2018) encontraron un cumplimiento negativo en las condiciones generales de limpieza en las áreas de preparación de alimentos, insuficiencia en la limpieza de equipos y artículos de mesa. En este estudio, las "condiciones de lavado de vajilla" han mejorado ($p = 0.046$). Inicialmente, algunos restaurantes no tenían lavavajillas o no tenían procedimientos de prelavado. Los restaurantes con lavavajillas presentaron algunos problemas en el proceso de secado, debido a la falta de mantenimiento. Sin embargo, hubo una mejora estadísticamente significativa en el cumplimiento (valor de $p = 0{,}801$).

Se recomendó que los contenedores de desechos fueran de material lavable, con bolsas de plástico en el interior y con separación de desechos para reclinarse ($p = 0.420$). Garayoa et al. (2017) también verificaron la ausencia de contenedores de basura con pedal en el 60% de las cocinas; y Santana et al. (2009) encontró material desechable fuera de los contenedores.

Todos los restaurantes realizan "Control de plagas", sin embargo, hubo una mala gestión en la custodia del archivo de los certificados, el mapa de cebos y la identificación de su ubicación en las cocinas, así como la ausencia de telas metálicas en las ventanas para evitar la entrada de insectos ($p = 0.392$) (Santana et al., 2009).

BUENAS PRÁCTICAS DE FABRICACIÓN

Los brotes transmitidos por los alimentos pueden deberse a la contaminación de materias primas, contaminación cruzada, tiempos y temperaturas de cocción / almacenamiento inadecuados y trabajadores portadores (Haukijärvi y Lundén, 2017; Walker, Pritchard y Forsythe, 2003). Matias et al. (2013) declararon que los factores que contribuyen a la intoxicación por alimentos en los restaurantes son: “materia prima contaminada, manipulaciones inadecuadas que conducen a la contaminación, almacenamiento en frío y refrigeración inadecuados, prácticas de descongelación inadecuadas, preparación inadecuada, higiene personal deficiente , manipuladores infectados, mala higiene de los locales, equipos y utensilios, paños de cocina / esponjas utilizados para diversas funciones, alimentos preparados con mucha antelación y almacenados a temperatura ambiente, distribución lenta".

La evaluación de las buenas prácticas de manipulación, basada en los datos de auditoría, consta de 28 subítems seleccionados (Apéndice 2 - Tabla 2). Con respecto al ítem de "Recepción", hubo una mejora en la inspección de los productos (p = 0,968) y el estado de los mismos (p = 0,572). El estudio de Osimani et al., 2017 también tuvo una única deficiencia, que fue la aparición de cajas de embalaje vacías en el área de recepción, que no se observó en este estudio. Veiros et al., 2009 en "Recepción" presentaron el incumplimiento de la inspección de productos (por ejemplo, verificación de la cantidad, temperatura, integridad de los contenedores y fecha de caducidad de los alimentos, y no hay registros de control y seguimiento). Inicialmente, eso también se observó en este estudio, pero con la aplicación de FoodSimplex, se mejoró el cumplimiento.

La evaluación del ítem “Almacenamiento a temperatura ambiente” mostró una mejora general; también en “Separación de productos alimenticios y no alimenticios” (p = 0,433), “Inventario organizado” (p = 0,233) y “Productos de etiquetado” (p = 0,945), y una mejora estadísticamente significativa en “Productos y materiales no conformes” (p = 0,001). Para el ítem "Productos de la Tierra" hubo una disminución en el cumplimiento debido al almacenamiento de tubérculos, los investigadores tomaron en cuenta el hecho de que los pedidos de materia prima se hacen en grandes cantidades y no hay suficiente rotación de existencias para reducir el tiempo de almacenamiento (Baltazar et al., 2017). El estudio de Garayoa et al. (2011) también detectó desviaciones significativas en el cumplimiento de la etapa de almacenamiento (70% en refrigeración, 35% en congelación y 40% a temperatura ambiente) y se justificó con áreas de espacio insuficientes, iluminación inadecuada y estantes desprotegidos. La insuficiencia del almacenamiento a temperatura ambiente para productos no perecederos se relacionó con el contacto directo de los productos alimenticios con el suelo o con la no separación con productos de limpieza. Todos estos factores coinciden con los detectados inicialmente en este estudio, aunque mejoraron con el tiempo.

En "Almacenamiento en frío" también hubo una evolución general hacia el cumplimiento, con mejoras estadísticamente significativas en "condiciones de descongelación" ($p = 0.015$), "Productos y materiales no conformes" ($p = 0.009$) y "Temperaturas" ($p = 0.043$). La refrigeración adecuada y el mantenimiento de la temperatura de los alimentos perecederos se reconocen como las operaciones principales para garantizar la seguridad de los alimentos, especialmente en la restauración colectiva (Osimani et al., 2017).

El "procedimiento de congelación" también mejoró ($p = 0.528$). Inicialmente, los restaurantes solían congelar los productos frescos y las comidas cocinadas en los congelares ordinarios, si bien la mayor parte de los establecimientos adquirieron congeladores de choque. Osimani et al. (2017) también encontraron el mayor porcentaje de insuficiencia en el almacenamiento adecuado de preparaciones de alimentos cocinados y servidos en frío a <10°C.

En el apartado "Preparación", todos los subítems mejoraron para cumplir con las "Condiciones de preparación" (p = 0.097), “Desinfección adecuada de alimentos para consumir en crudo” (p = 0.887) y con significación estadística en el suítem “Manejo correcto de alimentos preparados” (p = 0.026). A diferencia de Vieros et al. (2009) las no conformidades se relacionaron principalmente con la desinfección de frutas y hortalizas, y Garayoa et al. (2017) también detectaron procedimientos incorrectos de desinfección vegetal en el 62% de los servicios de restauracion. Para este estudio, se consideró incorrecto el procedimiento si los manipuladores de alimentos no siguieron las instrucciones del fabricante (cantidad de desinfectante y / o tiempo de desinfección).

En "Cocinar", los subítems "Manipulación de alimentos cocinados" y "Muestreo" no tuvieron un número suficiente de observaciones, debido al hecho de que en el momento de la auditoría no hubo ninguna manipulación de alimentos cocinados (como quitar huesos de carne y pescado cocidos). Para el "Muestreo", en los restaurantes, se había recomendado tomar muestras de comida de los platos, cada vez que había una cena grupal con un menú pre-ordenado, hecho que era poco frecuente.

En el ítem "En servicio", "Emplatado" no había un número suficiente de observaciones debido al momento de la auditoría. Los otros subítems tuvieron una evolución positiva hacia el cumplimiento, “Condiciones de exposición a los alimentos” (p = 0.534), “Temperatura de exposición” y una mejora estadísticamente significativa en “Existencia de productos no conformes” (p = 0.001). Osimani et al., 2017 detectaron alimentos calientes con temperaturas inferiores a los 60°C. Este hecho se observó en la presente investigación, pero hubo una mejoría (p = 0.245). Al final de la investigación, hubo una mejora significativa hacia las buenas prácticas de manipulación (p = 0.012).

En este estudio, la documentación de los APPCC tuvo una importancia vital porque fue la razón principal de la resistencia al sistema HACCP. Era imperativo hacer que los propietarios y los manipuladores de alimentos entendieran que el marco práctico es esencial, pero conveniente reconocer que la evidencia lo requiere. La evaluación de la "documentación APPCC" no se menciona en los artículos, sin embargo, también se analizaron los puntos relacionados con este tema (Apéndice 2 - tabla 3). El ítem “archivos APPCC” tuvo una mejora significativa junto con la investigación, el subítem “Archivos” tuvo una evolución estadísticamente sustancial (p = 0,002). Los registros refieridos a limpieza y saneamiento, temperaturas, desinfección de frutas y verduras, entre otros, se convirtieron en parte de la rutina diaria del equipo. La organización de la carpeta de registros, "Organización de carpetas", también se evaluó, y también tuvo una mejora (p = 0,290).

Se creó la documentación de APPCC para cada restaurante y se capacitó al personal del servicio de restauración sobre este tema. Junto con el estudio, a través de una auditoría, se evaluó la actualización de la documentación. En general, hubo una mejora en la gestión de la documentación, “Plan de Saneamiento” (p = 0,112); “Hojas de datos de seguridad” (p = 0,580); “Plan HACCP” (p = 0,112); “Código de buenas prácticas de manipulación” (p = 0,572); Señalización (p = 0,300); “Control de plagas” (p = 0,623) y “Hojas de datos de salud” (p = 0,520).

Sin embargo, hubo subítems con un bajo porcentaje de cumplimiento. La “Evaluación de Proveedores” tuvo un 13,65% de conformidad; este hecho puede deberse a la ausencia de una respuesta de los proveedores hacia la certificación APPCC. Al igual que Santana et al. (2009), uno de los principales problemas identificados fue el mantenimiento deficiente; en este estudio, el “Plan de Mantenimiento” presentó un cumplimiento del 43,5%. La capacidad financiera de las PYMEs representa dificultades para cumplir con el mantenimiento preventivo. Hecho también fue puesto de manifiesto por Djekic et al. (2014).

Con respecto a la "Trazabilidad", no hubo un número significativo de observaciones en las auditorías, debido a la actualización del plan estratégico y la implementación de acciones en cada auditoría y reunión de capacitación. Djekic et al. (2014) que gestionan el APPCC a través de la documentación y el mantenimiento de registros, muestran un control deficiente tanto de los entrantes como de los salientes, lo que demuestra que este elemento compromete el cumplimiento del sistema APPCC. Sin embargo, en esta investigación, la "documentación APPCC" tuvo una mejora estadísticamente significativa en el cumplimiento ($p = 0{,}000$).

HIGIENE MICROBIANA

La evaluación microbiana de las manos de los manipuladores de alimentos mostró una mejora estadísticamente significativa en "Microorganismos 30°C" (p = 0,003). Los microorganismos mesófilos son uno de los indicadores microbiológicos de la calidad de los alimentos más difundida, lo que indica la idoneidad del control de la temperatura y la limpieza durante el procesado, el transporte, el almacenamiento y el procesado.

La limpieza y desinfección de las superficies en contacto con alimentos de los servicios de restauración costituye un punto importante para eliminar los peligros microbianos, lo que reduce el riesgo de brotes infecciosos (Sibanyoni y Tabit, 2019).

Los indicadores microbiológicos sirven para evaluar el nivel de higiene de los utensilios, superficies y equipos alcanzado mediante los procedimientos de desinfección aplicados. La contaminación de las superficies puede deberse a procedimientos de limpieza y desinfección ineficientes y / o eventos de contaminación cruzada durante la manipulación de los alimentos. El manipulador de alimentos en contacto con superficies contaminadas es una causa potencial de contaminación y, en consecuencia, de que se produzcan infecciones y toxinfecciones alimentarias.

En el estudio realizado por Valero et al. (2017), el 53,6% de las superficies tuvieron resultados positivos para bacterias mesófilas, enterobacterias, *Escheriquia coli* y/o *Staphilococcus aureus*. El 46% fueron positivas para los manipuladores y el 27% para los utensilios de cocina.

En el presente trabajo, el 24,1% de las superficies inicialmente presentaron resultados insatisfactorios. Pero en la evaluación final, hubo una mejora general de los datos microbianos para las superficies (p = 0.585) (Tabla 13). Estos resultados pueden indicar que la contaminación cruzada provocada por los manipuladores de alimentos no es la única razón para que las superficies tengan resultados microbianos deficientes. Los resultados "insatisfactorios" en las superficies también se deben a procedimientos de limpieza y saneamiento deficientes y al mal estado de conservación de los materiales.

ANÁLISIS DE ALIMENTOS

Los datos generales ponen de manifiesto un alto nivel de calidad microbiológica en los diversos grupos de alimentos, sin presencia de *Salmonella spp., Estafilococos* coagulasa positivos y *E. coli* (Apéndice 3. - Tablas 2, 3, 4 y 5) (Petruzzelli et al., 2018; Santana et al., 2009).

El Grupo de alimentos 1 presentó resultados satisfactorios para Salmonella spp., Estafilococos coagulasa positivos y E. coli ($p = 1$). A diferencia de algunos estudios, con presencia de E. coli en muestras de carne (Arranz, Gómez y Peña, 1995; Ferrer, Simón y Tarragó, 1992) y estafilococos coagulasa positivos en platos a base de huevos (Soriano et al., 2002), donde la presencia de *S. aureus* indica un manejo inadecuado y posible contaminación cruzada.

Los microorganismos a 30°C son los indicadores de la calidad de los alimentos más utilizados, por estar ligados a los procesos de limpieza, control de temperatura, descongelación, transporte y almacenamiento. Como tal, la microbiota mesófila es el principal indicador de la higiene general porque requiere las mismas condiciones de crecimiento que la mayoría de las especies patógenas presentes en los alimentos (Lacasse, 1995). Para este parámetro, hubo una mejora de los resultados desde "Aceptable" a "Satisfactorio" ($p = 0.527$). Sin embargo, el resultado insatisfactorio fue el mismo (5,3%); el mal manejo de las comidas después de la cocción y el estrés en el tiempo de servicio puede ser una de las razones de estos valores (Baltazar et al., 2019b).

Los microorganismos a 30°C en el Grupo de Alimentos 2 (Apéndice 3 - Tabla 3.), primera evaluación, presentaron valores como "Aceptable" y "Satisfactorio", y tuvieron una mejora del 100% a los resultados "Satisfactorios" (S) en la evaluación final ($p = 0.157$). En Marzano y Balzaretti (2011), se estudiaron las muestras de alimentos preparadas con múltiples ingredientes, cocidas y sin cocer, que presentaronn un recuento aeróbico positivos del 78,9%.

En el Grupo de Alimentos 3 (Apéndice 3 - Tabla 4), en la primera evaluación, existieron resultados "Insatisfactorios", pero después de la capacitación, todos los resultados mejoraron a "Aceptable" y "Satisfactorio" en la evaluación final. Estos resultados respaldaron los datos de auditoría de BPM para la mejora del subítem "Preparación - Desinfección de alimentos para consumir en crudo".

FOODSIMPLEX

El método FoodSimplex pone de manifiesto que la evaluación continua de la efectividad del sistema APPCC es esencial, debido a su papel crítico en la protección de la salud pública. La preocupación que generan los servicios de restauración de pequeño y mediano tamaño es debido a la falta de apoyo y la falta de control. Pues en el presente estudio se pone de manifiesto una solución metodológica fácil de aplicar en estos restaurantes con un objetivo global, mejorar la seguridad alimentaria y en consecuencia promocionar la salud de la población.

CHAPTER V – GENERAL DISCUSSION

This chapter is organized by sections with the significant points found in the study.

This struture was choosen to provide a fuller discussion by:

- analysing the specific results with those from other studies;
- mention inconclusive results and explain them;
- suggesting additional experiments;
- briefly describe the limitations;
- mention the highlights and the weaknesses in the research;
- providing a discussion of results and their meaning for researchers in the same field but also researchers in other fields, and the general public.

5.1 MASS CATERING SAMPLE

This study was applied in SME restaurants; at the beginning of the investigation, 50 establishments comply with the requirements of the sample. From the 50 restaurants that were contacted, 42 initiated the study with the 1st stage of FoodSimplex. The study was developed between 2010-2014, and one of the sample inclusion criteria was complying with the investigation time period. At the end of 2014, the sample was of 24 restaurants. In the first article, however the study is carried out in 22 restaurants, due to the lack of access to data at the moment from two of the restaurants. The remaining articles are based in 24 restaurants.

The reasons for this decrease can be due to various factors, namely the Portuguese economic crisis, reduction of the consumer' financial capacity to seek and enjoy these services and the few knowledge and management resources of the FBO to assess quality and customer satisfaction. However, it was considered that the economic crisis in Portugal was the primary issue.

This crisis began in 2007 in the USA, which started to be financial and became economic, was considered to be only reaching the USA and would easily be controlled, which was not the case. The crisis was swept to Europe, and Portugal was one of the countries hard hit, and the situation aggravated from 2008. According to Bank of Portugal (2011, p. 33), Portugal in 2009 presented the following condition: decrease in private consumption of 1.1%; decrease in national exports of 11.6% as well as a reduction of imports of 10.6%; decrease in Gross Domestic Product (GDP) of 2.5%; increase of public debt to 83% of national GDP; increase in budget deficit from 3.5% in 2008 to 10.1% in 2009.

All these factors, together with the global economic and financial crisis, were decisive for the Portuguese economy and especially for the SME. Regarding the restaurant and similar companies Fig. 6. in Chapter 1, showed a significant decrease in the number of restaurants in 2012, that's when a substantial part of the establishments in the study enters bankruptcy (PORDATA, 2017).

However, to discuss the impact of the economic crisis, two perspectives must be considered; the company's financial liquidity, that in SME it's reduced, but also through the consumer perspective, if economic power is lower, the use of restaurant services reduces because it's not a well of first necessity.

Table 4. Evolution of Number of companies in the accommodation, catering a similar Portuguese economic activity (adapted from PORDATA, 2019).

Years	Sector Portuguese economic activity Accommodation, catering and similar (nº companies)
2008	91 679
2009	89 867
2010	85 919
2011	85 756
2012	83 820
2013	82 170
2014	84 078

From a management point a view, probably the FBO may not have the strategies to counter the crisis, like using quality tools for adapting the offer towards the client with lower economic power or improve the service by assessing the client's satisfaction (Garcez, Fachin & Andrade Junior, 2000).

5.2 AUDITS

For this study, 352 audits were performed, between technical/functional audit (TFA), the pretest for the Food safety audit (FSA) checklist and the FSA in the companies that entered the investigation (N=42). However, not all the audit data was used for the results of this investigation due to sample criteria, and the aim of the study - assess the efficiency of FoodSimplex. The TFA was a significant piece in the methodologic plan, because proper infrastructure enabling GMP is essential at all types of food premises, especially at restaurants, which are the most common sites of foodborne outbreaks (Haukijärvi & Lundén, 2017; Zoonosis Center, 2015). The preparation of food in premises with inadequate facilities (for example, small spaces) may pose a GMP challenge and increase the risk for cross-contamination (Haukijärvi & Lundén, 2017). The premises' layout and the conditions of the facilities are seldom recognized as a contributing factor to outbreaks (Zoonosis Center, 2015).

The aim of the TFA was to identify the weak areas and elaborate a specific HACCP plan facing each establishments' premises and their hazard influence, but also provide information to follow-up and benefit the infrastructure, so their can meet the requirements and reduce the risk.

In the investigation, premises were mainly space inadequate, non or impractically installed hand-washing sites and Food flow diagram that facilitates cross-contamination. During the study, in the FSA, the premises items were also assessed since many outbreaks, and possible sporadic cases originate from restaurants. This establishment should have proper facilities with enabling and facilitate adherence to GMP (Haukijärvi & Lundén, 2017).

The FSA audit was used to gather information regarding the meals production and processing practices, identifying areas for improvement and areas that are deficient according to respective data, food safety practices, facilities, documentation and written procedures.

The audit reports were the “eyes and ears” for the HACCP team to understand the risks and to design a risk reduction plan based; the results were always reviewed in the training activities as mean to improve and implement corrective measures (Powell *et al*., 2013).

In the literature, there are many different types of audit tools that vary in length, complexity, and style. For the study, the audit tool (FSA checklist) was conceived for this methodology, with the application of FSA checklist pretest, to reduce the variability in the quality and reliability of the audits. The audit scope covered all operations, locations and products (Powell *et al*., 2013).

The discussion focuses on the FSA compliance percentages of the restaurants that remain in the study for the 4 years period, to assess the evolution in Food Safety matters.

HYGIENE ASSESSMENT

All sections of the audit data show a general improvement in hygiene during the study by comparison with their initial data (Appendix 2 – table 1). These results are similar to other studies (Charalambous *et al*., 2015; Santana *et al*., 2009).

Regarding the items concerning the meal production stages (reception, storage, preparation, cooking and distribution) the subitem “Hygiene of the facilities and equipment” presented a general improvement towards compliance, except in the cold storage (p=0.112). For this matter, the results might be due to the few numbers of equipment in the kitchens, that lead to ice accumulation, which compromises their hygiene status.

FBD has several origins. However, mainly biologic causes are the more relevant, microbiological sources stand out for posing a high risk to public health. Outbreaks for FBD are resultant from various factors, and among them, one of the most implicated is inadequate personal hygiene (Pichíler *et al.*, 2014; Rebouças et al., 2017).

In the module “Personal Hygiene”, there was a statistically significant improvement in the use of uniforms ($p = 0.028$). Regarding the “gloves” subitem there was not enough data to provide statistical analyse, because not always the food handlers tasks require their utilization, as so it was not a reliable number of observations in audit moment.

For the subitem “Evidence of adornments and/or lack of personal hygiene” there was a definite change, unlike the investigation of Rodríguez *et al.*, 2011, which verified noncompliant behaviours of handlers, towards the use and change of gloves, use of aprons for cleaning hands, and wearing jewellery. The studies by Rodríguez *et* *al*. (2011), Campos *et al*. (2009) and Veiros *et al*. (2009) detected the proper use of hair nets in only 23%, 33%, 24% respectively. In this investigation, 75% comply. Also, in Osimani *et al*. (2018a) and Santana *et al*. (2009) food handlers of a canteen were found to wear earrings and necklaces during food preparation, and the required cap was not always correctly worn. During the study, this kind of poor behaviour has received considerable attention through FoodSimplex training. These practices represent a concern, as jewellery or hairs could inadvertently fall into the prepared food and constitute a risk for the consumer.

For the subitem "Visible diseases" there was the maintenance of compliance (100%). In the "Dressing rooms" there was a statistically significant improvement (p=0.0013), the restaurants that didn't have lockers bought it, and the establishments that had started to use them correctly (all personal items had to be stored properly).

In the audit assessment for "General Sanitation", subitems like "Soap and disinfectant dispensers and towel rails" (p=0.210), "Cloths" (p=0.487), "Obsolete material and equipment" (p=0.474) and "Sanitary plan compliance" had improved towards compliance. In the study of Bergen *et al*. (2009) there was also an improvement in the use of cloths. In Santana *et al*. (2009) problems were identified in soap, disposable towels and liquid soap both in kitchens as well in lavatories. Some of these situations were also verified in the initial part of this investigation but improved.

The subitems “No washbasin with hot and cold water” there was a decline in compliance (p=0.981) because not all the washbasin had access to hot enough water or the two options, mainly for pumbling reasons. The “First aid kit” also has a decline in compliance (p=0.585), because or the use of some items in the kit was not replaced or for some products, the expiration date was reached.

The “use/conditions of non-food products” had a significant decline (p=0.042), and the reasons for that matter might be regarded with improper individual safety equipment for the use, no safety sheets, no proper storage room for cleaning utensils and the use of brooms.

For the item “Cleaning and Disinfection”, Osimani *et al*. (2018ª) found negative compliance in general conditions of cleanliness, concerning food preparation areas, low level of inadequacy for the sanitation of tools and tableware. In this study, “dishwashing conditions” have improved (p=0.046). Some restaurants initially didn’t have dishwashing machines, or with no pre-washing procedures. The restaurants with dishwashing machines presented some problems in the drying process, due to lack of maintenance.

However, there was a statistically significant improvement in compliance (p-value = 0.801).

Waste containers were recommended to be in washable material with plastic bags in the interior and with waste separation for reclining (p=0.420). Garayoa *et al.*. (2017) verified as well the absence of garbage bins with a pedal in 60% of the kitchens; and Santana et al. (2009) found a garbage disposable anywhere.

All the restaurants have “Pest control”, however, there was some poor management in the file sheets archive, map of baits and identification of its placement in the kitchens as well as the absence of Windows screens to prevent the entry of insects (p=0.392) (Santana *et al*., 2009).

The restaurants started to understand the importance of “Waste Treatment” (p=0.595) and started to have recycling procedures and agreements with oil recycling companies.
The “Chemical products storage” had significant improvement (p=0.093), since the establishment started to have separated and identified storage room for cleaning products.

Regarding the item “Facilities” there was a generally positive change to compliance. Initially, like Haukijärvi & Lundén (2017) the noncompliance was concerning infrastructure with cleaning facilities missing, adverse conditions of ceilings, walls and floors and with small spaces for their intended purpose. In Santana *et al*., 2009, regarding the sanitary condition of the building, were identified as the improper location, improper ventilation and lack of lightning protection. In this investigation, facilities "General Conditions" improved with hygiene practices ($p=0.440$), drinking water was potable ($p=0.392$), gas and electricity supply was adequate and remained in that condition through the study (p-value=1).

The suitability of the facilities had a decline in compliance ($p=0.069$) due to adulteration of the use of some areas in service time (e.g. preparation zone with unclean crockery) and free access by people with no food handlings tasks (Santana *et al*., 2009). The "march in front" subitem had a statistical significance improvement (p-value= 0.004), the design of flow diagrams in each kitchen layout and the training were the main reasons for the evolution. In the studies of Djekic *et al*., 2014 and Santana *et al*., 2009 structural requirements also revealed problems in the layout of the premises of all types of food establishments, with opportunities for cross-contamination. Infrastructure noncompliance showed to be challenging to improve, due to economic reasons and especially tricky when the restaurants have already started to work.

Proper facilities are essential at all types of food premises, especially in restaurants, which are the most common sites of foodborne outbreaks (Haukijärvi & Lundén, 2017; Zoonosis Center, 2015; Matias *et al*., 2013). The threats to food safety in the sector require recommendations and action regarding personal hygiene, cleaning of surfaces, equipment, utensils and materials, waste treatment, characteristics of plants, pest control, medical surveillance of workers, water supply and transportation of foodstuffs (Matias *et al*., 2013).

The FoodSimplex had a particular focus in these items, which allowed an evolution towards compliance in SME restaurants. At the end of the investigation and according to cleaning and sanitation assessment in audit data, there was a statistically significant improvement towards compliance (p-value=0.004). In the research done by Garayoa, *et al.*, 75% of the catering establishments were in conformity with the organization and cleaning items, and for this study, 76.1%.

GOOD MANUFACTURE PRACTICES ASSESSMENT

The foodborne outbreaks can be due to contamination of raw materials, cross-contamination, inadequate cooking/ storage times and temperatures, and infected workers (Haukijärvi & Lundén, 2017; Walker, Pritchard & Forsythe, 2003). Matias *et al.*, 2013 stated that the factors that contribute to the occurrence of food poisoning in restaurants are: “contaminated raw material, inadequate manipulations that lead to contamination, inappropriate cold storage and cooling, improper thawing practices, inadequate preparation, poor personal hygiene, infected handlers, poor hygiene of premises, equipment and utensils, dishcloths/sponges used to various functions, food prepared well in advance and stored at room temperature, slow distribution”.

The GMP assessment, based on audit data had 28 subitems selected from the audit checklist (Appendix 2 -Table 2). Regarding the “Reception” item, there was an improvement in products inspection (p=0,968) and the condition of the product (p=0,572). The study of Osimani et al., 2017 also had one sole inadequacy that was the occurrence of empty packing boxes in the receiving area, which was not verified in this study. Veiros *et al.*, 2009 in “Reception” presented noncompliance towards products inspection (e.g. verification of quantity, temperature, the integrity of containers and expiry date of the food, and no records for control and tracking). Initially, that was also verified in this investigation, but with FoodSimplex, it improved towards compliance.

The assess to “Room Temperature Storage” item shown general improvement, “Separation of food and non-food products” (p=0,433), “Organized stock” (p=0,233), “Labeling products” (p=0,945) and significant statistical improvement in “Non-according products and materials” (p=0,001). For the item “Earth products” there was a decline in compliance due to the storage of tubers, the researchers took into account the fact that the orders of raw material are made in high quantities; and there isn´t enough stock rotation to reduce storage time (Baltazar *et al*., 2017). The study by Garayoa, *et al*., 2011 also detected as significant deviations in the compliance of the storage stage (70% in refrigeration, 35% in freezing and 40% at room temperature) and justified with insufficient space areas, inadequate lighting, and unprotected shelves. The inadequacy for the room temperature storage for non-perishable products was related to the direct contact of the food products with the floor or by the nonphysical separation with cleaning products. All these factors coincide with those detected initially in this study, but improved.

In “Cold Storage” there was also a general evolution towards compliance, with statistically significant improvements in “Defrosting conditions” (p=0.015); “Non-according products and materials” (p=0.009) and “Temperatures” (p=0.043). Proper refrigeration and temperature maintenance of perishable foods are acknowledged as the primary operations to assure the safety of meals, especially in mass catering (Osimani *et al*., 2017).

The “Freezing procedure” also improved (p=0.528). Restaurants initially used to freeze food in the freezers, fresh food products and cooked meals, that procedure stopped happening, and the establishments that had an interest in continuing to freeze these products bought shock freezers. Osimani *et al*., 2017 also found the highest percentage of inadequacy in proper storage of cooked and cold-served food preparations at <10 °C.

In Veiros, *et al*. (2009) in cold storage presented nonconformities in visible labelling. In this study, there was a slight improvement, but it remains with a deficient compliance percentage in “Labelling/Products identification” (p=0.659). The inadequacy might be related to food non-identification (e.g. opening date of the food packaging; preparation date). The investigators connect this data with food handlers´ lack of time to identify the products during serving time. The cold storage the “Packaging “has improved (p=0.131) since the beginning of the study. However, it remains a low percentage (43.5%) with evidence of ice burns. The “Refreezing” condition improved as well (p=0.086). The GMP procedures and training towards this matter had results with 100% conformities at the end of the study.

In the item “Preparation”, all the subitems improved to compliance “Preparation conditions” (p=0.097); “Proper disinfection of food to consume in raw" (p=0.887) and with statistical significance in subitem "Correct handling of prepared food" (p=0.026). Unlike, Vieros et al. 2009 the non-conformities were mainly related with disinfection of fruits and vegetables, and Garayoa et al. (2017) which also detected incorrect procedures of vegetable disinfection in 62% of the kitchens. For this study, was considered incorrect the procedure if the food handlers did not follow the manufacturer's instruction (amount of disinfectant and/or disinfection time).

In "Cooking" the subitems "Handling cooked food" and "Sampling" didn't have a reliable number of observations, due to the fact that in audit moment there wasn't any cooked handling (like remove bones from cooked meat and fish). For "Sampling", in restaurants, we had recommended taking food samples from the dishes, every time there was a group dinner with a pre-ordered menu, which did not happen very often.

The improvement was general in all the other subitems "Absence of food at room temperature" (p=0.366), "Presence of leftovers and scraps" (p=0.651), "Frying oils conditions" (p=0.134) and "Eve cooking" (p=0.100). In the study of Osimani *et al*., 2017, and Santana *et al*., (2009) cooked and raw products were found to be not correctly separated. Initially, in this study were detected similar situations but improved along with the investigation.

In “Serving” item, “Plating” didn’t have a reliable number of observations because of the moment audit. The other subitems had a positive evolution towards compliance, “Food exposure conditions” ($p=0.534$), “Exposure temperature” and statistically significant improvement in “Existence of non-compliant products” ($p=0.001$). Osimani *et al.*, 2017 detected warm-served foods with temperatures below the 60 °C. This condition was observed in this investigation, but there was an improvement ($p=0.245$). At the end of the investigation, there was a statically significant improvement towards GMP ($p=0.012$).

HACCP DOCUMENTATION

HACCP documentation is an element which significantly determines the effective implementation of the system (Dzwolak, 2014). It has long been perceived also as the leading cause of HACCP system failure. A practical and flexible approach to HACCP may be useful for, at least partially, overcoming the problem of over-documenting of the HACCP system, especially in small food businesses. The simplifications of the HACCP system documentation are not an alternative to HACCP principles, but another form of presentation of some areas of HACCP system documentation which may be applicable to small food businesses (Wallace *et al*., 2012).

In this study, HACCP documentation had vital importance because it was the main reason for resistance to the HACCP system. It was imperative to make FBO and food handlers understand that the practical framework is essential but also recognize that the evidence it even required. The "HACCP documentation" assessment its not refered in the articles, however the items regarding this matter were also discussed (Appendix 2 – table 3). Item "HACCP records" had significant improvement along with the investigation, "Records" subitem had a statistically substantial evolution (p=0,002). The records refer to cleaning and sanitation, temperatures, disinfection fo fruits and vegetables, among others became part of the daily routine of the team. The organization of the records folder, "Folder Organization", was also evaluated, and it also had an improvement (p=0,290).

HACCP documentation was created for each restaurant and had training regarding this matter. Along with the study, through an audit, was assess the update of the documentation. Generally there was an improvement of the management of the documenation, "Sanitation Plan" (p=0,112); "Safety datasheets" (p=0,580); "HACCP Plan" (p=0,112); "Good Manifacturing Pratice Code" (p=0,572); Signage (p=0,300); “Pest control” (p=0,623) and “Health datasheets” (p=0,520).

However, there were subitems with a low percentage for compliance. “Suppliers Evaluation” had 13,65% conformities; this fact may be due to the absence of a response from the suppliers towards HACCP certification. Like Santana *et al*., 2009, one of the main problems identified was poor maintenance; in this study, the “Maintenance Plan” presented a 43,5% compliance. SME financial ability represent difficulties in complying with preventive maintenance and with some procedures like an archive of the technical sheets after support, which usually weren’t required. This data was also shown by Djekic *et al*., 2014.

Regarding “Traceability”, there wasn’t a reliable number of observations in audit due to the current update of the strategic plan and implementation of actions in each audit and training. In the study, Djekic *et al*., 2014 managing HACCP through documentation and record keeping shown poor control both incoming and external, which demonstrate that this item undertakes the compliance of HACCP system. However, in this investigation, “HACCP documentation” had a statistically significant improvement in compliance (p=0,000).

5.3 MICROBIOLOGICAL ANALYSES

Regulation (EC) nº 852/2004 requires that FBO shall establish procedures, which shall be done regularly, to verify that the HACCP system is working effectively. Microbiological analysis constitutes a valid tool of verification in this context (Petruzzelli *et al.*, 2018). Audits may be supplemented with microbiological and quality testing to help ensure adherence to recognized regulations and GMP (Powell *et al*., 2013). This investigation intended to support the FoodSimplex method through the combination of audit and microbial data.

HYGIENE SAMPLES

Recent literature reviews have highlighted the contribution of mass catering to the spread of FBD (Osimani & Clementi, 2016). Specifically, inadequate hygiene during food preparation and storage was the primary risk factor with staff members directly involved in most documented outbreaks (Petruzzelli *et al.*, 2018). Unhygienic handling of food causes a critical risk for food safety. Poor hygiene has been shown to lead to the detection of pathogens like *Salmonella enteritidis* on hand towel samples and *Staphylococcus aureus* and *Escherichia coli* O157:H7 in the working equipment (Sheth, Gupta, & Ambegaonkar, 2011).

Soares *et al*. (2012) have demonstrated the presence of pathogenic microorganisms in food handlers' hands, which makes them an essential vehicle of FBD. Therefore, improper handling is responsible for most cases of FBD, including inappropriate use of temperature during preparation and storage, cross contamination, poor personal hygiene and inadequate equipment. The attitude of food handler is also a crucial factor that may influence food safety behaviour and practices (Rebouças *et al*., 2017; Al-Shabib, Mosilhey & Husain, 2016).

FoodSimplex had in account mentioned risks but also other factors that influence the hygiene of food handlers, like the number of meals served, the socioeconomic status of the geographical area, the number and qualifications of the staff members (Bering, 2008; Griffith, 2002) and relies in recommended periodic microbiological assessment of highrisk food service operations, in addition to visual inspection, for minimizing the risk of FBD outbreaks (Appendix 3 – Table 1.).

The microbial assessment of food handlers' hands shown a statistically significant improvement in "Microorganisms 30°C" (p=0,003) along with the investigation. The mesophilic microorganism is one of the more general and extensively microbiological indicators of food quality, indicating the adequacy of temperature and sanitation control during processing, transport, storage, and revealing sources of contamination during manufacture.

In the study of Nasrolahei *et al*., 2017, 62.2% food handlers carried pathogenic bacteria which reflected, according to the authors, poor personal hygiene practice and environmental sanitation, lack of supply of safe water and ignorance of health promotion practices (e.g. hand washing practices after toilet use were low). The safe water didn't represent a hazard in this investigation. However, the personal hygiene, environmental sanitation and health-promoting practices were main issues initially. Negative results in audit and microbial data, resulted in training sessions, which were design to each team, so they could understand and take measures to correct inadequate practices. The final results of food handlers' hands confirmed better personal hygiene, GMP and improved use of the premises and materials (descartable hand towels, hand soap and disinfectant).

The cleaning and sanitising of food contact surfaces in food preparation facilities is also an importante step in the elimination of microbial hazards, thereby reducing the risk of outbreaks of FBD (Sibanyoni & Tabit, 2019).

As metioned, microbial indicators can assess the level of hygiene of utensils, surfaces, equipment through the quality of disinfection procedures. The presence of microbial indicators, in high numbers in environmental monitoring samples, can highlight potential deficiencies in the hygiene and sanitary food quality (Valero *et al*., 2017).

The contamination of surfaces can be due to inefficient cleaning and disinfection procedures and/or cross-contamination events during food handling. The food handler in contact with contaminated surfaces is a potential cause of cross-contamination and, consequently, FDBs outbreaks.

In the study of Valero *et al*., 2017, 53.6% of surfaces had positive microbial results for the bacterial group (mesophilic bacteria, *Enterobacteriaceae*, *E. coli* and *S. aureus*). The percentage of contaminated samples was higher in handlers'-contact (46%) that in food contact utensils (27%), regarding mesophilic bacteria (Valero *et al*., 2017).

In this investigation, surfaces in an initial assessment presented unsatisfactory results (24,1%). According to initial microbial results for food handlers as well, sequential contamination routes can be proposed. Some authors, proposed that microbial contamination in food handlers may be transferred to the surfaces, utensils and equipment in a bidirectional way (Valero *et al*., 2017; Santana *et al*., 2009), which could be the case.

In the final evaluation, there was a general improvement of microbial data for surfaces (p=0.585) (Table 13) (Marzano & Balzaretti, 2011), which followed the food handler's positive evolution, althouth food handlers' hands didn't present "unsatisfactory" results, surfaces continued to present 14,9%. These results may indicate that food handlers cross-contamination is not the only reason for surfaces poor microbial results. "Unsatisfactory" results in surfaces are also due to poor cleaning and sanitation procedures and poor state of materials conservation.

FOOD SAMPLES

In addition to providing appropriate nutrition and palatability, the microbiological safety of food prepared and served by a mass catering system is a primary objective that must be pursued by FBO (Petruzzelli *et al.*, 2018).

The authors Ropkins & Beck (2000) and Swanson & Anderson (2000) express that besides end product testing, it is also interesting to obtain information on the microbiological quality of incoming raw materials and/or half fabricates. However, for this investigation was intended, if the FBO create procedures to monitor the suppliers and to select them, as access to periodic microbiological testing of their products, there's no need for this SME to have extra costs with this microbial testing.

Overall data revealed a high level of microbiological quality in the meals examined by food groups, with no contamination founded towards *Salmonella spp*., *Coagulase-positive staphylococci* and *E. coli* (Appendix 3. - Tables 2, 3, 4 and 5) (Petruzzelli *et al.*, 2018; Santana *et al*., 2009).

Food Group 1 presented satisfactory results for *Salmonella spp*., *Coagulase-positive staphylococci* and *E. coli* (p=1) (Marzano & Balzaretti, 2011). Unlike some studies, with higher microbial values than recommended, for *E. coli* in meat samples (Arranz, Gómez & Peña, 1995; Ferrer, Simón & Tarragó, 1992) and for *Coagulase-positive Staphylococci* in eggs-based dishes (Soriano *et al*., 2002), which the presence of *S. aureus* indicates improper handling and possible cross-contamination.

The *Microorganisms at 30°C* found in food have been microbiological indicators of the quality of the most commonly used food, indicating if there were flaws in the cleaning and sanitation processes, temperature control, thawing, transportation and storage. As so, mesophyll microbiota is the primary indicator of general hygiene because it requires the same growth conditions as most pathogenic species in the meals (Lacasse, 1995). For this microbial parameter, there was an improvement between already positive results, from “Acceptable” to “Satisfactory” (p=0.527). However, the unsatisfactory result was the same (5,3%) this data can be due to the effectiveness of cooking plus the hot and cold temperatures before consumption (Marzano & Balzaretti, 2011), poor handling of meals after cooking and the stress in service time may also be one of the reasons for these values (Baltazar *et al*., 2019b).

Microorganisms at 30°C in Food Group 2 (Appendix 3 - Table 3.), first evaluation, presented values in an “Acceptable” and “Satisfactory” class and had an improvement to 100% to “Satisfactory” (S) results in the final evaluation (p=0.157). In Marzano & Balzaretti, 2011, study the food samples with multi-ingredient preparations, cooked and uncooked, presented for aerobic plate counts positive results (78,9%). Unlike, this investigation which the results where all “Acceptable” and “Satisfactory” for all the microorganisms (100%).

In Food Group 3 (Appendix 3 - Table 4), in the first evaluation, existed "Unsatisfactory" results (Marzano & Balzaretti, 2011), but after training, the results all improved to "Acceptable" and "Satisfactory" in the final evaluation. These results supported the GMP audit data for the improvement of the subitem "Preparation - Disinfection of food to consume in raw".

The WHO considers that the primary mechanism of transmission of *L. monocytogenes* to humans is through foodstuffs contaminated during production and/or processing.
In this investigation, *L. monocytogenes* was detected in" Unsatisfactory" values in the first evaluation in Food Group 3, constituted by salads (Appendix 3 - Table 4). Unlike other studies, *L. monocytogenes* was also found in meat, fish and seafood dishes (Soriano *et al.*, 2001; Santana *et al*., 2009).

Initially, some restaurants showed incorrect disinfection procedures, with no sodium hypochlorite to sanitize the vegetables or with wrong doses or time application (Baltazar *et al*., 2019b; Petruzzelli *et al*., 2018; Sospedra *et al.*, 2013; Legnani *et al*., 2004; Martínez-Tomé, Vera & Murcia, 2000; Soriano *et al.*, 2001). Due to the non-compliance in the microbial analysis, FoodSimplex methodology specifies the development of training activity to the food handlers to assess the possible causes of the high microbial deviation, and in the final microbial evaluation, the results were within the recommended values (Table 13).

These findings in microbial assessment for all food groups, suggest that some changes in manufacturing procedures enhance the microbiological quality of the meals, regarding *Microorganisms at 30°C* and *L. monocytogenes parameters* (Marzano & Balzaretti, 2011).
After application of FoodSimplex methodology, the microbiological quality of food has generally improved, with an equally important point that was the contribution of this results to the identification of weak spots in the general management of the food production process.

The knowledge of these problems was essential for the improvement of the control system of restaurants and to adjust the staff training contents, in order to obtain more excellent safety in mass catering services (Legnani *et al.*, 2004).

The presence of some of the microorganisms studied showed that there are some handling practices that require more attention, in the "cook-serve" system, like keeping the meals warmed or refrigerated after cooking, in proper containers to avoid the occurrence of microbiological contamination and proliferation

(Petruzzelli *et al*., 2018; Marzano & Balzaretti, 2011; Soriano *et al.,* 2002). The implementation of GMP reduces the amount of aerobic plate count, *staphylococci coagulase-positive* and thermotolerant coliforms in meals (Santana *et al*., 2009; Legnani *et al*., 2004), and in this study, FoodSimplex methodology contributed to microbial results improvement.

5.4 TRAINING

The catering sector employs large numbers of workers with a low level of formal education, offering a big promotion of temporary jobs with a limited average stay with the same employer (Martins *et al.*, 2012). Training is expressly required by Regulation (EU) No. 852/2004 (Chapter XII). In Portugal, the Food Safety and Economic Agency (ASAE) includes, in the checklist used in official inspections of companies in the catering sector, an item concerning the training of food handlers (ASAE, 2007). However, food handler certification is not mandatory in catering to food service facilities sector in Portugal (Martins *et al*., 2012).

It is evident that the proper training of staff is pivotal for risk prevention. However, it can be perceived by food handlers as a waste of time (Osimani *et al*., 2017). FBD has been associated with improper storage or reheating, food storage inappropriately, and cross-contamination (Walker, Pritchard & Forsythe, 2003). In this investigation, was found a secure link between those premises with poor practices and low levels of training and food safety knowledge.

In FoodSimplex methodology, training is useful, especially "on job" mode. The primary aim of the training was for the teams to understands the significant impact of food safety and the essential part that they represent in the HACCP and in the improvement of the restaurants, towards the standards of food handling practice.

A higher number of the workers had a low level of education, and it's known that the level of food hygiene knowledge and the level of education of the staff are strictly correlated (Osimani *et al*., 2017). Restaurant workers have normally selected for their operational skills and expertise rather than HACCP knowledge (Wallace *et al*., 2012) As so, for this structured study, training take into consideration the level of education of the team (language, taking examples, practice demonstration) (Fig. 9).

Initially, the food handlers presented unconsolidated knowledge on food safety and hygiene (Osimani *et al*., 2017). There was a lack of knowledge regarding cross-contamination, temperatures in food handling, hand hygiene, and other microbiological risks for food contamination. So if there are weaknesses in the food handlers' knowledge about how to apply food safety practices, it follows that there could be weaknesses in the system (Wallace *et al*., 2012).

In this study, the HACCP team it is multidisciplinary, and it was a generally held belief that the outcome of these teams approach will be a stronger FSMS than could be developed by individuals working alone (Wallace *et al*., 2012).

The identification of deficient practices leads to practical training, regarding non-compliances, inadequate practices and several corrective measures. The results of several studies had confirmed that training of food handlers could be useful (Bergen *et al*., 2009; Santana *et al*., 2009; Veiros *et al*., 2009). However, training should be repeated over time to overcome the reluctance of food handlers to apply the acquired knowledge, which it looked on with FoodSimplex.

Food handlers interact and share knowledge which was used to have an impact on food safety. Reinforcement and issue discussion was part of the training, engaging particularly workers with a difference of opinion, mainly senior food handlers (Wallace *et al*., 2012).

The FoodSimplex methodology defined a significant role in training. Recent meta-analyses had shown that food safety training increases knowledge and improves attitudes about food handler's hygiene practices and that refresher training and recurrent emphasis on good food handling behaviour may have ongoing positive effects (Rebouças *et a*l., 2017; Soon & Baines, 2012).

However, there are other studies (Buccheri *et al*, 2010; Park, Kwak & Chang, 2010) that report that the increase of knowledge in food safety does not always ensure that proper hygiene practices are being implemented, due to essential barriers such as supervisors and colleagues' inhibitory attitudes, time pressure and/or lack of staff, as well as structural factors, such as facilities and accessibility to supplies (Rebouças *et al*., 2017; Laiko-Roto & Nevas, 2014; Soares *et al*., 2012).

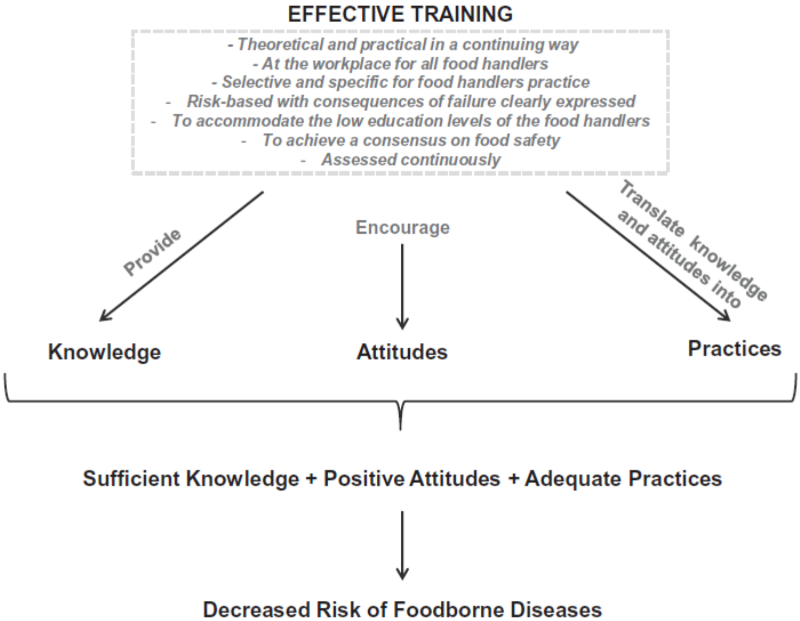

Figure 6. Factors for planning a program of training with efficience application of knowledge, attitudes and practices (Source: Zanin *et al*., 2017).

The Foodsimplex assured a stage to monitoring the teams along time, providing training inclusive to the top management.

The main difficulties in team training were recruitment from lower socio-economic classes with low education levels, rapid staff turnover, high level of seasonal staff, literacy and language problems and poor motivation due to low pay and job status (Toropilová & Bystrický, 2015; Walker, Pritchard & Forsythe, 2003). However, overall results showed an improvement in audit and microbial results for food, food handlers and surfaces. As so, training of food handlers' overtime, through FoodSimplex methodology, proved to have a positive impact to avoid the spread of microbial contamination in catering establishments (Valero *et al.*, 2017; Legnani *et al.*, 2004).

5.5 FOODSIMPLEX METHODOLOGY

The majority of FBD outbreaks may originate from restaurants (Zoonosis Center, 2015). The FoodSimplex methodology presented a practical and flexible approach to food safety, especially in small food businesses.

The first stage of FoodSimplex was diagnosis audit, which revealed to be very important, due to the individuality of each establishment. One of the investigations concerns, was to provide an individual food safety plan for each restaurant, recognizing that the reality of each business makes a difference in the food safety status and the quality of the meals. The diagnosis audit was essential to evaluate the restaurants primarily, but also to provide individual counselling and strategic plan for each one.

The layout of the premises and conditions of the facilities revealed to be a contributing factor to food safety hazards (Petran *et al.*, 2012; Buchholz *et al.*, 2002). As so, it was important the FBO commitment towards infrastructures, to meet the requirements or provide conditions to reduce the risks. The HACCP pre-requisites were evaluated towards compliance, and according to the state of the restaurants, the HACCP plan and all the documentation associated (layout, flowchart, product description, etc.) was elaborated.

Mainly the results revealed premises with small space, impractically installed hand-washing sites, or poorly cleaned, and workflow that facilitated cross-contamination. Many outbreaks and possible sporadic cases are originated from restaurants, as so it was essential to act in proper premises that enable and promote adherence to GMP (Haukijärvi & Lundén, 2017).

This continuos work, during the study, proved to be effective, the audit results showed an improvement in food safety status, audit hygiene assessment ($p=0.004$) and audit GMP assessment ($p=0,012$). The HACCP documentation was also a challenge, but it also presented positive results ($p=0,000$).

In FoodSimplex' stage 2, the diagnosis audit results were revealed, as well as the HACCP documentation. It was the first time that all workers understood, that they were an essential part of food safety, as a member of the HACCP team but also a responsible part for the safety of the meals produced. The diagnosis audit inadequacies

were presented but also were discussed the corrective measures, which reinforce the participation of all.
The training “Hygiene & Food safety – restaurants” was performed, which provided knowledge towards food safety concepts and GMP. For some workers, it was the first time they had food safety training.

In stage 3, started the audit and microbial assessment towards food safety compliance. The audit was performed with FoodSimplex Checklist, and the microbial hygiene samples were collected. Initially, only food handlers and surfaces samples were collected, because it was essential to evaluate efficacy of the sanitation plan and procedures.

The FoodSimplex Checklist, based explicitly on the food production activities, represented a fundamental pre-requisite for the execution of the audits. The data that emerged from the audits were useful to obtain an overview of improvements and emerging criticalities over the years (Osimani et al., 2017). The audit results are shown in this first evaluation, already positive trend (Table 19), and for microbial samples, 76,5% of the food handlers presented “acceptable” and “satisfactory” results, as the surfaces with 76%. This results confirm that the first and second stage of FoodSimplex had already a positive impact on food safety in these restaurants.

Table 5. Audit Compliance Percentage to Assessment Group

Audit Assessment Groups	First Audit Compliance Percentage (%)	Final Audit Compliance Percentage (%)
Hygiene	66	76,1
GMP	65,	77,55
HACCP documentation	72,2	79,1

The FoodSimplex' fourth stage, revealed to have a strategic effect, providing information to the HACCP team towards the results of all the evaluations, which represented to be a key to consolidate knowledge and provide motivation. Some authors presented results where food handlers and producers have an apparent lack of motivation with respect to the HACCP (Toropilová & Bystrický, 2015). As so, this stage had an extremely important effect in motivating the teams, there was an engagement of every part towards better results.

In theory, auditing can be helpful, but the audit reports and microbial results are shown to be only useful if the people involved (food handlers and FBO) review the results, understands the risks addressed by the standards and makes risk-reduction decisions based on the results (Osimani *et al*., 2017; Powel *et al*., 2013; Legnani *et al*., 2004).

The critical analysis of the results constituted a fundamental requisite, towards the implementation of corrective actions, that had to put in place to solve the significant inadequacies. In this context, staff training and experience played a crucial role in the success of the entire plan of improvement. (Osimani *et al*., 2017).

The long-term evolution of food safety compliance relies on the combination of factors in FoodSimplex. Namely, personalized HACCP plan, training to all the people involved (FBO and food handlers), frequent assessments (audit and microbial samples) and restaurant improvement plan. FoodSimplex method underlines that the continuous evaluation of the HACCP system effectiveness, and it proved to be essential because of its critical role in protecting public health (Ridderstaat & Okumus, 2019; Wallace *et al.*, 2014).

Table 6. Microbial Results Evolution for food handlers and surfaces

Microbial Analyses	Initial "Acceptable" and "Satisfactory" Percentages (%)	Final "Acceptable" and "Satisfactory" Percentages (%)
Food handlers	76,5	100
Surfaces	76	85,1

At the end of the study period, a general improvement towards food safety is notorious in audit data (Table 19) but also in microbial analyses results (Table 20 and 21).

Table 7. Microbial Results Evolution for all food groups

Microbial Analyses	**Initial "Acceptable" and "Satisfactory" Percentages (%)**	**Final "Acceptable" and "Satisfactory" Percentages (%)**
Microorganisms 30°C	94,2	97,1
Listeria monocytogenes	94,1	100
E. coli	100	100
Staphylococcus coagulase positive	100	100
Salmonella spp.	100	100

FoodSimplex methodology also intended with the fourth stage, to apply article 9 of the Regulation (CE) nº 2073/2005, on microbiological criteria for foodstuffs, that expressly states that, to prevent the occurrence of a microbial risk, FBO shall analyze trends in the test results, to take appropriate action when they observe a bias towards "Unsatisfactory" results. This was what happened, but not only the results where discuss with the FBO but also with the food handlers. Microbiological monitoring of end products has been effectively used to evaluate the HACCP plan and to discover persistent problems related to microbial contamination in catering premises (Petruzzelli *et al.*, 2018). In fact, through FoodSimplex methodology was possible to apply and certify better results in microbial data.

The data obtained represented a keystone of risk analysis, and it was used as an operational basis to the improvement plans of the restaurants (e.g. food handlers training, improve premises and good practices).

For this investigation, not all microbial parameters were measured, especially for food handlers and surfaces samples (for example, absence of *E. coli*, Enterobacteriaceae, S. aureus parameters) (Jacxsens *et al*., 2009; Legnani *et al*., 2004) but was noteworthy that, although microbial testing is widely recognized as an essential part of the HACCP system, a high number of analyses represented a prohibitive cost of FBO (Petruzzelli *et al.*, 2018; Jacxsens *et al*., 2009). As so, in this context, FoodSimplex tried to work with microbiological results, which do over time provided a better allocation of economic resources for FBO.

As part of investigation work, limitations were also recognized. The size of the sample was reduced than initially planned due to external factors. To respond to the inclusion criteria and to comply with the timeline of the study, there were a smaller number of restaurants that show availability or that stay in business.

One of the principal objectives was to study SME and the challenge that food safety might represent for these companies. However, this fact also turned out to be a limitation. The financial struggle to fulfil the recommendations regarding HACCP requirements (premises, material, and the microbial samples) it's a reality and was also a challenge in the study.

This study relied on the availability of FBO, as so before every assessment, the restaurant top management was contacted for audit and microbial analyses collection availability. This fact might present some inconveniences, not only it wasn't always possible to fulfil the agenda and the timeline proposed in FoodSimplex; but also, the fact that the assessments were previously agreed could had some effect on the results.

The high rotation of the restaurant workers, with season related contracts, difficulted the training agenda, and it could also have an effect on the assessment results. Another constraint was the food samples were also agreed with the FBO, and sometimes there wasn't any food prepared to sample, or the sample could represent a loss in the economic value of the day (less one meal to serve). This fact became an issue to the food sample collection agenda. During the study, was curious to be aware that the struggles and difficulties felt by this SME became a part also of the investigation. Finding a way to overcome the constraints made FoodSimplex more practical and closest to the actual working context.

For future perspectives, there must be considered the technical and scientific advances, such as novel analytical methods, gene-editing biotechnologies and new ways to produce food to respond to more efficient and resilient food systems; but its also importante to considerer the actual framework for food consumption.

The major scientific advances, such as Whole Genome Sequencing, promise to better identify, characterize, determine and respond to potential risks, and prevent and reduce hazards in the food chain. Showing that there are many opportunities to adapt and promote beneficial technologies. The innovative wearable technology could represent a importante role in food safety audits; predictive analytics, to assist experts with their data collection to determine how and where to focus their efforts and blockchain technology, which can significantly speed up the traceability.

Restaurants' kitchens rely on paper-based checks and records, which releave to te time-consuming, prone to human error and easy to falsify. Technology could help it in the future to provide automated monitoring, digital checklists and internet of things-based sensors to replace paper.

Another important role for science is in generating best evidence to inform decision makers, private sector and consumers. Currently, much food safety prioritization and management is not science-based and hence may not represent the best use of scarce resources. This study intented to create scientific data in real work context, to provide information for obstacles and opportunities for equitable implementation of food safety.

One of the major perspective its represensed by the consumers, which are more knowledgeable, engaged and demanding higher food safety standards.

The business damage and reputation when there are food safety failures are greater than ever, as so proactive businesses should embrace food safety and use high standards to differentiate them from the competition.

As mentioned abose, the food consumption is changing, more people are eating out, which can be good for the economic growth of restaurants, but it also brings challenges. The pressure increases to serve more customers but also on food suppliers, with a mandatory command to deliver more fresh ingredientes and more often. The challenge will be to comply with food safety standards while being able to keep up with the consumers demands and preferences, they are increasingly looking for healthy, high quality, locally sourced food.

At a governmental and strategic level, greater use could l be made of risk analysis and risk assessment and is likely to include judgements of what level of disease is “Acceptable”. However, more information is needed for these models with data on the spread and transmission of pathogens leading to cross-contamination, being a recognised “Achilles heel” of many existing risk assessments (Paoli, 2005). More information on this can be obtained from risk reenactment and studies using notational analysis (Racicot *et al*., 2019; Wu, Liu & Chen 2019; Redmond *et al.*, 2004; Clayton & Griffith, 2004).

The recognition of human behaviour linked to organisational culture has triggered new approaches to improving food safety. The application of psychological models possibly could help predict and change/improve food hanlders behaviour.

Training may involve a more significant social marketing element where the information communicated considers the recipient of the data more fully (Redmond *et al*., 2000). The same is likely to be true of consumer food safety campaigns, many of which have been relatively unstructured and uncoordinated in the past.

An future improvement could be convincing FBO to improve food safety, and the fact that is not a cheap option to ignore it, and it could involve more significant use of cost-benefit analysis and studies on consumer willingness to pay.

Regarding the aim of this study, future investigations should consider other regions, counties, and even countries in a similar analysis to assess both short- and long-term relationships in restaurant food safety. Forthcoming studies could consider both seasonal and cyclical characteristics of the data on restaurante food sanitation to further understand the behaviour in this activity (Ridderstaat & Okumus, 2019).

For this matter, the suggestions rely in create partnership between private food safety companies and government inspections (share data); provide regional state office to food safety system implementation, through FoodSimplex, to SME restaurants; recognize the food safety technicians and their Professional ID and implement specific training obligations to work in food service to food handlers but also to FBO.

The researches performed until now, on restaurant sanitation had focused on different angles of analysis, including the underlying factors of FBD in restaurants (e.g. factors affecting restaurant sanitation inspection results; diferences in inspection results; consumers' perceptions and attitudes towards restaurant food sanitation). Although there are many investigations on restaurant sanitation, this field of study is far from being saturated (Ridderstaat & Okumus, 2019).

The HACCP guidelines constitute essential support for the implementation, particularly for SME, the results of this thesis should be considered when revising the guidelines for SME and create support to the restaurants. The official controls should also profit from the results by a better understanding of the problems that this companies encounter when carrying out the HACCP analysis.

FoodSimplex method underlines that the continuous assessment of the HACCP system effectiveness is essential, due to its critical role in protecting public health. The major public health concern created by this SME restaurants, due to the lack of support, and ease of registration of establishments and authorization to start the activity, decreased. As so, this study brings to light a methodologic solution to be apply in this restaurants with a global and atual goal-food safety.

CHAPTER VI – CONCLUSION

1. FoodSimplex methodology, based on HACCP principles, showed to have significant improvement in portuguese restaurants.

2. The cleaning and sanitation conditions, GMP and HACCP documentation of SME restaurants had developed.

3. The microbial quality of the meals served had a significant improvement, confirmed by the decrease of bacteria contamination of the food groups analysed along the study.

4. The data for hygiene assessment through microbial analysis of surfaces and food handlers' hands had an evolution in the direction of compliance.

5. All of whichs, shows that FoodSimplex methodology was important for compliance of the food safety requirements in restaurants.

1. La aplicación de la metodología FoodSimplex, basada en el Análisis de Peligros y Puntos Críticos de Control (APPCC), muestra una mejora significativa en los restaurantes portugueses.

2. Las condiciones de limpieza y sanitarias, la documentación asociada a la aplicación de las buenas prácticas de manufactura (BPM) e higiene (BPH) y APPCC de los restaurantes de pequeño y mediano tamaño se han puesto a punto.

3. La calidad microbiológica de las comidas servidas tuvo una mejora significativa, confirmada por la disminución de la contaminación bacteriana de los grupos de alimentos analizados a lo largo del estudio.

4. Los datos para la evaluación de la higiene a través de los análisis microbiológicos de superficies y manos de manipuladores de alimentos tuvieron una evolución positiva.

5.- Todo ello demuestra que la metodología FoodSimplex es útil para cumplir con los requisitos de seguridad alimentaria establecidos.

CHAPTER VII – SCIENTIFIC PUBLICATIONS

FULL ARTICLE PUBLICATION

1.- **Baltazar A**, Figueiredo JP, Ferreira A, Manyes L and Mañes J (2017). *FoodSimplex in restaurants-how can it provide safer meals? Integr. Food Nutr. Metab.* 4(5):1-6.

2.- **Baltazar, A**; Ferreira, A; Manyes, L and Mañes, J (2019). *FoodSimplex as a mean to improve portuguese restaurants good manufacturing practices - audit and microbial assessment.* Current Nutrition and Food Science 15 (*in press*).

3.- **Baltazar, A**; Ferreira, A; Manyes, L and Mañes, J (2019*). FoodSimplex - a public health tool to improve restaurants cleaning and sanitation status*. Rev. Toxicol. (in press)

ABSTRACT PUBLICATIONS

1. **Baltazar A**, Figueiredo JP, Ferreira A, Manyes L and Mañes J (2018). *FoodSimplex – a new food safety methodology in mass catering.* Microbiological food safety Arh Hig Rada Toksikol 2018; 69 (Suppl.1): 34-36.

2. **Baltazar A**, Figueiredo JP, Ferreira A, Manyes L and Mañes J (2019). *FoodSimplex: New food saefty methodology for microbial safer meals.* Journal of Clinical Nutrition & Dietetics, vol. 5. DOI: 10.4172/2472-1921-C1-004

CHAPTER VIII – CONGRESS PRESENTATIONS

Oral Presentations

1. *Safety control evaluation of food storage in mass caterer.*

   SHO 2017 - *International Symposium on Occupational Safety and Hygiene*, Guimarães – Portugal 10-11 April 2017.

2. *Programa de segurança alimentar no processo de armazenagem da restauração pública.*

   V Congresso Nacional de Saúde Pública, Porto - Portugal 15-17 February 2017

3. *FoodSimplex - New food safety methodology in mass catering*.

   2nd International Congress on Food Safety and Quality, Opatija –Croatia. 13-16 November 2018.

4. *FoodSimplex - Food safety methodology for restaurants.*

   6th Food Safety Congress, Istambul – Turkey. 03-04 May 2018.

5. *FoodSimplex – New food safety methodology for microbial safer meals.*

   3rd World Congress on Nutrition and Dietetics, Prague – Czech Republic.24- 27 February 2019.

CHAPTER IX – REFERENCES

Acikel, CH; Ogur, R; Gocgeldi, E; Ucar, M; Kir, T (2008). *The hygiene training of food handlers ate a teaching hospital.* Food Control 19(2), 186-190.

Al-Shabib, NA; Mosilhey, SH & Husain, FM (2016). *Cross-sectorial study on food safety knowledge, attitude and practices of male food handlers employed in restaurants of King Saud University, Saudi Arabia*. Food Control 59, 212-217.

Ahmed, AM; Shimamoto, T (2015). *Molecular characterization of multidrug-resistant Shigella spp. of food origin.* International Journal of Food Microbiology 194, 78–82.

Amorim, J (2006). *Lista de Verificação Higiene Alimentar na Restauração Coletiva*. In. Portugal: Dr. Ricardo Jorge Nacional Institute; Portugal Health Council; P.26.

ANZFA (2001) *Food Safety: an audit system. Australian New Zealand Food Authority.* (Available at: www.info@anzfa.gov.eu. Retrieved february, 20, 2019)

APHORT (2008). Code of Good Practices in Food Safety. Portuguese Association of Hotels, Restaurants and Tourism. Portugal.

Argudín, MA; Mendoza, MC; Gonzaléz-Hevia, MA; Bances, M; Guerra, B; Rodicio, MR (2012). *Genotypes, exotoxin gene content, and antimicrobial resistance of staphylococcus aureus strains recovered from food and food handlers.* Appl. Environ. Microbiol. 78(8), 2930-2935.

Arranz, AS; Gómez, DPM & Peña, CE (1995). *Sanitary quality from snacks in bars in the summertime*. Alimentaria 265:73-77.

Auvolat, A; Besse, NG (2016). The challenge of enumerating Listeria monocytogenes in food. Food Microbiology 53, 135-149.

Arranz, AS; Gómez, DPM & Peña, CE (1995). Sanitary quality from snacks in bars in the summertime. Alimentaria 265:73-77.

ASAE. Ficha Técnica de Fiscalização Restauração e Bebidas. In: Ministério Economia e Inovação; Autoridade Segurança alimentar e económica; 2006. P. 30.

Ashraf, AM; Shimamoto, T (2015). *Molecular characterization of multidrug-resistant Shigella spp. of food origin.* International Journal of Food Microbiology 194, 78–82.

Balasubramanian, D; Harper, L; Shopsin, B; Torres, VJ (2017). *Staphylococcus aureus pathogenesis in diverse host environments*. Pathog Dis 75(1).

Baltazar, AL (2016). Food Safety – A Long Term Perspective in Portugal. Nutrition and Food Technology: Open Access (2), 1-2.

Baltazar, A; Figueiredo, JP; Ferreira, A; Manyes, L; Mañes, J (2017). *FoodSimplex in restaurants - how can it provide safer meals?* Integr Food Nutr Metab 4(5): 1-6.

Baptista, P & Antunes, C (2005). Hygiene and Food Safety in Catering: Volume II - Initiation. Forvisão. Guimarães, Portugal.

Baptista, P & Linhares, M. (2005). Hygiene and Food Safety in Catering: Volume I - Initiation. Forvisão. Guimarães, Portugal.

Bank of Portugal (2011). Sector Analysis of accommodation, catering and the like. Studies of central balances. Lisbon, Portugal.

Bas, M; Ersun, AS & Kivanç, G (2006). *The evaluation of food hygiene knowledge, attitudes, and practices of food handlersÕin food businesses in Turkey*. Food Control 17, 317–322.

Bergen, LK; Meyer, M; Høg, M; Rubenhagen, B; Andersen, LP (2009). *Spread of bacteria on surfaces when cleaning with microfibre cloths*. Hosp. Infect. 71,132–137.

Bering, CC (2008). *Condicões higiénico-sanitárias no preparo de refeicões em creches comunitárias de Belo Horizonte, Minas Gerais*. Tese de Mestre em Ciência de Alimentos, Facultade de Farmácia da UFMG, Belo Horizonte, Minas Gerais, Brazil.

Besser, JM (2018). *Salmonella epidemiology: A whirlwind of change.* Food Microbiology 71, 55-59.

Berrada, H; Soriano, JM; Picó, Y & Mañes, J (2006). *Quantification of Listeria monocytogenes in salads by real time quantitative PCR*. International Journal of Food Microbiology 107, 202-206.

Boer, A. & Bast, A (2018). *Demanding safe foods – Safety testing under the novel food regulation (2015/2283).* Trends in Food Science & Technology 72, 125-133.

Brown, LG; Hoover, ER; Selman, CA; Coleman, E; Rogers, HS (2017). *Outbreak Characteristics Associated with Identification of Contributing Factors to Foodborne Illness Outbreaks*. Epidemiol. Infect. 2017;145(11):2254-62

Buccheri, C; Mammina, C; Giammanco, S; Giammanco, M; La Guardia, M; Casuccio, A (2010). *Knowledge, attitudes and self-reported practices of food service staff in nursing homes and long-term care facilities*. Food Control 21, 1367-1373.

Buchanan, RL; Gorris, LGM; Hayman, MM; Jackson, TC; Whiting, RC (2017). *A review of Listeria monocytogenes: An update on outbreaks, virulence, dose-response, ecology, and risk assessments*. Food Control 75, 1-13.

Capunzo, M; Cavallo, P; Boccia, G; Brunetti, L; Buonomo, R; Mazza, G (2005). *Food hygiene on merchant ships: the importance of food handlers'training.* Food Control, 16(2), 183-188.

Campos, AKC; Cardonha, AMS; Pinheiro, LBG; Ferreira, NR; Azevedo, PRM; Stamford, TLM (2009). *Assessment of personal hygiene and practices of food handlers in municipal public schools of Natal, Brazil*. Food Control 20(9), 807-810.

Cavalli, SB & Salay, E (2004). *Food quality and safety control activities in commercial foodservice in the cities of Campinas (SP) and Porto Alegre (RS), Brazil.* Foodservice Research International 14 (4), 211-223.

CDC. The Listeria initiative. Atlanta, GA: US Department of Health and Human Services, CDC; 2016. (Available at: https://www.cdc.gov/listeria/surveillance/listeria-initiative.html. Retrieved February 19, 2018).

Center for Disease Control and Prevention (2017). One Health. (Available at: https://www. cdc.gov/onehealth/index.html) Retrieved February 9, 2018.

Chaibenjawong, P; Foster, SJ (2011). Desiccation tolerance of Staphylococcus aureus. Arch Microbiol. 193(2), 123-35.

Charalambous M, Fryer PJ, Panayides S, Smith M (2015). Implementation of Food Safety Management Systems in small food businesses in Cyprus. Food Control 57: 70-75.

Codex Alimentarius Commission (1993). Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering. CAC/RCP 39-1993. Rome.

Codex Alimentarius Commission (2003). Code of practice - general principles of food hygiene. CAC/RCP 1-1969, Rev. 4-2003. Rome.

Codex Alimentarius Commission (2007). Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Foods. CAC/GL 61-2007. Rome.

Codex Alimentarius Commission (2008). Proposed draft guidelines for the validation of food safety control measures. CAC/GL 69-2008 Rome.

Commission Recommendation 2003/361/EC, 6 May 2003, concerning the definition of micro, small and medium-sized enterprise.

Copenhagen (2015). Complex food chain increases food safety. World Health Organization (WHO).

Cormier, RJ; Mallet, M; Chiasson, S; Magnússon, H; Valdimarsson, G (2007). Effectiveness and performance of HACCP-based programs. Food Control, 18, 665-671.

Dahsten, E; Lindström, M; Korkeala, H (2015). Mechanisms of food processing and storage-related stress tolerance in Clostridium botulinum. Research in Microbiology 166, 344-352.

Direção Regional de Agricultura e Pescas do Centro (nd). Segurança Alimentar – Síntese de Legislação. (Available at: http://www.drapc.min-agricultura.pt/base/geral/files/seguranca_alimentar.pdf. Retrieved February 19, 2018).

Dzwolak, W (2014). HACCP in small food businesses – The Polish experience. Food Control 36, 132-137.

Edelstein, S. (2011). Nutrition in Public Health: a handbook for developing programs and services. 3rd edition by Jones & Bartlett Learning, USA.

EFSA (2018). The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2017. EFSA journal 2018, 16 (12): 5500.

EFSA (2015). Strong - evidence outbreaks in Reporting Countries. Access in https://dwh.efsa.europa.eu

EFSA (2016). EU summary report on zoonoses, zoonotic agents and food-borne outbreaks 2015. (Available at: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4634/epdf Retrieved February 19, 2018).

EFSA (2018). General Food Law. (Available at: https://ec.europa.eu/food/safety/general_food_law_en. Retrieved February 19, 2018).

EFSA & ECDC. (2016). The European Union summary report on trends and sourcesof zoonoses, zoonotic agents and foodborne outbreaks in 2015. EFSA, ECDC, 2016. EFSA Journal, 14(12), 20449. (Available at https://doi.org/10.2903/j.efsa.2016.4634. Retrieved February 19, 2018).

European Union (2017). Annual Report on European SMEs 2016/2017.

Fakruddin, MD; Mannan, KSB & Andrews, S (2013). *Viable but Nonculturable Bacteria: Food Safety and Public Health Perspective*. ISRN Microbiology, Article ID 703813.

FAO & WHO (2016). Codex Alimentarius – Understanding Codex. (Available at http://www.fao.org/3/a-i5667e.pdf. Retrived 23 january, 2019).

FAO/WHO (2004). Second FAO/WHO global forum of food safety regulators. Building effective food safety systems, Bangkok, Thailand, 12e14 October. 2004. Issued by the Joint Secretariat of the FAO/WHO Global Food of Food Safety Regulators, FAO, Rome. (Available at: ftp://ftp.fao.org/docrep/fao/meeting/008/y5871e/y5871e00.pdf. Retrieved February 20, 2019).

FDA (1997). NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS. (Available at https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines. Retrieved January 15, 2018).

FDA (1992). Bacteriological Analytical Manual. Arlington. Association of Official Analytical Chemists, 7.ed., USA.

Ferrer, MD; Simón, M & Tarragó, C (1992). Presence of microorganisms in prepared cooked foods. Alimentaria 299: 69-70.

Fitzgerald, C (2015). Campylobacter. Clin Lab Med 35, 289–298.

Figueiredo, VF & Neto, PLOC (2001). Implantação do HACCP na indústria dos alimentos. Revista Gestão de Produção 8 (1), 100-111.

Food and Drugs Administration (1997). HACCP Principles & Application Guidelines. (Available at: https://www.fda.gov/food/guidanceregulation/haccp/ucm2006801.htm#app-a). Retrieved February 19, 2018).

Forsythe, 2010. The Microbiology of safe food. 2nd edition. Wiley-Blackwell. USA.

Forsythe SJ, Hayes PR (1998) Food Poisoning and other foodborne hazards. In: Forsythe SJ, Hayes, PR (eds). Food hygiene, microbiology and HACCP. Third edition. Gaithersburg, MD: Aspen Publication, pp: 21-85.

Fraser, R & Monteiro, D (2009). A conceptual framework for evaluating the most cost-effective intervention along the supply chain to improve food safety. Food Policy, 34, 477-481.

Garayoa, R; Díez-Leturia, M; Bes-Rastrollo, M; García-Jalón, I; Vitas, AI (2014). Catering services and HACCP: Temperature assessment and surface hygiene control before and after audits and a specific training session. Food Control 43, 193-198.

Garayoa, R; Abundancia, C; Díez-Leturia, M; Vitas, AI (2017). Essential tools for food safety surveillance in catering services: On-site inspections and control of high-risk cross-contamination surfaces. Food Control 75, 48-54.

Garayoa, R; Vitas, AI; Díez-Leturia, M; García-Jalón, I (2011). Food safety and the contract catering companies: Food handlers, facilities and HACCP evaluation. Food Control, 22 (12), 2006-2012.

Garcez, E; Fachin, G & Andrade Júnior, PP (2000). Indicadores da qualidade em restaurantes: um estudo de caso. Revista de Ciências da Administração 2(3), 29-38

Griffith CJ (2000) Food safety in catering establishments. In: Farber JM, Todd ECD (eds) Safe Handling of Foods, Marcel Dekker, New York, NY.

Griffith C (2006) Food safety: where from and where to? Br Food J 108: 6-15.

Gonçalves, ML (2006). Novas exigências legais e controlo oficial dos géneros alimentícios. Revista Segurança e Qualidade Alimentar nº1, 20-22.

Gomes-Neves, E; Araújo, AC; Ramos, E; Cardoso, CS (2007). Food handling: Comparative analysis of general knowledge and practice in three relevant groups in Portugal. Food Control 18, 707-712.

Gruenfeldova, J; Domijan, K; Walsh, C (2019). A study of food safety knowledge, practice and training among food handlers in Ireland. Food Control 105, 131–140.

Guchait, P; Neal, JA; Simons, T (2016). Reducing food safety errors in the United States: Leader behavioral integrity for food safety, error reporting and error management. International Journal of Hospitallity Management 5, 11-18.

Gould, LH; Rosenblum, I; Nicholas, D; Phan, Q; Jones, TF (2013). Contributing factors in restaurant – associated foodborne diseases outbreaks, FoodNet Sites, 2006 and 2007. Journal Food Prot. 76, 1824-1828.

Han, Z; Pielsticker, C; Gerzova, L; Rychlik, I; Rautenschlein, S (2016). The infuence of age on Campylobacter jejuni infection in chicken. Developmental and Comparative Immunology 62, 58-71.

Hamidiyan, N; Salehi-Abargouei, A; Razaei, Z; Dehghani-Tafti, R; Akrami-Mohajeri, F (2018). The prevalence of Listeria spp. food contamination in Iran: A systematic review and meta-analysis. Food Research International 107, 437–450.

Haukijärvi, V; Lundén, J (2017). Does waiving preventive food control inspections in Finland weaken the prerequisites for safe food handling in restaurants? Food Control 71, 187-192.

Harper, SWM (2016). Future of an ageing population; executive summary, keyfindings, future of an ageing populationeevidence base. Government Office for Science, 6 -16.

Havelaar, AH; Kirk, MD; Togerson, PR; Gibb, HJ; Hald, T; Lake, RJ; Praet, N; Bellinger, DC; de Silva, NR; Gargouri, N; Speybroeck, N; Cawthorne, A; Mathers, C; Stein, C; Angulo, FJ;

Devleesschauwer, B (2015). World Health Organization Global Estimates and regional Comparisons of the burden of foodborne disease in 2010. PLoS Med 12(12): E1001923. http://doi.org/10.1371/journal.pmed.1001923

Hedberg, CW; Palazzi-Churas, KL; Radke, VJ; Selman, CA; Tauxe, RV (2008). The use of clinical profiles in the investigation of foodborne outbreaks in restaurants: United States, 1982-1997. Epidemiology and Infection 136 (1), 65-72.

Henroid, D & Sneed, J (2004). Readiness to implement hazard analysis and critical control point (HACCP) systems in Iowa schools. Journal of the American Dietetic Association, 104(2), 180-185.

Hermans, D; Van deun, K; Martel, A; Van Immerseel, F; Messens, W; Heyndrickx, M; Haesebrouck, F; Pasmans, F (2011). Colonization factors of Campylobacter jejuni in the chicken gut. Vet Res. 42(1): 82.

Herrera A.G. (2001) Mesophilic Aerobic Microorganisms. Spencer J.F.T., de Ragout Spencer A.L. (eds) Food Microbiology Protocols. Methods in Biotechnology, vol 14. Humana Press.

Hoelzer, K; Switt, AIM; Wiedmann, M; Boor, KM (2017). Emerging needs and opportunities in foodborne disease detection and prevention: From tools to people. Food Microbiology (article in press).

Holt, G & Henson, SP (2000). Information for good hygiene practice in small businesses. British Food Journal 102 (4), 320-337.

Huang, L; Li, C.; Hwang, CA (2018). Growth/no growth boundary of Clostridium perfringens from spores in cooked meat: A logistic analysis. International Journal of Food Microbiology 266, 257–266.

Humphrey, T; O'Brien, S; Madsen, M (2007). Campylobacters as zoonotic pathogens: A food production perspective. International Journal of Food Microbiology 117, 237- 257.

Hussain, MA; Dawson, CO (2013). Economic Impact of Food Safety Outbreaks on Food Businesses. Foods 2, 585-589.

International Commission on Microbiological Specifications for Foods (ICMSF) (2006). Microorganisms in Foods 4: Application of the Hazard Analysis Critical Control Point (HACCP) System to

Ensure Microbiological Safety and Quality. Blackwell Scientific Publications, Ltd. Boston, USA.

ICMFS (2006). A Simplified guide to understanding and using food safety objectives and performance objectives, p. 4

Jacxsens, L; Kirezieva, K; Luning, PA; Ingelrham, J; Diricks, H; Uyttendaele, M (2015). Measuring microbial food safety output and comparing self-checking systems od food business operators in Belgium. Food Control 49, 59-69.

Jacxsens, L; Kussaga, J; Luning PA; Van der Spiegel, M; Devlieghere, F; Uyttendaele, M (2009). A microbial assessment scheme to measure microbial performance of food safety management systems. International Journal of Food Microbiology 134, 113-125.

Jarvis, NA; O'Bryan, CA; Dawoud, TM; Park, SH; Kwon, YM; Crandal, PG; Ricke, SC (2016). An overview of Salmonella thermal destruction during food processing and preparation. Food Control 68, 280-290.

Jones, TF; Angulo, FJ (2006). Eating in restaurants: a risk factor for foodborne disease?. Clinical Infectious Diseases 43, 1324-8.

Karipidis, P; Athanassiadis, K; Aggelopoulos, S; Giompliakis, E (2009). Factors affecting the adoption of quality assurance systems in small food enterprises. Food Control 20(2), 93-98.

Kendrovski, V; Gjorgjev, D (2012). Climate Change: Implication for Food-Borne Diseases (Salmonella and Food Poisoning among Humans in R. Macedonia). Structure and Function of Food Engineering, Ayman Amer Eissa, IntechOpen, Available from: https://www.intechopen.com/books/structure-and-function-of-food-engineering/climate-change-implication-for-food-borne-diseases-salmonella-and-food-poisoning-among-humans-in-r-m

Kirezieva, K; Nanyung, J; Jacxsens, L; Van der Vorst, JGAJ; Uyttendaele, M; Luning, PA (2013). Context factors affecting design and operation of food safety management systems in the fresh produce chain. Trends in Food Science & Techonology 32, 108-127.

Ko W (2015). Food suppliers' perceptions and practical implementation of food safety regulations in Taiwan. Food Drug Anal 23, 778–787.

Koydemir, HC; Külah, H; özgen, C; Alp, A; Hasçelik, G (2011). MEMS biosensors for detection of methicillin resistant Staphylococcus aureus. Biosensors and Bioelectronics 29(1) 1-12.

Kuo, HW; Schmid, D; Jelovcan, S; Pichler, AM; Magnet, E; Reichart, S; Allerberger, F. (2009). A foodborne outbreak due to norovirus in Austria. Journal of Food Protection 72(1), 193-196.

Laiko-Roto, T & Nevas, M (2014). Restaurant business operators' knowledge on food hygiene and their attitudes toward official food control affect the hygiene in their restaurants. Food Control 43, 13-20.

Lahou, E; Jacxsens, L; Van Landeghem, F; Uyttendaele, M (2014). Microbiological sampling plan based on risk classification to verify supplier selection and production of served meals in food service operation. Food Microbiology 41, 60-75.

Lahou, E; Jacxsens, L; Verbunt, E; Uyttendaele, M (2015). Evaluation of the food safety management system in a hospital food service operation towards Listeria monocytogenes. Food Control 49, 75-84.

Lee, JY; Kang, DH (2016). Development of an improved selective medium for the detection of Shigella spp. LWT - Food Science and Technology 65, 311-317.

Legnami, P; Leoni, E; Berveglieri, M; Mirolo, G; Alvaro, N (2004). Hygienic control of mass catering establishments microbiological monitoring of food and equipment. Food Control 15, 205-211.

Lindström, M; Heikinheimo, A; Lahti, P; Korkeala, H (2011). Novel insights into the epidemiology of Clostridium perfringens type A food poisoning. Food Microbiology 28, 192-198.

Linscott, AJ (2011). Food-borne Illness. Clinical Microbiology Newsletter, 33:6.

Little, CI & Louvois, J (1998). The microbiological examination of butchery products and butchers' premises in the United Kingdom. Journal Appl. Bascteriology 85:177-186.

Luber, P (2011). The Codex Alimentarius guidelines on the application of general principles of food hygiene to the control of Listeria monocytogenes in ready-to-eat foods. Food Control 22, 1482-1483.

Lues, JFR & Van Tonder, I (2007). The occurrence of indicator bacteria on hands and aprons of food handlers in the delicatessen sections of a retail group. Food Control 18(4): p. 326-332

Madden, RH; Hutchison, M; Jordan, K; Pennone, V; Gundogdu, O; Corcionivoschi, N (2018). Prevalence and persistence of Listeria monocytogenes in premises and products of small food business operators in Northern Ireland. Food Control 87, 70-78.

Macausin, E (2003). The boss, the owner, the proprietor the food hygiene manager? The Journal of the Royal Society for the Promotion of Health 123 (4), 229-232.

Mariano, G. & Cardo, M (2007). Princípios Gerais da Legislação Alimentar. Segurança e Qualidade Alimentar 2, 46-47.

Matias, JCO; Fonseca, JMJ; Barata, IG; Brojo, FMRP (2013). HACCP and OHS: can each other improve the other in the catering sector?. Food Control 30, 240-250.

Martinez, MG; Fearne, A; Caswell, JÁ; Henson, S (2007). Co-regulation as a possible model for food safety governance:

Opportunities for public–private partnerships. Food Policy 32, 299–314.

Martínez-Tomé, M; Vera, AM; Murcia, MA (2000). Improving the control of Food production in catering establishments with particular reference to the safety of salads. Food Control 11, 437-445.

Martinović, T; Andjelković, U; Gajdošik, MS; Rešetar, D; Josić, D (2016). Foodborne pathogens and their toxins. J Proteomics 147, 226-235.

Martins, BM; Hogg, T & Otero JG (2012). Foodhandlers' knowledge on Food hygiene: The case of a catering company in Portugal. Food Control 23, 184-190.

Martins, ML & Rocha, A (2014). Evaluation of prerequisite programs implementation at schools foodservice. Food Control, 39(1), 30-33.

Marzano, MA & Balzaretti, CM (2011). Cook-serve method in mass catering establishments: Is it still appropriate to ensure a high level of microbiological quality and safety? Food Control 22, 1844-1850.

Matias, JCO; Fonseca, JMJ; Barata, IG; Brojo, FMRP (2013). HACCP and OHS: Can each one help improve the other in the catering sector? Food Control 30, 240-250.

Medeiros, CO; Cavalli, SB; Proença, RPC (2012). Human resources administration processes in commercial restaurants and Food Safety: The actions of administrators. International Journal of Hospitality Management 31, 667-674.

Melngaile, A & Karklina, D (2013). Microbiological risk analysis in catering establishments. Proceedings of the Latvian Academy of Sciences. Section B, Vol. 67, No. 4/5 (685/686), pp. 340–349.

Membré, J; Diao, M; Thorin, C; Cordier, G; Zuber, F; André, S (2015). Risk assessment of proteolytic Clostridium botulinum in canned foie gras. International Journal of Microbiology 210, 62-72

Miyagishima, K; Moy, G; Miyagawa, S; Motarjemi, Y; Käferstein, FK. (1995). Food Safety and public health. Food Control, vol. 6, nº5, 253-259

Motarjemi, Y; Käferstein, F (1999). Food safety, Hazard Analysis and Critical Point and the increase of foodborne diseases: a paradox?. Food Control 10, 325-333

Motarjemi, Y; Käferstein, F; Moy, G; Miyagawa, S; Miyagishima, K (1996). Importance of HACCP for public health and development - The role of the World Health Organization. Food Control 7, 77-85

Moran, F; Sullivan, C; Keener, K; Cullen P (2017). Facilitating smart HACCP strategies with Process Analytical Technology. Current Opinion in Food Science 17: 94–99.

Moreb, NA; Priyadershini, A & Jaiswal, AK (2017). Knowledge of food safety and food handling practices amongst food handlers in the Republic of Ireland. Food Control 80, 341-349.

Motarjemi, Y & Käferstein, F (1999). Food safety, Hazard Analysis and Critical Control Point and the increase in foodborne diseases: a paradox? Food Control 10, 325-333.

Mukhopadhyay, S; Ramaswamy, R (2012). Application of emerging technologies to control Salmonella in foods: A review. Food Research International 45, 666–677.

Nasrolahei, M; Mirshafiee, S; Kholdi, S; Salehian, M; Nasrolahei, M (2017). Bacterial assessment of food handlers in Sari City, Mazandaran Province, north of Iran. Journal of Infection and Public Health 10, 171—176.

Nayak, M & Waterson, P (2017). The Assessment of Food Safety Culture: Na investigation of current challenges, barriers and future opportunities within the Food industry. Food Control 73, 1114-1123.

De Noordhout, CM; Devleesschauwer, B; Angulo, FJ; Verbete, G; Haagsma, J; Kirk, M; Havelaar, A; Speybroeck (2014). The global burden of listeriose: a systematic review and meta-analysis. Lancet Infect Dis. 14(11), 1073-1082.

NP EN ISO 19011. Guidelines for audits of quality management systems and / or environmental management. Portuguese Quality Institute, Lisboa.

Nunes JL, Curto H, Varela M (2016) Gestão de Tesouraria: O impacto da atual crise económica e financeira nas PME portuguesas. Business and Economics School, Lisbon. Available in http://hdl.handle.net/10400.26/15250.

Nyamari, J (2013). Evaluation of compliance to food safety standards amongst food handlers in selected hospitals in Kenya. School of Public Health, Kenyatta University, Kenya.

Nyarugwe, SP; Linnemann, A; Hofstede, GJ; Fogliano, V; Luning, PA (2016). Determinants for conducting food safety culture research. Trends in Food Science & Technology 56, 77-87.

O Cliver, D & Riemann, HP (2002). Foodborne Diseases. 2nd edition. Academic Press. USA.

Organji, SR; Abulreesh, HH; Elbanna, K; Osman, GEH; Khider, M (2015). Occurrence and characterization of toxigenic Bacillus cereus in food and infant feces. Asian Pac J Trop Biomed 5(7), 515-520.

Osimani, A; Aquilanti, L & Clementi, F (2018a). Bacillus cereus foodborne outbreaks in mass catering. International Journal of Hospitality Management 72, 145–153.

Osimani, A; Milanovic, V; Polverigiani, S; Garafalo, C; Clementi, F (2018b). Hygiene auditing in mass catering: a 4-year in a university canteen. Public Health I59, 17-20.

Panisello PJ, Quantick PC (2001) Technical barriers to Hazard Analysis Critical Control Point (HACCP). Food Control 12: 165-173.

Park, MS; Park, KH; Bahk, GJ (2018). Combined influence of multiple climatic factors on the incidence ofbacterial foodborne diseases. Science of the Total Environment 610-611; 10-16.

Phraephaisan, C; Khumthong, R; Takahashi, H; Ohshima, C; Kodama, K; Techaruvichit, P; Vesaratchavest, M; Taharnklaew, R; Keeratipibul, S (2017). A novel biomarker for detection of Listeria species in food processing factory. Food Control 73, 1032-1038.

Peck, MW; van Vliet, AHM (2016). Impact of Clostridium botulinum genomic diversity on food safety. Current Opinion in Food Science 10, 52–59.

Pérez, E; Raposo, A; Millán, R; Sanjuán, E; Carrascosa, C (2011). Microbiological Evaluation of Prepared/Cooked Foods in a HACCP Environment. Food and Nutrition Sciences 2, 549-552.

Petruzzelli, A; Osimani, A; Tavoletti, S; Clementi, F; Vetrano, V; Di Lullo, S; Paolini, F; Foglini, M; Micci, E; Orazietti, N; Luchetti, T;

Tonucci, F (2018). Microbiological quality assessment of meals and work surfaces in a school-deferred catering system. International Journal of Hospitality Management 68, 105-114.

Pichíler, J; Ziegler, J; Aldrian, U & Allerberger, F (2014). Evaluating levels of knowledge on Food safety among Food handlers from restaurants and various businesses in Viena, Austria 2011/2012. Food Control 35, 33-40.

PORDATA (2016). Base de dados Portugal Contemporâneo – Números de Portugal. (Available at: https://www.pordata.pt/Portugal/Quadro+Resumo/Portugal-230616 Retrieved February 02, 2018).

PORDATA (2017) Pequenas e médias empresas: total e por sector de atividade económica. Base de Dados Portugal Contemporâneo. https://www.pordata.pt

Powell, DA; Erdozain, S; Dodd, C; Morley, K; Costa, R & Chapman, BJ (2013). Audits and inspections are never enough: A critique to enhance food safety. Food Control 30, 686–691.

Preußel, K; Milde-Busch, A; Schmich, P; Stark, K; Werber, D (2015). Risk factors for sporadic non-pregnacy associated listeriosis in

Germany – Immunocompromised patiens and frequently consumed ready-to-eat products. PLoS One 10(11).

Quinlan, JJ (2013). Foodborne Illness Incidence Rates and Food Safety Risks for Populations of Low Socioeconomic Status and Minority Race/Ethnicity: A Review of the Literature. International Journal of Environmental Research and Public Health 10 (8), 3634-3652.

Racicot, M; Zanabria, R; Paradis, M; Gaucher, M; Arsenault, J; Leroux, A; Letellier, A; Tiwari, A; Griffiths, M; Charlebois, S; Holley, R; Gill, T; Quessy, S (2019). Identification of risk factors to be considered for food establishments' risk assessment models. Microbial Risk Analysis 11, 1–10.

Redmond EC, Griffith CJ (2003) Consumer food handling in the home: a review of food safety studies. J Food Prot 66: 130-161.

Regulation (EC) No. 178/2002, 31th January, of the European Parliament and Council, lawing down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Regulation No. 852/2004, 29th April 2004, of the European Parliament and Council on the hygiene of foodstuffs.

Regulation (EC) No 853/2004, 29th April 2004, of the European Parliament and Council, laying down specific hygiene rules for food of animal origin.

Regulation (EC) No 854/2004, 29th April 2004, of the European Parliament and Council, laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Regulation (EC) No. 882/2004, 29th April, of the European Parliament and Council, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

Regulation No. 2073/2005, 15 November, of the European Parliament and Council, on microbiological criteria for foodstuffs and subsequent amendments.

Regulation (EU) No 1441/2007, 5th December, of the European Parliament and Council, on microbiological criteria for foodstuffs.

Regulation (EC) No. 1169/2011. The European Parliament and the Council of 25th.

Rebouças, LT; Santiago, LB; Martins, LS; Menezes, ACR; Araújo, MPN; Almeida, RCC (2017). Food safety knowledge and pratices of food handlers, head chefs and managers in hotels' restaurants of Salvador, Bahia. Food Control 73, 372-381.

Ridderstaat, J; Okumus, B (2019). Hidden restaurante sanitation inspection results: A weekday and monthly examination of reported data. International Journal of Hospitality Management 79, 110–122.

Rodríguez, M; Valero, A; Posada-Izquierdo, GD; Carrasco, E; Zurera, G (2011). Evaluation of Food handler practives and microbiological status of ready-to-eat foods in long-term facilities in the Andalusia region of Spain. Food Protection 74(9), 1504–1512.

Röhr, A; Lüddecke, K; Drusch, S; Müller, MJ; Alvensleben. RV (2005). Food quality and safety – consumer perception and public health concern. Food Control 16, 649-655.

Royo-Bordonada, M & Román-Maestre, B (2015). Towards public health ethics. Public Health Reviews 36:3.

Rubab, M; Shahbaz, HM; Olaimat, AN; Oh, DH (2018). Biosensors for rapid and sensitive detection of Staphylococcus aureus in food. Biosensors and Bioelectronics 105, 49–57.

Saeedi, P; Yazdanparast, M; Behzadi, E; Salmanian, AH; Mousavi, SL; Nazarian, S; Amani, J (2017). A review on strategies for decreasing E. coli O157:H7 risk in animals. Microbial Pathogenesis 103, 186-195.

Santana, NG; Almeida, RCC; Ferreira, JS; Almeida, PF (2009). Microbiological quality and safety of meals served to children and adoption of good manufacturing practices in public school catering Brazil. Food Control 20, 255-261.

Santos MC (2005). Segurança alimentar Porto/EURO 2004. Universidade Técnica de Lisboa, Lisboa.

Santos, MI; Correia, C; Campos Cunha MI, et al. (2005). Valores Guia para avaliação da qualidade microbiológica de alimentos prontos a comer preparados em estabelecimentos de restauração. Revista da Ordem dos Farmacêuticos 64, 66-8

Scallan, E; Griffin, PM Angulo, FJ; Tauxe, RV; Hoekstra, RM. (2011). Foodborne illness acquire in the United States – unspecified agents. Emerg. Infect. Dis. 17, 16-22.

Schothorst, M; Zwietering, MH; Ross, T; Buchanan, RL; Cole, MB; International Commission on Microbiological Specifications for Foods (2009). Relating microbiological criteria to food safety objectives and performance objectives. Food Control 20, 967-979.

Scott, E (2003). Food safety and foodborne diseases in 21th century homes. Canadian Journal of Infectious Disease and Medical Microbiology, 14(5), 277-280.

Sibanyoni, JJ & Tabit, FT (2019). An assessment of the hygiene status and incidence of foodborne pathogens on food contact surfaces in the food preparation facilities of schools. Food Control 98, 94-99.

Silva, FVM; Gibbs, PA (2012). Thermal pasteurization requirements for the inactivation of Salmonella in foods. Food Research International 45, 695–699.

Sheth, M; Gupta, A; Ambegaonkar, T (2011). Handlers' hygiene practices in small restaurants of Vadodara. Nutrition & Food Science 41(6), 386-392.

Smith, TJ; Hill, KK; Raphael, BH (2015). Historical and current perspectives on Clostridium botulinum diversity. Research in Microbiology 166, 290-302.

Soares, LS; Almeida, RCC; Cerqueira, ES; Carvalho, JS & Nunes, IL (2012). Knowledge, attitudes and practices in food safety and the presence of coagulase-positive staphylococci on hands of food handlers in the school of Camacari, Brazil. Food Control 27, 206-213.

Soares, K; Garcia-Diez, J; Esteves, A; Oliveira, I; Saraiva, C (2013). Evaluation of food safety training on hygienic conditions in food establishments. Food Control 34 (2), 613-618.

Soon, JM & Baines, RN (2012). Food safety training and evaluation of hand washing intention among fresh produce farm workers. Food Control 23, 437-448.

Soriano, JM; Blesa, J; Rico, H; Moltó, JC; Mañes, J (2002a). Incidence of staphylococcus aureus in meal from cafeterias. Journal of Food Safety 22, 135-140.

Soriano, JM; Font, G; Moltó, JC; Mañes, J (2002b). Enterotoxigenic staphylococci and their toxins in restaurant foods. Trends in Food Science & Technology 13, 60-67.

Soriano, JM; Rico, H; Mólto, JC; Mañes, J (2002c). Effect of introduction of HACCP on the microbiological quality of some restaurant meals. Food Control 13, 253–261.

Sospedra, I; Mañes, J; Soriano, JM (2012). Report of toxic shock syndrome toxin 1 (TSST-1) from Staphylococcus aureus isolated in food handlers and surfaces from foodservice establishments. Ecotoxicology and Environmental Safety 80, 288-290.

Sospedra, I; Rubert, J; Soriano, JM & Mañes, J(2012). Incidence of microorganisms from fresh orange juice processed by squeezing machines. Food Control 23, 282-285.

Sospedra, I; Rubert, J; Soriano, JM & Mañes, J (2013). Survey of microbial quality of plant-based foods served in restaurants. Food Control 30, 418-422.

Sousa, CP (2008). The impact of food manufacturing practices on foodborne diseases. Brazilian Archives of Biology and Technology, 51(4), 815- 823.

Sperber, WH (1998). Auditing and verification of food safety and HACCP. Food Control, Vol. 9. No. 2-3, 157-162.

Sarter G, Sarter S (2012) Promoting a culture of food safety to improve hygiene in small restaurants in Madagascar. Food Control 25: 165-171.

Stringer, M (2005). Food safety objectives—role in microbiological food safety management. Food Control 16, 775–794.

Sun, Y. & Ockerman, HW. (2005). A review of the needs and current applications of hazards analysis and critical control point (HACCP) system in foodservice areas. Food Control 16, 352-332.

Szabo, EA; Porter, WR; Sahlin, CL (2008). Outcome based regulations and innovative food processes: an Australian perspective. Innovative Food Science and Emerging Technologies 9(2), 249-254

Taylor, SL (2017). Foodborne Diseases. Chapter 1 – Diseases Processes in foodborne illness.

Tewari, A & Abdullah, S (2015). Bacillus cereusfood poisoning: internationaland Indian perspective. Journal of Food Science and Technology 52(5):2500–2511.

Toropilová, J & Bystrický, P (2015). Why HACCP might sometimes become weak or even fail. Procedia Food Science 5, 296 – 299.

Tood, EC; Greig, JD; Bartleson, CA; Michaels, BS (2007). Outbreaks where food workers have been implacted in the spread of foodborne disease. Food Prot. 70(8,), 1975-93.

Trafiałek, J; Lehrke, M; Lücke, F; Kołozyn-Krajewska, D; Janssen, J (2015). HACCP-based procedures in Germany and Poland. Food Control 55, 66-74.

Tsola, E; Drosinos, EH & Zoiopoulos, P (2008). Impact of poultry slaughter house modernisation and updating of food safety management systems on the microbiological quality and safety of products. Food Control, 19, 423-431.

Valero, A; Ortiz, JC; Fongaro, G; Hernández, M; Rodríguez-Lázaro, D (2017). Definition of sampling procedures for collective-eating establishments based on the distribution of environmental microbiological contamination on food handlers, utensils and surfaces. Food Control 77, 8-16.

Veiros, MB; Proença, RPC; Santos, MCT; Rocha, A; Kent-Smith, L (2007). Proposta de check-list hígio-sanitária para unidades de restauração. Alimentação Humana, 13 (3), 51-61.

Veiros, MB; Proença, RPC; Santos, MCT; Kent-Smith, L; Rocha, A (2009). Food safety pratices in a Portuguese canteen. Food Control 20, 936-941.

Vila, J; Sáez-López, E; Johnson, JR; Römling, U; Dobrindt, U; Cantón, R; Giske, CG; Naas, T; Carattoli, A; Martínez-Medina, M; Bosch, J; Retamar, P; Rodríguez-Baño, J; Baquero, F; Soto, SM (2016). Escherichia coli: an old friend with new tidings. FEMS Microbiology Reviews 40, 437–463.

Vos, E (2000). EU food safety regulation in the aftermath of the BSE crisis. Journal of Consumer Policy 23(3), 227-255. Wagstaff, DJ. (1986) Public Health and Food Safety: a Historical Association. Public Health Reports, vol. 101, nº6, 624-631.

Walker, E & Jones, N (2002). An assessment of the value of documenting food safety in small and less developed catering businesses. Food Control 13, 307-314.

Walker, E; Pritchard, C; Forsythe, S (2003). Food handlers' hygiene knowledge in small food business. Food Control 14, 339-343.

Wallace, CA; Holyoak, L; Powel, SC; Dykes, FC (2012). Re-thinking the HACCP team: An investigation into HACCP team knowledge and decision-making for successful HACCP development. Food Control 47, 236-245.

Wallace, CA; Holyoak, L; Powel, SC; Dykes, FC (2014). HACCP - The difficulty with Hazard Analysis. Food Control 35, 233-240.

Wallace, C & Williams, T (2001). Pre-requisites: a help or a hindrance to HACCP?. Food Control 12, 235-240.

Will M & Guenther, D (2007). Food Quality and Safety Standards as required by EU Lawand the Private Industry with special Reference to MEDA Countries‘ Exports of Fresh and Processed Fruits and Vegetables, Herbs and Spices: A Practitioners‘ Reference Book. (2nd ed.) GTZ – Division 45.

Wilhelm, B; Rajic, A; Greig, J; Waddell, L; Harris, J (2011). The effect of Hazard Analysis Critical Control Point Programs on microbial contamination of carcasses in abattoirs: a systematic review of published data. Foodborne Pathogens and Disease 8, 949-960.

WHO, World Health Organization (2012). European Action Plan for Strengthening Public Health Services. (Available at: http://www.euro.who.int/__data/assets/pdf_file/0005/171770/RC62wd12rev1-Eng.pdf. Retrieved February 19, 2018).

WHO, 2015. WHO Estimates of the Global Burden of Foodborne Diseases (Available at: http://apps.who.int/iris/bitstream/10665/199350/1/9789241565165_eng.pdf?ua¼1/ Retrieved February 21, 2018).

WHO (2018). Food Safety – Data and Statistics. (Available at: http://www.euro.who.int/en/health-topics/disease-prevention/food-safety/data-and-statistics. Retrieved February 19, 2018).

WHO (2019). WHO strategic plan for food safety 2013-2022. (Available at: https://www.who.int/news-room/fact-sheets/detail/food-safety. Retrieved June 10, 2019).

Worsfold, D; Griffith, C (1997). Assessment of the Standard of Consumer Food Safety Behavior. Food Protection 60 (4), 399-406.

Wu, Y; Liu, P; Chen, J (2018). Food safety risk assessment in China: Past, present and future. Food Control 90, 212-221.

Yang, Y; Wei, J; Pei, J (2019). Application of meta-analysis technique to assess effectiveness of HACCP based FSM systems in Chinese SLDBs. Food Control 96, 291–298.

Young, I & Waddell (2016). Barriers and facilitators to safe food handling among consumers: a systematic review and thematic synthesis of qualitative research studies. PloS One 11 (12), e0167695.

Zanin, LM; Cunha, DT; Rosso, VV; Capriles, VD; Stedefeldt, E (2017). Knowledge, attitudes and practices of Food handlers in Food Safety: An integrative review. Food Research International 100, 53-62.

Zoonosis Center (2015). Food poisonings. Finnish Food Safety Authority Evira and National Institution for Welfare and Health

Accessed 07.04.18 http://www.zoonoosikeskus.fi/portal/fi/ruokamyrkytykset.

APPENDIXES

APPENDIX 1. FOOD SAFETY AUDIT CHECKLIST

FoodSimplex

Food Safety Audit Checklist

Restaurant: ______________________________ Address: ______________________ Telf. __________ Audit nº ___/_____ date: __/__/__ time: __:__ C: _____ NC:_____	**HACCP technician**

Section A. Reception

Ref.	Checkpoints	C	NC	NA
1.	Products inspection			
2.	Conditions of the products			
3.	Hygiene of the facilities and equipment			

Section B. Room Temperature Storage

Ref.	Checkpoints	C	NC	NA
1.	Separation of food and non-food products			
2.	Organized Stock (FIFO / FEFO)			
3.	Earth products			
4.	Labeling / Products identification			
5.	Non-according products and materials			
6.	Hygiene of the facilities and equipment			

Section C. Cold Storage

Ref.	Checkpoints	C	NC	NA
1.	Defrosting conditions			
2.	Organized Stock (FIFO / FEFO)			
3.	Freezing Procedure			
4.	Labeling / Products identification			
5.	Packaging			
6.	Non-according products and materials			
7.	Hygiene of the facilities and equipment			
8.	Temperatures			
9.	Refreezing conditions			

Section D. Preparation

Ref.	Checkpoints	C	NC	NA
1.	Preparation conditions			
2.	Correct handling of prepared foods			
3.	Proper disinfection of food to consume in raw			
4.	[illegible]			

Section E. Cooking

Ref.	Checkpoints	C	NC	NA
1.	Handling cooked food			
2.	Absence of food at room temperature			
3.	Presence of leftovers and scraps			
4.	Frying oils conditions			
5.	Sampling			
6.	Eve cooking			
7.	Hygiene of the facilities and equipment			

Section F. Serving				
Ref.	**Checkpoints**	**C**	**NC**	**NA**
1.	Food exposure conditions			
2.	Exposure temperature			
3.	Plating procedure			
4.	Existence of non-compliant products			
5.	Hygiene of the facilities and equipment			

Section G. Personal Hygiene				
Ref.	**Checkpoints**	**C**	**NC**	**NA**
1.	Uniforms			
2.	Gloves			
3.	Evidence of adornments and/or lack of personal hygiene			
4.	Visible diseases			

Section H. General Sanitation				
Ref.	**Checkpoints**	**C**	**NC**	**NA**
1.	Dressing rooms			
2.	Soap and disinfectant dispensers and towel rails			
3.	Manual washbasin with hot and cold water			
4.	First aid kit			
5.	Cloths			
6.	Obsolete material and equipment			
7.	Use/conditions of non-food products			
8.	Sanitary plan compliance			

Section I. Cleaning & Disinfection				
Ref.	**Checkpoints**	**C**	**NC**	**NA**
1.	Dishwashing conditions			
2.	Operational dishwasher equipment			
3.	Waste containers			
4.	Pest Control			
5.	Waste Treatment			
6.	Chemical Products Storage			

Section J. HACCP records				
Ref.	**Checkpoints**	**C**	**NC**	**NA**
1.	Records			
2.	Folder organization			

Section L. HACCP Documentation				
Ref.	**Checkpoints**	**C**	**NC**	**NA**
1.	Sanitation Plan			
2.	Safety Data Sheets			
3.	HACCP Plan			
4.	Work Instructions			
5.	Packaging			
6.	Good Manifacturing Practice Code			
7.	Pest Control			
8.	Health Datasheets			
9.	Suppliers Evaluation			
10.	Maintenance Plan			
11.	Traceability			

Section M. Facilities				
Ref.	**Checkpoints**	**C**	**NC**	**NA**
1.	General conditions			
2.	Suitability			
3.	Drinking Water			
4.	Gas and electricity			
5.	March in Front			

Legend: C – compliance; NC – non-compliance; NA – not applicable

Observations

APPENDIX 2. AUDIT RESULTS

Table 1. Percentage of hygiene compliances in the audit moments

	Compliance percentage (%)				p-value
Items	**Aud. 1**	**Aud. 2**	**Aud. 3**	**Aud. 4**	
Reception - Hygiene of the facilities and equipment	91,3	100,0	87,0	100,0	0,475
Room Temperature Storage - Hygiene of the facilities and equipment	52,2	62,5	58,3	83,3	0,085
Cold Storage - Hygiene of the facilities and equipment	20,8	25,0	8,3	4,2	0,112
Preparation - Hygiene of the facilities, equipment and utensils	60,9	58,3	50,0	82,6	0,088
Cooking - Hygiene of the facilities, equipment and utensils	45,8	39,1	54,2	65,2	0,157
Serving - Hygiene of the facilities, equipment and utensils	81,0	95,7	78,3	83,3	0,249
Personal Hygiene - Uniforms	73,9	47,6	65,2	75,0	0,028
Personal Hygiene – Gloves	80,0	83,3	90,0	100,0	a)
Personal Hygiene – Evidence of adornments and/or lack of personal hygiene	81,0	95,5	90,9	95,0	0,417
Personal Hygiene – Visible diseases	100,0	100,0	100,0	100,0	0,468
General Sanitation - Dressing rooms	33,3	47,8	56,5	77,3	0,013
General Sanitation - Soap and disinfectant dispensers and towel rails	52,2	58,3	54,2	78,3	0,210
General Sanitation - Manual washbasin with hot and cold water	38,5	26,1	27,3	28,6	0,981
General Sanitation - First aid kit	55,0	38,9	57,9	47,4	0,585
General Sanitation – Cloths	60,9	78,3	70,8	75,0	0,487
General Sanitation – Obsolete material and equipment	70,8	73,9	63,6	79,2	0,474
General Sanitation – Use/conditions of non-food products	95,8	95,7	77,3	94,7	0,042
General Sanitation – Sanitary plan compliance	80,0	83,3	83,3	100,0	a)
Cleaning & Disinfection - Dishwashing conditions	41,7	20,8	25,0	54,5	0,046

Items	Compliance percentage (%)				p-value
	Aud. 1	Aud. 2	Aud. 3	Aud. 4	
Cleaning & Disinfection - Operational dishwasher equipment	95,8	95,7	95,8	95,8	0,801
Cleaning & Disinfection - Waste containers	17,4	25,0	25,0	36,4	0,420
Cleaning & Disinfection – Pest Control	59,1	57,1	42,9	57,1	0,392
Cleaning & Disinfection - Waste Treatment	83,3	90,5	85,0	95,2	0,595
Cleaning & Disinfection – Chemical Products Storage	54,2	69,6	45,5	73,9	0,093
Facilities - General conditions	45,8	62,5	58,3	58,3	0,440
Facilities - Suitability	100,0	83,3	79,2	91,7	0,069
Facilities - Drinking Water	100,0	100,0	100,0	100,0	0,392
Facilities - Gas and electricity	100,0	100,0	100,0	100,0	1,000
Facilities - March in Front	75,0	83,3	66,7	100,0	0,004
Total - Hygiene assessment	66,0	66,9	63,8	76,1	0,004

a) not a reliable number of observations in audit

Table 2. Percentage of Good Manifacture Practices compliances in the audit moments

Items	Compliance percentage (%)				p-value
	Aud. 1	Aud. 2	Aud. 3	Aud. 4	
Reception - Products inspection	33,3	46,2	40,0	58,3	0,968
Reception - Conditions of the products	95,7	100,0	95,8	100,0	0,572
Room Temperature Storage - Separation of food and non-food products	65,2	75,0	75,0	83,3	0,433
Room Temperature Storage - Organized Stock (FIFO / FEFO)	65,2	87,5	73,9	70,8	0,233
Room Temperature Storage – Earth products	100,0	100,0	95,5	95,7	0,051
Room Temperature Storage - Labeling / Products identification	16,7	13,0	13,0	17,4	0,945
Room Temperature Storage - Non-according products and materials	53,3	73,9	83,3	83,3	0,001
Cold Storage - Defrosting conditions	80,0	77,8	71,4	90,9	0,015
Cold Storage - Organized Stock (FIFO / FEFO)	75,0	75,0	75,0	70,8	0,972
Cold Storage - Freezing Procedure	47,8	41,7	54,2	60,9	0,528
Cold Storage - Labeling / Products identification	16,7	8,3	8,3	17,4	0,659
Cold Storage - Packaging	25,0	29,2	54,2	43,5	0,131
Cold Storage - Non-according products and materials	76,9	85,7	77,3	87,5	0,009
Cold Storage - Temperatures	75,0	81,8	76,2	100,0	0,043
Cold Storage - Refreezing conditions	90,5	91,3	95,8	100,0	0,086
Preparation - Preparation conditions	93,8	85,7	93,8	100,0	0,097
Preparation - Correct handling of prepared foods	100,0	77,8	100,0	100,0	0,026

Items	Compliance percentage (%)				p-value
	Aud. 1	Aud. 2	Aud. 3	Aud. 4	
Preparation - Proper disinfection of food to consume in raw	61,1	61,9	52,4	84,6	0,887
Cooking - Handling cooked food	80,0	50,0	80,0	100,0	a)
Cooking - Absence of food at room temperature	61,9	45,5	63,6	72,7	0,366
Cooking - Presence of leftovers and scraps	87,5	94,4	94,4	94,1	0,651
Cooking - Frying oils conditions	57,9	78,9	75,0	69,6	0,134
Cooking - Sampling	100,0	100,0	100,0	100,0	a)
Cooking - Eve cooking	68,4	85,0	83,3	81,8	0,100
Serving - Food exposure conditions	72,7	90,5	69,6	72,7	0,534
Serving - Exposure temperature	88,2	90,0	70,6	88,2	0,245
Serving - Plating procedure	100,0	100,0	100,0	100,0	a)
Serving - Existence of non-compliant products	91,7	100,0	100,0	94,7	0,001
Total GMP assessment	65,5	70,2	70,5	77,5	0,012

a) not a reliable number of observations in audit

Table 3. Percentage of HACCP Documentation compliances in the audit moments

Itens	Compliance percentage (%)				p-value
	Aud. 1	Aud. 2	Aud. 3	Aud. 4	
HACCP records - Records	60,9	52,2	70,8	91,7	0,002
HACCP records - Folder organization	87,5	91,7	95,8	100,0	0,290
HACCP Documentation - Sanitation Plan	57,1	50,0	45,5	77,3	0,112
HACCP Documentation - Safety Data Sheets	63,6	60,9	61,9	72,7	0,580
HACCP Documentation - HACCP Plan	95,7	100,0	100,0	100,0	0,112
HACCP Documentation - Work Instructions	100,0	66,7	100,0	100,0	a)
HACCP Documentation - Good Manifacturing Practice Code	100,0	95,8	100,0	100,0	0,572
HACCP Documentation - Signage	100,0	100,0	100,0	100,0	0,300
HACCP Documentation - Pest Control	61,9	63,6	57,1	65,2	0,623
HACCP Documentation - Health Datasheets	81,3	76,5	73,9	87,5	0,520
HACCP Documentation - Evaluation Suppliers	33,3	13,0	4,3	13,65	0,106
HACCP Documentation - Maintenance Plan	50,0	10,5	9,1	43,5	0,004
HACCP Documentation - Traceability	100,0	0,0	0,0	0,0	a)
Total HACCP Documentation	72,2	66,1	66,7	79,1	0,000

a) not a reliable number of observations in audit

APPENDIX 3. MICROBIAL ANALYSIS RESULTS

Table 1. Percentage of conformities regarding hygiene of handlers and surfaces in the initial and final evaluation (Unsatisfactory (US), Acceptable (A), Satisfactory (S))

Analyses object	**Nº sample**	**Parameters**	**First evaluation (%)**			**Final evaluation (&)**			**p-value**
			US	**A**	**S**	**US**	**A**	**S**	
Food handlers	23	*Microorganisms 30º*	23,5	32,4	44,1	0,0	10,0	90,0	0,003
Surfaces	36		24,1	13,0	63,0	14,9	17,0	68,1	0,585

Table 2. Percentage of conformities related to the initial and final microbiological analyzes for Food Group 1 (Unsatisfactory (US), Acceptable (A), Satisfactory (S))

Analyses	**Nº sample**	**First evaluation (%)**			**Final evaluation (%)**			**p-value**
		US	**A**	**S**	**US**	**A**	**S**	
Microorganisms 30º	19	5,3	26,3	68,4	5,3	15,8	78,9	0,527
Listeria monocytogenes	19	0,0	5,3	94,7	0,0	5,3	94,7	1,000
E. coli	19	0,0	0,0	100,0	0,0	0,0	100,0	1,000
Staphylococcus coagulase positiva	19	0,0	0,0	100,0	0,0	0,0	100,0	1,000
Salmonella spp	19	0,0	0,0	100,0	0,0	0,0	100,0	1,000

Table 3. Percentage of conformities for the initial and final microbiological analyzes for Food Group 2 (Unsatisfactory (US), Acceptable (A), Satisfactory (S))

Analyses	Nº sample	First evaluation (%)			Final evaluation (%)			p-value
		US	A	S	US	A	S	
Microorganisms 30º	9	0,0	22,2	77,8	0,0	0,0	100,0	0,157
Listeria monocytogenes	9	0,0	0,0	100,0	0,0	0,0	100,0	1,000
E. coli	9	0,0	0,0	100,0	0,0	0,0	100,0	1,000
Staphylococcus coagulase positiva	9	0,0	0,0	100,0	0,0	0,0	100,0	1,000
Salmonella spp	9	0,0	0,0	100,0	0,0	0,0	100,0	1,000

Table 4. Percentage of conformities for the initial and final microbiological analyzes for Food Group 3 (Unsatisfactory (US), Acceptable (A), Satisfactory (S))

Analyses	Nº sample	First evaluation (%)			Final evaluation (%)			p-value
		US	A	S	US	A	S	
Microorganisms 30º	6	16,7	66,7	16,7	0,0	16,7	83,3	0,025
Listeria monocytogenes	6	16,7	16,7	66,7	0,0	0,0	100,0	0,180
E. coli	6	0,0	0,0	100,0	0,0	0,0	100,0	1,000
Staphylococcus coagulase positiva	6	0,0	0,0	100,0	0,0	0,0	100,0	1,000
Salmonella spp	6	0,0	0,0	100,0	0,0	0,0	100,0	1,000

Table 5. Percentage of conformities for the initial and final microbiological analyzes for Food Groups 1, 2 and 3 (Unsatisfactory (US), Acceptable (A), Satisfactory (S))

Analyses	Nº sample	First evaluation (%)			Final evaluation (%)			p-value
		US	A	S	US	A	S	
Microorganisms 30º	34	5,9	32,4	61,8	2,9	11,8	85,3	0,029
Listeria monocytogenes	34	2,9	2,9	91,2	0,0	2,9	97,1	0,180
E. coli	34	0,0	0,0	100,0	0,0	0,0	100,0	1,000
Staphylococcus coagulase positiva	34	0,0	0,0	100,0	0,0	0,0	100,0	1,000
Salmonella spp	34	0,0	0,0	100,0	0,0	0,0	100,0	1,000