University of Kassel

Faculty of Organic Agricultural Sciences

Dissertation for the acquisition of the academic degree Doktor der Agrarwissenschaften (Dr. agr.) of the University of Kassel

PhD Thesis

HACCP in Germany and Lebanon

First Examiner: Prof. Dr. Angelika Ploeger

Section of Organic Food Quality and Food Culture

Second Examiner: Prof. Dr. Johann Janssen

Faculty of Nutritional, Food and Consumer Sciences

Submitted by: Karine Haddad

Tag der mündlichen Prüfung: 11.01.2018

Acknowledgements

Firstly, I would like to express my sincere gratitude to my advisor Prof. Dr. Johann Janssen for the continuous support of my PhD study and related research, for his patience, motivation, and immense knowledge. His guidance helped me in all the time of research and writing of this thesis. I could not have imagined having a better advisor and mentor for my study.

My sincere thanks also goes to Prof. Dr. Angelika Ploeger, who provided me with an opportunity to join her team, and who gave access to resources and research facilities. Without her precious support it would not have been possible to conduct this research.

I thank Dr. Joanne Taylor for the mentorship and continuous advice on the details of the study. Also on the internship opportunities offered in Qatar in 2014.

Last but not least, I would like to thank my family: my sister, my aunt, and my fiancée for supporting me spiritually, mentally and financially throughout writing this PhD thesis. I would like to thank God because he is the beginning and the end of all the work in my life.

Abstract

Food borne outbreaks have been on the rise in Lebanon and in Germany in recent years. Food safety systems have been developed over a period of years starting from HACCP which was established in the 1950's unto the European directive 93/43/EEC established in 1993, to directive (EC) No 178/2002 until today in order to prevent and control hazards in the different food safety fields. Such systems which started with HACCP (hazard analysis and critical control point) and was later integrated into private systems such as ISO 22000:2005 and then into regulations such as (EC) No 852/2004 and others. In spite of the emergence of these systems, foodborne illnesses continue to occur. This study investigates the application of HACCP based systems in selected food industries and through certain consultants, auditors and inspectors in Germany and Lebanon in light of the continuous food borne outbreaks.

The study addresses the positive and negative factors influencing the application of HACCP among food experts. The methods used are inductive qualitative methods. They comprise of primary outbreak analysis in the world, standards and regulation comparison, leading to thorough qualitative interviews in both countries inquiring the understanding and perception of HACCP principles with food safety experts. Food experts were chosen from different fields such as quality control managers, plant managers, raw material suppliers, university professors, consultants, auditors and government inspectors in Lebanon and Germany. The questions focused on the knowledge and the understanding that the experts had on Codex (2003) and the other systems and regulations.

The results show that the application of HACCP in those areas was not always implemented according to the Codex standard in all the HACCP steps. The areas mostly affected were: flow diagrams, hazard analysis, critical control points and validation. The roles of the HACCP team, consultants, auditors and governmental inspectors were investigated as well and revealed to have a huge influence on the common trends and misinterpretations found.

Overall, there was no country difference in terms of understanding and perception but the dynamics differed depending on the role of the government and advising experts in each country. A risk-based approach is not always used in food safety systems, rather the approach is influenced by what the consultants or the auditors request. Not all governmental bodies were up to date with all recent standards of food safety and guidelines, much like consultants and auditors had interpretations based on personal understanding of HACCP. Harmonization among

standards, regulations and trainings is a step that is needed towards solving the paradox of the rise of food borne illnesses and the increasing amount of standards.

I. Table of Contents

II. List of Abbreviations

2D – Two Dimensional

ASEAN – Association of South East Asian Nations

AUB – American University of Beirut

BfR – Bundesinstitut für Risikobewertung

BIOHAZ – Biological Hazard

BRC – British Retail Consortium

CAC – Codex Alimentarius Commission

CCP – Critical Control Point

CDC – Centers for Disease Control and Prevention

CFR – Code for Federal Regulation

CIA – Consultant/Inspector Auditor

CIP – Cleaning in Place

COA – Certificate of Analysis

CP – Control Point

DIN – Deutsches Institut für Normung / German Institute for Standardization

EC – European Commission

E.coli – Escherichia coli

EFSA – European Food Safety Authority

EHEC – Enterohaemorrhagic E. coli

EU – European Union

FAO – Food and Agriculture Organization of the United Nations

FC – Flow diagram

FDA – Food and Drug Administration

FMEA – Failure Mode and Effects Analysis

FSA – Food Safety Authority

FSAI – The Food Safety Authority of Ireland

FSH – First Step HACCP

FSIS – Food Safety and Inspection Service in the United States

FSKN – Food Safety Knowledge Network

FSMS – Food Safety Management System

FSSC – Food Safety System Certification

GFSI – Global Food Safety Initiative

GHP – Good Hygienic Practices

GL – Guideline

GMO – Genetically Modified Organisms

GMP – Good Manufacturing Practices

GPFH – General Principles of Food Hygiene

GVH – GMP versus HACCP

H1N1 – Influenza A Virus Subtype (Swine Flu)

H5N1 – Influenza A Virus Subtype (Avian Flu)

H7N9 – Avian Influenza A Virus (Avian Flu)

HA – Hazard Analysis

HACCP – Hazard Analysis and Critical Control Point

HPAI – Highly Pathogenic Asian Influenza

HPLC – High Performance Liquid Chromatography

HR – Human Resources

HS – HACCP Safer

HT – HACCP Team

IFIS – International Food Information System

IAFP – International Association for Food Protection

IFS – International Featured Standard

IFSQN – International Food Safety and Quality Network

ILSI – International Life Sciences Institute

IRI – Industrial Research Institute

IS – Information System

ISO – International Organization for Standardization

IT – Information technology

JECFA – Joint Expert Committee on Food Additives

LFGB – Lebensmittel und Futtermittelgesetzbuch

LMHV – Lebensmittelhygiene-Verordnung

MOPH – Ministry of Public Health

MS – Many Systems

NASA – National Aeronautics and Space Administration

No – Number

OIE – Office International des Epizooties, known today as World Organization for Animal Health

OPRP – Operational Pre-Requisite Program

PRP – Prerequisite Program

QA – Quality Assurance

QC – Quality Control

QUALEB – Quality Lebanon

R&D – Research and Development

RASFF – Rapid Alert System for Food and Feed

RCP – Code of Practice

RDM – Raw Drinking Milk

RKI – Robert Koch Institute

RM – Raw Material

SC – Scope of System

SLDB – Small and/or Less Developed Business

SME – Small and Medium-Sized Enterprise

SOP – Standard Operating Procedure

SS – Successful System

SU – System Update

TQM – Total Quality Management

UHT – Ultra High Treatment

UK – United Kingdom

UNDC – United Nations Office on Drugs

UNIDO – United Nations Industrial Development Organization

US – Updated System

USA – United States of America

USDA – U.S. Department of Agriculture

V – Validation

WHO – World Health Organization

WIP – Work in Process

WTO – World Trade Organization

III. List of Figures and Tables

IV. List of Definitions

Definitions taken from Codex Alimentarius 2003

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

Food safety: Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Primary production: Those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing.

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

Critical control point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit: A criterion which separates acceptability from unacceptability.

Deviation: Failure to meet a critical limit.

Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Validation: Obtaining evidence that the elements of the HACCP plan are effective.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

Definitions taken from ISO 22000:2005 of words not defined in Codex Alimentarius

The following terminologies defined by ISO 22000:2005 will be used in all the parts of the thesis instead of the Codex, or EC terminologies. The only exception will be when writing from publications, then the terms will stay as the publications have used them.

Hazard analysis: Divided into hazard identification, hazard assessment and selection and assessment of control measures.

Hazard Identification: All food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities shall be identified and recorded. The identification shall be based on

a) The preliminary information and data collected according to 7.3,

b) Experience,

c) External information including, to the extent possible, epidemiological and other historical data, and

d) Information from the food chain on food safety hazards that may be of relevance for the safety of the end products, intermediate products and the food at consumption.

The step(s) (from raw materials, processing and distribution) at which each food safety hazard may be introduced shall be indicated.

Hazard Assessment: A hazard assessment shall be conducted to determine, for each food safety hazard identified (see 7.4.2), whether its elimination or reduction to acceptable levels is essential to the production of a safe food, and whether its control is needed to enable the defined acceptable levels to be met. Each food safety hazard shall be evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence. The methodology used shall be described, and the results of the food safety hazard assessment shall be recorded.

Selection and assessment of control measures: Based on the hazard assessment of 7.4.3, an appropriate combination of control measures shall be selected which is capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels.

In this selection, each of the control measures as described in 7.3.5.2 shall be reviewed with respect to its effectiveness against the identified food safety hazards.

The control measures selected shall be categorized as to whether they need to be managed through operational PRP(s) or by the HACCP plan.

Prerequisite programme: Basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain (3.2) suitable for the production, handling and provision of safe end products (3.5) and safe food for human consumption.

Operational PRP - operational prerequisite programme PRP: Identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards (3.3) to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment.

Correction: Action to eliminate a detected nonconformity.

Definitions taken from FAO/WHO 1995

Hazard identification: The identification of known or potential health effects associated with a particular agent.

Hazard characterization: The qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical, and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. Exposure assessment: the qualitative and/or quantitative evaluation of the degree of intake likely to occur.

Risk characterization: Integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attending uncertainties.

Definitions taken from (EC) No 178/2002

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

Risk analysis: A process consisting of three interconnected components: risk assessment, risk management and risk communication;

Risk assessment: A scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization;

Risk management: Means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

Risk communication: Means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

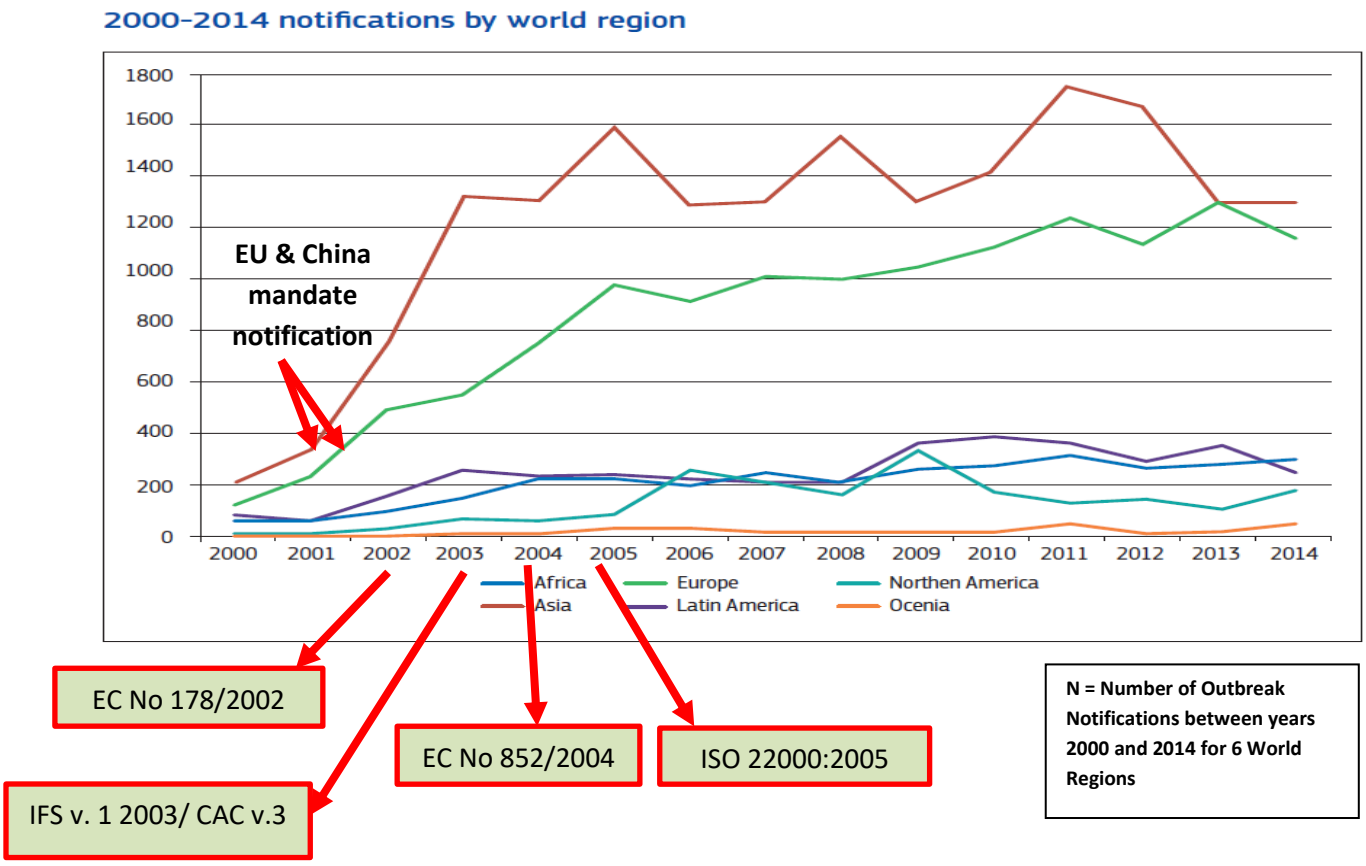
V. Introduction

Food safety systems play a primary role in the protection of consumers from food borne diseases. These systems are designed to be preventive systems that are risk based (Mortimore and Wallace, 2013). They comprise a tool to analyze every step along the supply chain, find the existing hazards, and control them in the most effective manner (Codex, 2003). Unsafe food causes many acute and life-long diseases, ranging from diarrheal diseases to various forms of cancer (WHO, 2012). WHO estimates that food borne and water-borne diarrheal diseases taken together kill about 2.2 million people annually, 1.9 million of them are children. International and European authorities have been putting immense weight on the subject of food safety every year (FAO, 1997). Be it, the EC (European Commission), or the WHO (World Health Organization) or the FAO (Food and Agriculture Organization) or FDA (Food and Drug Administration), all have established regulations and guidelines for food safety systems and deployed them locally to several countries. Their main goal is the management of risks associated with food by means of GMP (Good Hygienic Practices), and HACCP (Hazard Analysis and Critical Control Points) in order to protect public health.

Studies about HACCP were showing that the biggest challenge for companies is carrying out the first two steps of HACCP (Taylor, 2001). Identifying hazards and obtaining critical controls points were the first two principles in HACCP used for every HACCP based system such ISO 22000 (2005) and IFS (2012). However, companies have found different methods of implementing them in ways that often cause the limitations in HACCP (Mortimore and Wallace, 2013). Assessing the hazards and conducting risk assessments were considered as some of the main challenges for HACCP due to the limited data on populations and methodology (Buchanan and Whiting, 1998). Studies have shown links between the first two principles of HACCP and the occurrence of outbreaks (Edmunds et al, 2013).

In parallel, WHO has done an intensive job of collecting monitored food outbreaks in several countries and reporting them through the WHO surveillance program for control of food borne infections and intoxications showing and proving that outbreaks are still increasing. (Figure 1)

Outbreaks' Notifications by World Region



N1: 2000-2014 Outbreaks Notifications by World Region (RASFF, 2015).

Germany has been monitoring outbreaks since 1983 and Poland since 1990. It was only until 2001, that the countries mandated notifying these outbreaks by law (WHO, 2012). The statistics show that the number of outbreaks in Germany has dropped since then, from 160 cases in 1995 to 90 cases in 2000 (WHO, 2000). This came in line with the Food Hygiene Directive (EC) No 93/43 that was recommended to European countries in the year 1993 (Directive, E. C., 1993). However, since 2000 until today, and in spite of the introduction and increase of new food safety regulations like (EC) No 178/2002 and (EC) No 852/2004, and other international or private standard systems like ISO 22000, BRC, or IFS, food borne outbreaks have been increasing in line with the increased regulation spread and awareness (BfR, 2007, 2008, 2009; Figure 2). In Poland, a similar trend can be observed with a general higher number of outbreaks; 450 outbreaks in 1993, and 350 in year 2000. Between years 2001 to 2004, the ascension of Poland into the

European Union occurred and resulted in Poland's compliance to (EC) No 852/2004 whereby all food related sectors needed to implement HACCP (Trafiałek and Kołożyn-Krajewska, 2011; Baumann-Popczyk and Sadkowska-Todys, 2010). In spite of this ascension into the EU and adoption of EU regulations, food borne outbreaks kept increasing to date. (Figure 1) Lebanon does not have literature about a monitoring system for outbreaks. However, El-Jardali et al (2014) state that the ministry of Public Health reported that in 2010 there were 1926 cases of food and water borne illnesses. Moreover, continuous testing of different Lebanese food shows that the presence of pathogenic microorganisms such as E. coli, Salmonella and other bacteria exists in levels that surpass international standards. (Kassaify et al, 2010)

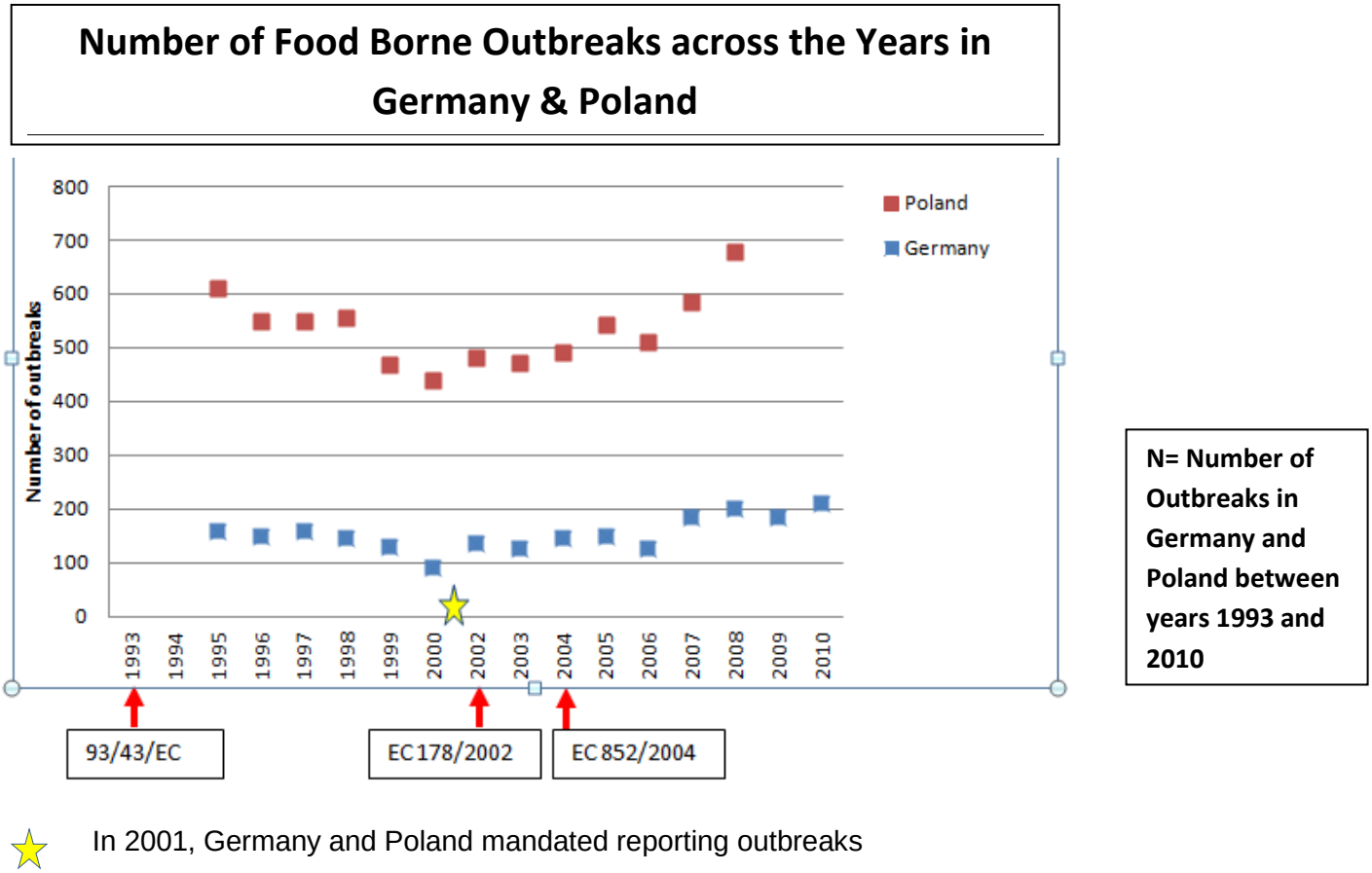


Figure 2: Number of Food-borne Outbreaks in Germany and Poland (WHO, 2000, RKI, 2011, Baumann-Popczyk and Sadkowska-Todys, 2010)

The gaps found in HACCP and the increase of outbreaks in spite of emerging food safety systems has led to the initiation of this study in order to understand which factors in HACCP are contributing to its success and failure. The primary focus was on specific methods needed in the first two principles of HACCP being hazard analysis and critical control point. Due to the initial literature reviews conducted, the focus would be on SME's (Small to Medium Enterprises) in Germany, Poland and Lebanon. The study was designed in this order:

1) Analyze existing outbreaks worldwide and monitor their link to HACCP

2) Conduct a thorough literature study on HACCP based systems and regulations and guidelines

3) Understand the specific challenges inside the HACCP steps from existing literature

4) Derive a questionnaire from the latter steps to conduct a qualitative research with HACCP certified food experts in the chain

5) Derive results and discuss the factors influencing HACCP success and failure

After the first three steps, the scope of the study was adjusted to include companies that are HACCP certified from all sizes not just SME's because the literature showed that the problem with HACCP is not only limited to SME's (Mayes and Mortimore, 2001). Outbreaks are also caused by big companies and affect a wider population when they occur.

Another change of scope occurred in the study during part 4 when the questionnaire was conducted in Poland by another trained researcher. Although the questions and the method were the same, the results were not scientifically comparable due to translation limitation (Squires, 2009). Therefore, the decision was to continue the study excluding the analysis of the results from Poland.

The methodology used for this study is an inductive approach and qualitative research. This is because the attempt is to understand reasons behind the pass or fail of the application of food safety systems (Flick, 2009). The hypothesis states that success and failure in HACCP is due to the factors affecting the application of hazard analysis and critical control steps or principles in food safety. The researcher interviewed different parties from the food sector such as company experts, consultants, auditors, and inspectors from the government. The research was conducted with a qualitative semi-structured questionnaire containing open and closed questions. The questions were with the aim of capturing the understanding of each expert about HACCP or the

HACCP based system they are using. After the interviews were transcribed, coded and categorized, the results reflected the perception of HACCP from the different parties. The results have yet increased the scope to more factors influencing HACCP such as flow diagrams and validation plans along with the first two principles of HACCP and the role of experts whether consultants or auditors or governmental inspectors. The discussion was able to compare the areas where most of the HACCP misunderstanding is taking place and the effect of the influence from the different roles of experts.

VI. Literature Review

A. Regulations and Standards

Regulations and standards greatly impact how companies implement food safety systems (Lee, 2006). All food businesses in Germany, Poland and Lebanon are required by law to implement Hazard Analysis and Critical Control Point, HACCP, or its principles in their food companies (EC 852/2004; Trafiałek et al., 2015; MOPH, 2011). However, many do that through private systems such as ISO 22000 (2005), FSSC 22000, Version 6 IFS Food (2012), or BRC. Other small to medium sized enterprises implement only the EC regulations or the national law (EC) No 852/2004 in Europe or LIBNOR standards in Lebanon, which are also HACCP based (Lücke and Trafiałek, 2010). The choice of the system itself depends on several factors. According to literature, those factors are influenced by customer demand, national law demand, trade needs, internal knowledge and abilities, and resources. (Lee, 2006)

This research focuses on the following regulations and standards:

- EC No 178/2002 lays down the general principles and requirements of food laws, establishes the European Food Safety Authority and details food safety procedures (EC, 2002). This regulation emphasizes that in order to achieve a high level of protection, food laws should be based on a risk analysis process comprising risk assessment, risk management, and risk communication among all food handlers and the governmental sectors. This regulation also sets up the EFSA (European Food Safety Authority) providing scientific support for the testing of the food and feed. The regulations give legal effect to RASFF (rapid alert system for food and feed).

- EC No 852/2004 was issued by the European Parliament and of the Council on 29/4/2004 to regulate the hygiene of foodstuffs (EC, 2004). It integrates the seven principles of HACCP, and requires that the regulation is used under national law. It excludes primary production for domestic use. It emphasizes that food safety is to be done throughout the supply chain starting from primary production. It takes particular account of the application of basic common hygiene requirements and discusses the registration or approval for certain food establishments.

- CAC/RCP 1-1969 which was revised on 4/2003, contains HACCP in the Annex which designates general principles of food hygiene using 7 HACCP principles and 5

preliminary steps (Codex, 2003). This document is comprised of pre-requisite programs or good hygiene practices describing how to operate a food safety establishment using the general principles of hygiene. In its annex the HACCP system (hazard analysis and critical control point) was later added.

- ISO 22000 (2005) is an international standard that concerns food safety management systems. It is a merge between HACCP steps and ISO 9001 standard. It focuses on establishing food safety through HACCP in addition to new definitions that it brings to HACCP and quality control through principles of ISO 9001. ISO 22000 emphasizes on a food safety management system with business objectives and the need for communication across sectors. It covers a wide scope of the entire supply chain. ISO 22000 doesn't offer detailed descriptions for pre-requisite programs. (ISO 22000, 2005)

- IFS Food 2012 International Featured Standard, Version 6, is the standard for auditing quality and food safety of food products (IFS, 2012). Being designed by distributors in the food sectors, IFS food covers food processing companies and companies that pack loose food products, focusing on requirements in terms of procedures and results in the food safety process but not for the entire food chain. IFS clearly addresses the pre-requisite programs as well as testing the product and focuses on highlighting control of food safety daily.

- FSSC 22000 (2014) Version 3.1 concerns food safety systems certification and is an updated version of ISO 22000 with high emphasis on pre-requisite programs (FSSC 22000, 2014). Thus, it is a GFSI recognized standard.

EC regulations represent the European Parliament and Council's perspective on food safety and hygiene of foodstuffs (Martinez et al, 2007). CAC, also known as Codex Alimentarius Commission, was initiated by the WHO. It has later added HACCP as an Annex to the document after NASA and Pillsbury Company have created it in 1969. Codex later developed international guidelines based on HACCP in the 1990's. (Sperber, 2005) IFS Food Version 6 (2012), BRC (2011), ISO 22000 (2005) and FSSC 22000 (2014) are standards, HACCP based, used in Europe or internationally to give certificates to companies after implementing their food safety systems (Codex Alimentarius, 2003).

The first HACCP system developed was adopted by Codex Alimentarius Commission. In the 1995, the World Trade Organization made HACCP a requirement for international trade (Taylor J., 2012). HACCP was later adopted by other regulations and private standards (Caswell and Hooker, 1996; Henson and Humphrey, 2011). Many companies in Europe apply HACCP in the form of the private standard such as IFS Food and BRC to control the food safety system and gain freedom of trade within Europe (Lee, 2006). A study by Williams et al. (2005) indicates that BRC and IFS Food cover 80 % of the same issues. Therefore, comparison and literature will only be collected from IFS Food and not from BRC. ISO 22000 is used by most of the companies who would like to export goods internationally. It is then identified as the main standard for food safety in Lebanon as well as in many companies in Germany and Poland (Massoud et al, 2010; Trafiałek et al, 2015).

GFSI, Global Food Safety Initiative emerged in the year 2000 with the aim ensuring food safety in Europe. (Surak and Gombas, 2009) It is retailer driven in order that they would protect their brands. It combines food experts from different parts of the supply chain, through conferences and discussion groups in order to discuss harmonized approaches to ensure food safety worldwide. (Henson and Humphrey, 2011) GFSI assures that it is not a stand-alone standard, however it provides a guidance document with the aim of benchmarking between the existing food safety standards and recognizing food safety schemes to defined requirements. (Valder, 2009) GFSI has recognized specific food safety schemes based in requirement in the Guidance and of those schemes are: IFS Food, BRC, and FSSC 22000 (GFSI, 2016b). ISO 22000 has not been recognized due to these topics: “Lack of defined prerequisite programs, differences in accreditation, and ownership and accountability issues (Surak and Gombas, 2009). In 2013, GFSI has created an auditor’s competence manual describing the skills and knowledge auditors shall have. This is in order to ensure certification credibility across the food sector. (Surak and Gombas, 2009) GFSI plans to include an “Auditor Scheme Requirements” in the next Guidance Document planned to be released in 2016. (GFSI, 2016a)

B. What is HACCP?

Hazard Analysis and Critical Control Point (HACCP) itself is a concept which was developed by the Pillsbury Company and NASA in 1969. This happened at a time when they wanted to send safe food with the astronauts to space. The HACCP system was made to be scientifically driven. The method is to identify specific hazards and measure their control in order to ensure the safety

of food. HACCP is a tool that focuses on prevention instead of finished product testing. (Codex Alimentarius, 2003)

C. Scope of HACCP Compared to Other Standards

The scope of HACCP inside the regulations and food standards varies widely (Codex Alimentarius, 2003). The scope of HACCP according to Codex Alimentarius (2003) covers the following: primary production, processing, manufacturing, and distribution until the point of consumption. It encourages the government officials to use the standard for inspection and for promoting international trade. When HACCP is to be applied at food industries, it asks that hazard analysis be performed to the complete supply chain. This approach starts at the farm where they reap the product, goes through distribution, processing, transportation, holds it in the supermarket until sale and later consumption. (Codex Alimentarius, 2003) To understand if this is applicable in the food businesses nowadays, a random selection of 54 food borne outbreaks that happened in Europe and the world was collected and analyzed to understand the root cause of the outbreaks (Annex, 1). Several outbreaks that occurred were caused by raw materials which were contaminated originally at the farm level, or during the transport phase to the industries or Caterers (Annex, 1).

This diverts the question to the direction of which scope does HACCP cover in the supply chain of foods for the EU regulations, and the private standards like ISO 22000 and IFS Food. (EC) No 852/2004 states in recital 11 that the application of HACCP principles, to primary production, is not yet generally feasible. However, it suggests that a guide to good practices should be encouraged in farms. It focuses on the scope of HACCP in specific relation to food business operators where official control inspects and audits them according to HACCP principles. It adds that HACCP shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production, as stated in (EC) No 852/2004, Article 5, paragraph 3 (EC, 2004).

In 2011, a study was done on farms as an attempt to understand this exclusion and investigate what is feasible and desirable for primary production (Cerf et al, 2011). It concluded that because many things happen on the farms – such as cattle rearing or corn production –, cross contamination of hazards occurs between the different activities. This necessitates the control of transfers by focusing primarily on GHPs. Thus, Principle 1 of hazard analysis is used to present a horizontal complement to GHP.

In Annex (1), 17 outbreaks of the 54 outbreaks revised were linked with receiving contaminated raw material that had escaped the receiving system at the industry or caterers and later caused an outbreak. The Sprouts' outbreak is one example of how a hazard was not detected by companies, prior to purchasing and processing in both Germany and USA. This is one of the biggest challenges to caterers (RKI, 2011a; Timeline and Maps, 2012). Sprouts in Germany and USA caused major outbreaks by transferring E. coli to the consumers of salads or sandwiches at different restaurants which include sprouts as one of their raw ingredients (RKI, 2011a; Timeline and Maps, 2012). Caterers, unlike industries, don't normally have the knowhow or the resources to control all purchased goods – such as the contaminated sprouts – upon receipt (Taylor et al, 2011).

Moreover, a report was prepared by the European Commission for the council and the parliament with the aim of sharing the experience gained from the application of the hygiene regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004. It highlighted that HACCP needs to be done in a flexible manner in food businesses, especially in the small ones. This flexibility applies to small food businesses where it is not possible to identify critical control points and in which, in some cases, good hygienic practices can replace the monitoring of critical control points. This annex was added to provide flexibility in establishing a safe framework to small markets, bars, coffee shops, grocery shops, transportation, and storage of pre-packed food, or non-perishable food; i.e. all places where there is no actual preparation of food. In such conditions, CCPs do not need to be established, but usually a combination of Good Hygienic Practices (GHP) and HACCP-based elements are used as a guide for implementation. (EC, 2009)

(EC) No 852/2004 discusses distribution or transportation in the scope of responsibilities of the HACCP. Some of the outbreaks originated from the transportation of finished goods to restaurants, which were held in inappropriate temperature or humidity conditions (Soon, et al, 2016). This specific step is outside of the manufacturing industry's processing wall, but is nonetheless a part of the supply chain prior to consumption (Motarjemi et al, 1998). Moreover, it is a vital step that is often disregarded by food business operators. Such examples were portrayed during the ice-cream salmonellosis outbreak that happened in USA in 1994 and which affected 224,000 people (Hennessy et al, 1996). The final analysis of this outbreak concluded that if the manufacturer had included transportation of the pre-mix inside the HACCP study, the step would have been recognized as critical control point and could have been closely monitored and thus the outbreak prevented.

A similar case took place in 2004 when the English government did a workshop on risk assessment and establishing control for better food safety. Due to time limitations, they decided to draw flow diagrams while stripping out transportation steps. (Comer, 2004)

IFS food covers the scope of processed products and hazards of product contamination during the primary packing (IFS, 2012). The food safety system in it covers all raw materials, products or product groups, as well as every process from goods into dispatch, including product development and product packaging. It further includes traded manufactured goods bought and sold as finished products. Those products need to also have IFS food certification. IFS, however, does not apply to 'importation' (offices, e.g. typical broker companies), transport, storage or distribution. There is a separate IFS called IFS transportation for this purpose. IFS Food does not mandate the suppliers or customers to apply IFS Transport; however, it makes it available in case they want to. It mandates the business operators to ensure food safety via the contracts. (IFS, 2012)

IFS Food has extensively detailed requirements which cover the whole food chain except for farmers (IFS, 2012). In order to be specific, it has formulated the criteria for different parts of the food chain differently. This goes in contrast to Codex (2003) HACCP's scope which encourages the application of HACCP, starting with raw material producers rather than raw materials themselves. Codex (2003) is very general, therefore it can only be applied as it is to the whole food chain, without a need for differentiation of the different parts of the food chain.

In FAO's report about the application of risk assessment in the fish industry, they tried to understand how risk assessment is linked to HACCP when it comes to transportation. They concluded that when there is a thorough risk assessment showing all the possibilities of contamination, it is then possible to evaluate if risks are high enough to integrate a step such as transportation into the HACCP plan and validate it. (Sumner et al, 2004)

The ISO 22000 scope applies to all organizations in the food chain such as – but not limited to – feed producers, harvesters, farmers, producers of ingredients, food manufacturers, retailers, food services, catering services, organizations providing cleaning and sanitation services, transportation, storage and distribution services (ISO 22000, 2005). However, it does not mandate the supply chain linked to a food business to be ISO 22000 certified or to apply hazard analysis; it only recommends it to use specifications that indicate that the supplier is applying HACCP.

Contrary to EC regulations, the Codex and the ISO 22200 do not force the supplier to apply hazard analysis.

Transportation, for instance, is not excluded from the scope of ISO 22000 (ISO 22000, 2005). It is handled as a pre-requisite program that needs to be maintained and controlled under a PRP procedure. It is not handled as part of HACCP where hazard analysis steps are to be applied. Raw materials are discussed in Codex as a separate program, whereas ISO 22000 considers them a pre-requisite program and requires analyzing them inside hazard analysis. (ISO 22000, 2005)

D. HACCP Steps and Principles

HACCP according to Codex (2003) consists of 12 steps which include the 7 principles identified in the logical sequence of HACCP application. The 12 steps start with assembling the HACCP team and end with the last step of documentation. Other standards such as IFS Food or ISO 22000 regard the segmentation of HACCP in a different way as will be described below (IFS, 2012; ISO 22000, 2005).

D.1. Assemble the HACCP Team

Assembling the HACCP team is the first step of the 12 steps HACCP system (Codex, 2003). Moreover, HACCP, IFS and ISO 22000 indicate that the team which is conducting HACCP needs to be a trained team containing multidisciplinary people and experts in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry and engineering, in addition to operational staff. They encourage the recruitment and involvement of experts with full knowledge of the standards or regulations as part of the team and as a source of needed information in order to perform effective hazard analysis. Furthermore, HACCP talks about the use of guidelines for easier application of standards when needed.

D.1.a. HACCP Team Challenges

Many studies done, with the aim of understanding why HACCP is failing, indicate that the lack of a multidisciplinary team or weaknesses of member expertise in it, are often the cause of systems to fail (Mortimore and Wallace, 2013; Wallace et al, 2012). A study done in the Philippines about the obstacles of HACCP team to guideline adherence, shows that those barriers are caused by the lack of expertise or HACCP regulations awareness in the team members (Azanza and Zamora-Luna, 2005). Keener (2001) points out that the lack of people from marketing or product

development departments in the HACCP team can lead to outbreaks. For example, information from the marketing department can help analyze hazards since it understands the consumers better and can tell who will purchase and how they will handle such a product and what type of illnesses or weakness they might have (Keener, 2001). On the other hand, the product development department is also needed on the HACCP team because its personnel would be able to design new products with a hazard analysis built-in mentality (Keener, 2001; Surak and Wilson, 2007). The product development department would not need to adapt the new process to an existing running system of HACCP so as to skip hazards related to the intended use of the product (Keener, 2001; Surak and Wilson, 2007). Cross functional involvement – such as the marketing and sales departments – is an important factor to consider when performing an effective hazard analysis (Surak and Wilson, 2007).

Since SMEs generally have a small number of employees, they often cannot formulate a team, and only the production manager or the quality manager would design the HACCP study sometimes with the aid of guidelines or consultants (Taylor, 2001). The limited choice on the team and the exclusion of operators is seen as a cultural problem by Taylor (2001) because managers often think operators cannot help by being a part of the team. However, Taylor (2001) affirms that the work force's presence is crucial for efficient hazard analysis, because these workers are on-site into the process, and they have the most exposure and experience. Small companies also don’t often feel encouraged to hire consultants because they cannot afford it and they do not feel it is rewarding in terms of output (Taylor and Taylor, 2004; Mortimore, 2001c). Trafiałek et al, (2015) say that several companies in Germany and Poland use guidelines and consultants to implement HACCP in small companies in specific. The influence of these two on the implementation of HACCP is discussed in the last chapter of the literature review.

Taylor E. (2008) focused on finding new methods to apply HACCP without the so called 'HACCP Jargon', where the first step emphasizes allocating a multi-disciplinary team as a building block to establish better implementation. These deficiencies and problems in the team of HACCP – whether in relation to different departments than processing, or work force on the team, or external consultants – often pose a huge barrier to finding the right hazards (Mortimore and Wallace, 2013). To make HACCP actually work, the HACCP team needs to be knowledgeable in the raw materials, product itself, processes, and hazards (Mortimore, 2001c).

D.2. Describe Product

While (EC) No 852/2004 has no mention of the product description step, HACCP (Codex, 2003) mentions that the description of the product should be done including the description of relevant safety information, such as:

- composition or ingredients
- physical/chemical structure and interactions
- microcidal/static treatments such as heat treatment, freezing, brining, smoking, etc
- packaging or packaging material
- shelf-life and storage conditions
- method of distribution, or conditions during transport

In special cases such as catering, it is permitted to group products with similar characteristics or processing steps (Codex, 2003). European commission issued a guidance document for the application of HACCP based on (EC) No 852/2004 and within that document it highlights that descriptions of the product such as: 'instructions for use, any microbiological or chemical criteria applicable' should be included (EC, 2005).

On the other hand, IFS (2012), excludes the last two criteria needed in the description, and follows the initial requirements of (Codex, 2003).

ISO 22000 (2005) changes the concept of description into a concept called product characteristics, and splits it into two parts:

- Raw materials, ingredients and product-contact materials, and
- Characteristics of the end product.

In the first part which is related to raw materials, ingredients, and product contact material, ISO 22000 (2005) applies the same elements of description of product that Codex (2003) indicated; however, it adds to them the following: inclusion of origin, preparation and/or handling before use or processing, and food safety-related acceptance criteria or specifications of purchased materials

and ingredients appropriately. For the characteristics of the finished product, ISO 22000 also uses the same descriptions as Codex (2003) for the finished products and adds labels relating to food safety and/or instructions for handling, preparation and usage.

D.3. Identify Intended Use

Codex (2003), ISO 22000 (2005), and IFS (2012), define the step of identifying the intended use of the product as the need to identify to the consumer this product and its relative vulnerabilities, so that they can be later included in the hazard analysis steps. ISO 22000 states that any "unintended but reasonably expected mishandling and misuse of the end product" shall be considered and described in documents as needed to conduct the hazard analysis. Keener (2001) and Mortimore (2001a) both discuss the failures in the HACCP system due to the lack of identification of all possible consumers using these products, and leading to a food safety hazard. Keener (2001) says that without the right functions in the HACCP team, specific target consumers are often not identified for the intended use. Keener (2001) specifically claims that: 'This type of confusion will have a profoundly negative impact on the subsequent steps in the HACCP development process and jeopardize the integrity of the entire food safety plan.'

On the other hand, the IAFP (2014) guidance document on implementing HACCP linked one of the limitations of identifying hazards to the failure of understanding the key characteristics of the product, such as the intended shelf life or the vulnerability of the consumer. This causes major difficulties in determining the true hazards and their possible effects on the finished product and eventually on the consumer.

D.4. Construct a Flow diagram

As defined by Codex (2003), ISO 22000 (2005), and IFS (2012) flow diagrams must be constructed by the HACCP team and should cover all the steps in the operation of a specific product. Attention should be given to steps preceding and following any production step. Codex (2003), in particular, highlights that the same flow diagram can be used for a number of products that are manufactured using similar processing steps. Neither ISO 22000 nor IFS Food talk about this point. However, a WHO (1999) report that studies strategies of implementing HACCP in small to medium businesses, advises to use condensed flow diagrams for practical reasons especially in catering businesses. It advises applying it in one of two ways:

- The flow diagram categorizes the processing of products according to risk

- The flow diagram categorizes the processing of products according to the order of the process

IFS (2012) on the other hand focuses on new and different items when constructing a flow diagram. IFS Food asks the users to add CCPs directly to the constructed flow diagrams. Moreover, it indicates that any change in the process needs to be immediately updated in the flow diagrams.

ISO 22000 (2005) joins the two steps constructing the flow diagram and confirming it on-site into one step, while in Codex (2003), these are two separate consecutive steps. In addition to what the other standards mentioned, ISO 22000 (2005) requires that the control measures, process parameters and/or the rigorousness with which they are applied, should be mentioned inside the flow diagram so that they could aid in the hazard analysis. ISO 22000 (2005) focuses also on the importance of mentioning the by-products to the process, and the waste released or removed, and on any outsourced processes and subcontracted work. None of the other standards or regulations go into those details which ISO 22000 mentions.

The European commission issued a guidance document subsequent to the Article 5 of the directive (EC) No 852/2004 to help food businesses implement HACCP (EC, 2009). Concerning flow diagrams, (EC) No 852/2004 highlighted a new point in the processes which is the need for making sure flow diagrams include delays during or between steps, starting from the receiving of raw materials until placing the end product at the market. Additionally, it includes premises plans, cross contamination possibilities and equipment inside the flow diagram.

Another guidance document written by the International Food Protection Agency has detailed descriptions of how to construct a flow diagram similar to the EU guidance, however with few additions and subtractions (IAFP, 2014). It recommends mentioning the general locations rather than the names of all machines. It stresses on the importance of the following factors:

- “Identify processes that are outsourced or third-party storage/work e.g. freezing at a third-party distribution center, or packing at another plant

- Identify where raw materials, ingredients, WIP products and packaging enter the process

- Identify every process input e.g., Nitrogen, CO_2, water, air and other manufacturing ingredients and aids
- Identify every process output e.g., end products, intermediate products, by-products and waste that are released or removed
- Include all transfer points e.g., conveyors, buggies/cart"

These types of specifications are with the aim of including all needed details for hazard analysis in the process (IAFP, 2014, p.12).

D.4.a. Problems with Flow Diagrams

According to Surak (2009) – who looked at the evolution of HACCP for the last 50 years –, many HACCP auditors report that most working flow diagrams are weak and contain insufficient details regarding the areas where hazards can occur in the manufacturing process. In this study, Surak (2009) was trying to identify the most effective method to conduct HACCP, and he advised that the flow diagrams should at least include flow of materials, by-products, rework, waste, and flow of workers within the premise. Other problems related to flow diagrams are mentioned by Mayes and Mortimore (2001) as being due to national governments encouraging generic forms of flow diagrams which SMEs would adapt and apply to their processes. This usually does not help in identifying important steps where problems are most likely to occur and should exist on the flow diagrams so they can become CCPs. Another problem associated with using generic models is that one generic process step cannot allow risk assessment of the individual product. For example, if the generic model says to check the temperature upon reception of new materials, then the SMEs would check the temperature of any new raw material – even fruits – due to the lack of knowledge of the staff and due to the will to follow procedures (Mayes and Mortimore, 2001).

A project financed by the EU gave some detailed advice on how companies can write down flow diagrams without missing out any points through walking through the process and performing a vocal recording which can be transcribed afterwards as an exact flow diagram (Bonne et al, 2005). In their opinion, this produces a precise and continuous operations description, produced without having to look away or be distracted in order to write down the flow diagram.

For small companies, WHO (1999) sees flow diagrams as a foundation for the systematic approach which is essential to the application of HACCP, covering food and operations from

receipt to delivery to the customer. Flow diagrams help easier identification of ways of contamination and methods of control of critical control points (CCPs).

Taylor (2012) often find the problem companies have with drawing flow diagrams is that the design of the chart is not suggested within Codex (2003) guideline. They recommend points that need to be there when looking for flow diagrams are: transportation, cooking, cooling, purchase, storage, all ingredients, process aids, packaging, no lose ends like garbage and rework, different shifts, and floor plan in the background to avoid cross contamination (Taylor, 2012).

D.5. On-site Confirmation of Flow Diagram

On-site confirmation of flow diagrams is mentioned by IFS (2012), and Codex (2003) as a separate process, and in ISO 22000 (2005) as part of the previous process. This step as described by Codex (2003) and IFS (2012) must enable the team to verify what was written in the constructed flow diagrams on the floor of the plant to ensure all steps have been mentioned. Wallace et al, (2010) affirms that serious flaws can result from not performing an on-site confirmation, because it is common that steps are missed in the initial flow diagram or process step connections and consequently to have errors in the early process flow drafts. Wallace et al, (2010) ensures that this can cause hazards to be missed or their significance is misunderstood. Taylor (2012) mentions several tricks that need to be carried out when confirming different flow diagrams, like at different times of the day, and different stages of the year, e.g. busy schedules in a restaurant versus the not so busy schedules.

IAFP (2014) details on-site confirmation of flow diagrams. It highlights the importance of having a complete team – rather than only a single party – do the confirmation together. The same team can be responsible for further changes in the process. The IAFP document links the confirmation on-site with changes that could occur with the product or process or raw material. It also stresses that this flow diagram needs to be a moving document based on changes or new observations from the team to avoid skipping potential hazards. Moreover, IAFP identified that one of the reasons hazards can't be identified is because the team lacks to check on-site flow diagrams precisely or update it as often as needed. This causes the HACCP team to miss on specific hazards (IAFP, 2014).

D.6. Principle 1: Hazard Analysis

The meaning of a ‘hazard’ according to (EC) No 178/2002 article 3 No 13, ISO 22000 (2005) section 3.3, Codex (2003) section 2.3, and IFS (2012) annex 1, is a: 'biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect'.

D.6.a. Hazard Analysis in CAC/RCP

HACCP defines ‘conducting a hazard analysis’ as: 'the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan' (Codex Alimentarius, 2003, p.25). HACCP considers this step to be the 6th step of the 'logic sequence for application of HACCP' and the 1st principle of the HACCP plan. This step is divided into three parts: listing hazards for each step, conducting hazard analysis, and considering measures to control identified hazards. In order to perform hazard analysis, HACCP suggests – but does not mandate – a few steps. First of all, the suggestion is to perform where possible 'the likely occurrence of hazards and severity of their adverse health effects”, without indicating a specific method. (Codex, 2003, p.26) further suggests performing a qualitative and/or quantitative evaluation of the presence of hazards, survival or multiplication of micro-organisms of concern, production or persistence of toxins, chemicals or physical agents, and the conditions leading to them. Although this standard was revised in the year 2003 after the (EC) No 178/2002 regulation was issued on risk assessment, it mentioned no further information on risk assessment or on where to get the acceptable levels of risks from.

D.6.b. Hazard Analysis in EC Regulations

Hazard analysis needs to be implemented in food businesses according to (EC) No 852/2004. It does not mention how to implement it, and does not provide any details or definitions. The only statement used to describe it is that hazard analysis needs to be done to prevent or eliminate risks.

(EC) No 178/2002 does not use or define ‘hazard analysis’. Instead it defines ‘risk analysis’ as a prevention method, as 'a process consisting of three interconnected components: risk assessment, risk management and risk communication'. EC (2002, p.7) defines risk as: 'a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard'. Risk assessment according to (EC) No 178/2002 is a “scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and

risk characterization. These steps provide a systematic methodology for determining effective, proportionate and targeted measures or other actions to protect health." However, the regulation is not exclusive since it does point out in the second page of the regulation, that in some cases the feasibility of controls and other factors need to be taken into consideration such as societal, economic, traditional, ethical and environmental factors. The steps are defined thoroughly in the regulation through risk management and risk communication. Risk management is concerned with assessing other policies of risk that considers other needed factors, and therefore selecting the suitable control points. Risk communication on the other hand is concerned with communicating the information about different risk analysis policies and communicating across the food chain. (EC, 2002, p.8)

Although risk assessment is mentioned in (EC) No 178/2002, the steps to implement it are not mentioned or described. A study by FAO/WHO (1995) has defined these parts as follows:

i. "Hazard identification: the identification of known or potential health effects associated with a particular agent.

ii. Hazard characterization: the qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical, and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data is obtainable.

iii. Exposure assessment: the qualitative and/or quantitative evaluation of the degree of intake likely to occur.

iv. Risk characterization: integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attending uncertainties." (FAO/WHO, 1995, p10)

(EC) No 178/2002 does not include details or principles of HACCP and its application. It merely suggests preventing hazards in foodstuffs through the use of the risk analysis method mentioned above. (EC, 2002)

D.6.c. Hazard Analysis in IFS

Hazard analysis in IFS (2012) is similar to Codex (2003) in format and in definition. Hazard analysis in HACCP should consider the likely occurrence of hazards and the severity of their adverse health effects. Furthermore, hazard analysis needs to be done for each step of the HACCP process. However, both do not offer a detailed or defined method on how to conduct the hazard identification or risk assessment.

Moreover, IFS (2012) is different from Codex (2003) and to both (EC) No 178/2002 and (EC) No 852/2004 mentioned previously, in that it discusses how allergens are also considered hazards in addition to biological, chemical, and physical hazards. Rather than having calling the process 'Hazard Analysis' like in Codex (2003) or ISO 22000, IFS Food names it 'HACCP Analysis'. The latter includes the description of the raw materials, processes and finished products (IFS, 2012). All of the 7 HACCP principles are included in IFS (2012) excluding the step 'assembling the HACCP team' which is not considered as a part of the HACCP analysis specific process. This research then focuses on the raised questions about how serious are companies about this step, and subsequently, how important is the choice of the people on the HACCP team, and how do they affect the process of 'conducting hazard analysis'.

IFS (2012) standard states that 'hazard analysis and assessment of associated risks' needs to be applied to all system parts including processing. This includes several chapters of IFS which are not part of the HACCP steps such as: chapter 2, Resource Management, Personnel Hygiene, Training and instruction, and chapter 3, Planning and Production Process such as purchasing, infrastructure, equipment and product packaging. All of these departments which are normally considered under GMPs (Good Manufacturing Practices) in Codex (2003) will need to apply hazard analysis and assessment of associated risks to each step even if it is not immediately involved in the process of manufacturing. This is different than what Codex (2003), (EC) No 852/2004, and (EC) No 178/2002 contain about hazard analysis where they say that the application of hazard analysis is only done to process related steps and not to other departments like IFS. No further details on methods of how to conduct this hazard analysis and assessment of associated risks are specified in IFS (2012).

D.6.d Hazard Analysis in ISO 22000

ISO 22000 (2005) handles hazard analysis differently than IFS (2012) and Codex (2003). It divides the 'hazard analysis' section into "preliminary steps to enable hazard analysis", followed

by 'hazard analysis' as a second step. The preliminary steps ensure that a professional team is needed to describe the specifics of the process from raw material until the process of making the product. From the standards and regulations mentioned above, only ISO 22000 and Codex (2003) have reported that all those sections are part of hazard analysis. Moreover, studies show that the presence of HACCP team as part of the hazard analysis steps is highly important, and that not having the right team members is one of the barriers to implementing HACCP correctly (Vela and Fernández et al., 2003).

The second part of “hazard analysis” is also divided into several parts being: 7.4.2 hazard identification and determination of acceptable levels, 7.4.3 hazard assessment and 7.4.4. selection and assessment of control measures.

For 7.4.2, ISO 22000 encourages food industries to identify hazards in relation to the type of product, type of process and actual processing facilities. This identification should be based primarily on all internal information and descriptions available inside the premises, and then on checking every type of regulation or external document available. The hazard identification should be resulting from observing the processes, equipment, functions, facilities and surroundings. The experience of plant employees is needed in order to perform this task. In order to determine acceptable levels of hazards, statutory and regulatory requirements, customer food safety requirements, the intended use of the product and other relevant data, must be collected and considered.

For 7.4.3, Hazard assessment is needed for each identified hazard in order to determine whether elimination or reduction to acceptable levels is essential and needed (ISO 22000, 2005). This is done when each food safety hazard is evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence. There is no further methodology offered on how to perform this assessment.

For 7.4.4, Furthermore, ISO 22000 states that the selection and assessment of control measures should be done logically. These controls should take into consideration 7 points: effect of the control on the hazard identified, ability to monitor in a timely manner, position of control relative to other controls, likelihood of process failure or process variability, severity in case of functional failure, specificity of control measures, and interactions between two or three controls.

Most importantly, only after these 3 steps can a company decide if the control measures for the identified hazard will be considered as a critical control point (CCP) or as an operational prerequisite program (OPRP) (ISO 22000:2005).

D.6.e. Problems with Hazard Identification and Hazard Characterization

A joint FAO/WHO committee was organized in 2014 in Peru to discuss the need for a revision of HACCP (Codex, 2014). The reason for revision is that although preventive, some aspects of HACCP have proven to be difficult. This is especially seen in small and less developed businesses (SLDBs), as well as for developing countries, which often lack the access to appropriate technical assistance in the practical application of all of the HACCP principles.

The problem with hazard assessment is addressed as a lack of clarity in the methods of defining the hazard or carrying out the task of hazard analysis (Codex, 2014). Hazard analysis and risk assessment are the same steps. Because both address identifying a hazard, assessing its risk, and determining the right control for it, there is a confusion between their terminologies and which terminology to use (ISO 22000:2005, EC No 178/2002). Codex guidance addresses the challenges of hazard identification in that they focus too much on microbiological hazards, while chemical and physical hazards are given less importance. This reflects the historical focus of HACCP in the initial guidelines. Now, chemical and physical hazards need to be addressed to cover non-microbiological issues such as the effective management of allergens with respect to food safety (Codex, 2014).

Codex Alimentarius issued in 1999 the 'Principles and Guidelines for the conduct of a microbiological risk assessment' where it presented the concept of risk assessment as being divided into 4 parts: hazard identification, hazard characterization, exposure assessment and risk characterization (Codex, 1999). This regulation, however, covers only the microbiological risk. Codex (2003) is not linked to this standard about microbiological risk assessment. Therefore, industries who plan to apply the HACCP from Codex (2003) do not gain the knowledge from it about a further guideline which specifies how to assess other risks. Moreover, even if the industries locate this regulation, the assessment method is only described for microbiological hazards and not for biological, chemical or physical hazards (Codex, 1999).

EFSA Panel on Biological Hazards (BIOHAZ) was asked to deliver a scientific opinion on the public health risks related to the consumption of raw drinking milk (RDM) (EFSA, 2015). A

quantitative microbiological risk assessment for these hazards could not be undertaken because country and EU-wide data are limited.

Several studies described below investigate the failure of HACCP in the food business and have linked this failure to the step of hazard analysis. Mortimore (2001c) identified the complexity of the HACCP system as one of the reasons why HACCP fails. Other reasons are the inability to identify significant hazards. Mortimore further suggested that only when the HACCP teams prepares a qualitative risk evaluation during hazard analysis to identify the right hazards and decide what hazards are likely to occur, will they be able to identify the relevant control points (CP), or critical control points (CCPs).

Moreover, Trafiałek et al (2015) showed that most companies do not have specific terminologies for the identified hazards. Most hazards are identified by names such as ‘microbiological’ or ‘pathogens’ without mentioning the specific name or type of the possible bacteria or chemical or physical agent. Trafiałek et al. indicate that an accurate specification of the biological hazards is therefore essential for choosing an appropriate critical control point (CCP). This goes in line with the IAFP (2014) guidance document which says that many hazards are missed on because of using general terminologies which hinder the understanding, and therefore the control of the characteristics of the hazard. One of the major problems with hazard analysis is that companies often choose too many hazards and therefore have a wide range to focus on (Taylor J., 2012). In addition to that, they do not prioritize the hazard group (biological, chemical or physical per hazard) and this leads to further loss of focus.

The BfR (2010) guidance document for health assessments details what risk assessment should look like. It stresses on watching out and using consistent terminology for risk characterization such as:

- “frequency of adverse events from 'often' to 'unknown to have occurred',
- severity of an adverse effect from 'serious' to 'mild',
- probability of occurrence from 'certain' to 'practically impossible',
- evidence of risk from 'generally accepted proof' to 'no indications of risk',
- source of data, e.g. publication, own study, and

- quality of data, e.g. systematic review." (BfR, 2010, p. 7)

BfR (2010) document addresses emergence of risk and links it with coordination with governmental bodies. It asks to discuss different control measures and look for governmental research and methods to detect such hazards.

Furthermore, when writing a manual of how to implement HACCP for the University of Florida, Schmidt and Newslow (2007) specified at the step of hazard identification that terminologies need to be clear and precise. More generic terminologies (e.g., pathogens, chemicals) should be avoided in order to have correct and precise hazard identification.

Taylor (2001) identified the lack of expertise as one of the main burdens of HACCP in small companies. Team experts fail to prioritize the risks from physical, microbiological and chemical hazards. Taylor (2001) explains this in relation to small companies who should focus on the most significant hazards which pose a threat to the public. Examples were given from caterers who should focus on microbiological hazards where as farmers should focus on foreign body contamination. The problem described is that companies tend to group hazards, and study them as groups in hazard analysis and this leads to confusion and have a wide variety of controls. This drives the company to choose common hazards from research whether they are relative or not.

In fact, WHO (1998) issued a report on HACCP discussing the reasons why hazards are difficult to identify. They have stated that one of the reasons making hazards difficult to identify is the lack of regulatory requirements for many hazards. Also, the fact that there is restricted access to technical information specific to each country and associated with that country's raw materials and appropriate control measures is another difficulty in the face of HACCP. WHO (1998) also linked the failure to identify hazards to the lack of access of some countries to facilities such as laboratories, equipment, and calibration facilities needed for validation.

A study by FAO/WHO (1995) linking the application of risk analysis to food standards has also identified limitations to hazard identification. Limitations included the expense and technical difficulty involved in outbreak investigations, the lack of reliable or complete epidemiological data and the inability to isolate and characterize new pathogens. According to FAO/WHO (1995) the problem lies in quantifying biological hazards, whereas chemical hazards are easy to quantify. That is because, for many foodborne pathogenic bacteria, dose-response data are limited or non-existent. Another conflict arises when solving one hazard, biological for example, creates a rise

in another hazard such as a chemical hazard; adding chlorine for example will solve a microbiological hazard but may initiate a chemical hazard which is the presence of chlorine.

The committee of FAO/WHO (1995) did an in-depth study on uncertainty and variability in hazard assessment. Three issues were considered as potentially significant contributors to uncertainty and variability in hazard identification. The report stated the first issue lies in the correct or false hazard identification. The second issue is about the screening method to allocate the hazards. And the third issue is about being able to link it to existing human hazards. The challenge there is that epidemiological studies are very limited and those are key to predict the exposure assessment on human beings.

There are even more limitations to hazard characterization which involves the information about dose-response estimates. This is difficult to find and may also be inaccurate for a range of reasons, such as (FAO/WHO, 1995, p.22):

- “Host susceptibility to pathogenic bacteria is highly variable;
- Attack rates from a specific pathogen vary widely;
- virulence of a pathogenic species is highly variable;
- Pathogenicity is subject to genetic variation resulting from frequent mutation;
- Antagonism from other bacteria in foods or in the digestive system may influence pathogenicity; and
- Foods can modulate the ability of bacteria to infect and/or otherwise affect the host.”

This is will lead companies to face difficulties in assessing qualitatively and quantitatively the severity and likelihood of the occurrence of hazards (FAO/ WHO, 1995).

D.6.f. Problems with Exposure Assessment and Risk Characterization

i. Quantification of Risk Characterization

FAO/WHO (1995) argued that a quantitative risk characterization for biological hazards is not yet possible. However currently a qualitative risk approach to characterizing risk is the only

alternative. The reasons identified are that in most cases there are many uncertainties associated with predicting pathogenic potential and evolution quantitatively.

BfR (2010) have pursued studies on the topic and analyzed reasons behind the lack of the ability to quantify hazards to date. They assessed biological hazards to cause human illness through two different ways. One way is producing intoxicating toxins, and the second way is causing pathological responses due to the ingestion of viable infectious organisms. The challenge is that in case of intoxication, a quantitative assessment is possible. However, in case of an infection, qualitative risk assessment is what is usually used. Over all, the mathematical information is not always available to do an accurate estimate. (Cliver et al, 2011)

Moreover, qualitative risk assessment has its challenges and will depend on the several factors in order to succeed (FAO/WHO, 1995). Those factors are: “experience with a specific food, knowledge of ecology of bacterial pathogens, epidemiological data, and expert judgment regarding hazards associated with the manner in which the food is produced, processed, stored, and prepared for consumption". This type of expertise can only be done if the HACCP is multidisciplinary and different experts are involved as mentioned in the section of HACCP team.

Elaborating on the latter point, Almabrouk (2007) assessed the quantitative risk assessment model of human salmonellosis which is linked to the consumption of camembert cheese made from raw milk. His findings show that there is a gap in the data on food especially the lack of quantitative data for risk assessment of hazards of certain foods. This again illustrates the importance of quantitative data to characterize risk. This is why Almabrouk (2007) tried to quantify salmonella artificially, and from that he derived a method to perform quantitative risk assessment and to demonstrate its benefit, not only as a risk evaluation tool but also, as a helping device in the decision-making and the risk management.

Edmunds et al (2013) attempted to develop HACCP into a tool that responds to emerging disease outbreak. The background of this study stems from the lack of data on outbreaks that would help the industries in quantifying risk. Edmunds et al (2013) performed this trial on avian influenza virus (HPAI) strain H5N1, which caused outbreaks in more than 50 countries. HACCP assessment was conducted for HPAI viruses within Vietnam’s domestic poultry trade. His findings proved that outbreak data has a potential to be used as a tool in hazard analysis. This tool can be a tool that prevents outbreaks. Therefore, until today, there is no official quantification method for risk

assessment or characterization. The company can only apply qualitative methods. However, quantitative methods are needed in order to ensure accuracy in risk assessment.

ii. Lack of Specified Methodology for Hazard Assessment

In the market, there are several methods that can be used for hazard assessment. The most common method implemented in Germany is the FMEA (Failure Mode Effect Analysis; Trafiałek et al, 2015). FMEA is a qualitative analysis method which works through risk assessment of all kinds of failure, prioritizing the hazards according to how serious their consequences are, how frequently they occur and how easily they can be detected (Arvanitoyannis and Varzakas, 2007). The purpose of the FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority hazards. A matrix is normally used to calculate the amount of risk and a key is given, depending on the guideline the company consults, and that defines which risk level is acceptable and which is not (Rausand and Høyland, 2004). Moreover, a study conducted in Germany and Poland by Trafiałek et al (2015) showed that in Germany the FMEA is predominantly used along with severity and likelihood matrix provided with the method. However, in Poland, the risk assessment is applied mainly based on a company' own estimates.

There are other methods of hazard assessments used in the companies. FAO in 1998, for example, has created a matrix for ranking food hazards (Quality, 1998). The matrix works on a 2D matrix, where likelihood of occurrence exists on one side with levels of 'remote, low, medium, high', and severity on the other side with 'low, medium, high'. When a hazard meets a high/high, it is clear that a significant hazard is present and needs to enter the HACCP plan, and vice versa when the hazard is marked low/low. However, all of the options in the middle cause confusion in the application of the HACCP plan in different levels depending on the product and the HACCP team because it is not clear if they are dangerous or not (Schmidt and Newslow, 2013).

There are other types of risk assessment similar to FMEA but separately designed by each consultant or company as per the examples below. A food consultant, Nolan, designed a system where severity and frequency are each ranked using a 10 point ranking scale. The team then decides which score outcome is significant as a hazard. This system, although systematic, is still arbitrary and subject to the team's safety culture. Finally, another quite common hazard assessment method is the 'simplified hazard analysis' approach. This approach is simply done based on the team's evaluation, and it includes no actual tools or grids (Schmidt and Newslow, 2013).

Clarke (2010) as part of FAO, wrote a report about the effect of private standards on Codex (2003) and national regulations. One of the main observations was that industries complain that Codex (2003) is not specific enough in giving detailed and prescriptive operational procedures like private standards. The problem is that it focuses on what factors need to be considered and what results need to be achieved but not on how the results should be achieved in recognition of the wide range of realities facing member countries. This is in demand in the companies because producers need to be clear on their deliverable before auditors, and suppliers need to know what is expected from them in terms of food safety. (FAO, 2010)

Moreover, Panisello and Quantick (2001) claimed that because industries have no direction provided by the standards or guidelines as to where to get a real hazard assessment method, they fail to do this step. Creating a method which links the outbreak data to hazard analysis and control points. This can lead to having the correct and accurate severity and occurrence data needed for hazard analysis. The method uses statistical figures and observations to assess quantitatively significant risks and to prevent them via HACCP.

Gilling et al (2001) mentioned a problem about the lack of methodology in carrying out hazard analysis. The problem was discovered from field interviews, and it was that the guidelines for HACCP are generic, and did not provide an exact framework for every product or business. In fact, one company owner complained about the lack of one final procedure. Companies would very much like to have a specific guideline helping them to implement HACCP.

Toma et al (2002) researched the stages of hazard assessment, which he called “risk analysis” in his research, in relation to quantitative and qualitative approaches. He observed that in order to determine the acceptable risk for the hazard, a system needs to be established where one can compare the estimated risk along with the acceptable risk. Such a method could ensure the allocation of the correct risk analysis procedure. Toma et al (2002) proved the findings of the previous studies. It highlighted the importance of having a standard method to assess risks on food safety. This research investigated findings on quantitative risk assessment which proved that the lack of a standard method to collect, process and diffuse data for hazard identification, from official governments or industries, complicates the problem of risk assessment.

iii. Lack of Link between HACCP and Risk Assessment

Hazard analysis in Codex (2003) states that in order to perform hazard analysis, one needs to perform exposure assessment, and both qualitative and qualitative analysis of the hazard (Codex,

2003). However, it states that only as a choice. IFS (2012) follows a similar approach. The standard does not explain how to assess risks; it only implies that one should do that. Moreover, IFS Food does not link this step to the HACCP principles.

FAO (2004) wrote a guideline about the application of risk assessment in the fish industry. One of the sections of the guideline spoke about the relationship that HACCP has with risk assessment. It stated that most people acknowledge a link between the two; however, they do not know how they work together. FAO (2004) has supplied an example in the fishery industry about how HACCP is important to be integrated with risk assessment. The example discussed an airfreight of tuna that has been delayed and was resting in an inadequate storage temperature. Using a risk assessment method named 'Risk Ranger', the producer was able to quickly estimate changes in risk of becoming ill from histamine, and adjust the changes to the HACCP plan, while including the delay which occurred, and calculating the needed temperature and holding time for it.

Similarly, Buchanan and Whiting (1998) demonstrated that the limitations of HACCP are caused by the inability to quantify the potentially combined influence of multiple control-point deviations and to relate the successful operation of a HACCP system to a measurable public-health impact. The study argued that unless HACCP is integrated within dynamic risk assessment models, entire farm-to-table continuum cannot happen and relating food-manufacturing operations to public health goals will also fall short.

iv. Differences in Terminologies of ‘Risk’ between Standards

There are differences between terminologies in the standards and regulations. For instance, terms like hazard assessment, risk analysis, hazard analysis, risk assessment and assessments of risks are used in Codex (2003), EC (2002), IFS (2012) and ISO 22000 (2005) interchangeably and defined similarly.

BfR (2010) wrote about health assessment and included a section about the importance of harmonization of terminologies in risk assessment. This is important for national governments and states so that they avoid ambiguity, misinterpretation, and confusion of terms. Moreover, in order to avoid misunderstandings originating from linguistic diversity, synonyms should be avoided, especially in the case of the characterization of health risks. Consistent terminology – specifically in risk characterization – needs to be maintained to avoid confusion.

Industries that import to more than one continent often have to apply more than one standard or regulation depending on the country (Bremner, 2002). The differences in terminologies between different standards can cause a confusion for the companies.

v. Emerging Diseases

'New food-borne pathogens emerge when previously unrecognized pathogens are identified and are linked to foodborne transmission from the beginning, or when foodborne transmission is documented for pathogens that are already well known' (Behravesh et al, 2012, p1). Since 1980, on average, one new emerging infectious disease has appeared in humans every eight months; with the emergence of these pathogenic infectious diseases representing a substantial global threat to human health (Karesh et al, 2005). An example of an emerging disease causing huge outbreaks recently is the highly pathogenic avian influenza (HPAI) and most recently, the avian influenza A H7N9 (OIE, 2013).

Emerging diseases have been investigated more often recently by the institute of medicine in the USA. It has been discovered that between 2006 and early 2012, 15 new specific food types were identified as food vehicles in outbreaks affecting the United States. The surprise item for them was that plants are the new food vehicles for these outbreaks. This includes plant-derived processed foods – like peanut butter, peanut paste, and spinach powder –, spices – such as black and white pepper–, tree nuts, and fresh produce items (Behravesh et al, 2012).

In Germany, a salmonella outbreak from herbal supplements occurred due to the fact that the industry did not expect salmonella – as a potential hazard – to be present in their raw materials and processes (Stöcker et al, 2011). Norovirus in strawberries in Germany was caused under similar conditions (Bernard et al, 2014). The catering places such as school did not expect norovirus as a potential hazard. This resulted in an outbreak causing more than 11000 children and youths to fall ill. Another example was the outbreak of Salmonella Bredeney in the United States in peanut butter in 2012 (FDA, 2012). The company did not expect this strain of salmonella to be present in such a medium.

Comer (2004), an experienced risk management consultant from the UK, wrote a report about risk assessment and discussed the difficulties in locating hazards due to the fact that food companies do not share information on existing outbreaks and problems and hazards that they face. This limits the information for other companies, especially when the information is about a new hazard which may come across in their industries or foods sectors.

Edmunds et al. (2013) did his research out of the need to use systems like HACCP in providing a framework for a rapid response to emerging infectious disease outbreaks. He conducted a HACCP assessment for HPAI viruses within Vietnam's domestic poultry trade. The findings of the rapid HACCP assessment provided strong evidence for the potential that HACCP analyses may have as a framework for helping local personnel in formulating a rapid response to an emerging health threat.

On the other hand, regulations and standards discussed above advise users to update the system when the process changes or when new raw material is represented in the system, but it does not ask to update the system based on emerging new diseases. For example, IFS (2012), it says that updates in hazard analysis need to be done upon modification in the product, process or any steps. ISO 22000 (2005), similarly to IFS (2012), affirms that modifications may include changes in control measures (i.e. process parameters, rigorousness and/or their combination) and/or change(s) in the raw materials, manufacturing technologies, end product characteristics, methods of distribution and/or intended use of the end product.

D.7. Principle 2: Critical Control Point

After applying the step of hazard analysis, HACCP dictates that companies should assess the significance of those hazards to indicate if they need to be controlled via a special control point – called critical control point –, a control step – called control point –, or a procedure of GMPs.

Codex (2003) says that there can be more than one CCP for the same hazard. Identifying a critical control point is done via a decision tree however it is important to have trained people for using this tree.

IFS (2012) has the same description as Codex, however, it differs in that it states that whatever cannot be controlled using a CCP needs to be controlled under the CP.

ISO 22000 (2005) writes no further details about CCPs beyond the main definition. However, in the hazard assessment, it identifies that some hazards will be controlled via Operational prerequisite programs known as an Operational PRPs. Nothing further is mentioned about the difference between the two terminologies. Moreover, ISO specifies that an Operational PRP is to be controlled in the same way as a CCP, and the same monitoring principles in the HACCP plan need to be applied. Operational PRP should include be dealt similarly as a critical control point, first identifying the food safety hazards, doing the hazard assessment, then choosing control

measures, monitoring, corrections and corrective actions; and finally, with records of specified responsibilities for verifying people. The only difference ISO 22000 shows between a critical control point and Operational prerequisite program is that a CCP needs to be monitored in a timely manner with critical limits defined for it where as an OPRP is monitored via a program with no critical limits defined.

The output of risk assessment is crucial since it forms the scientific basis for the next steps of risk management (Wilke et al, 2012). A failure in risk assessment results in a failure in its following steps of management and control of hazards. Moving from risk assessment to risk management is more challenging in practice than it appears to be. Such forms of risk do not offer a concrete method for the user to identify if they are a critical or not. This causes the industries, consultants, auditors and official bodies to translate this information into the form they find best according to their own knowledge and experience.

Moreover, the EU directives such as (EC) No 852/2004 include the HACCP requirements to account for the principles contained in the Codex (2003). However, they advise small businesses to be more flexible in their approach so that it would be applicable in all situations. They add that the food chain needs to remember that for some food businesses, CCPs are not possible to identify, and they can be substituted by good hygienic practices.

One problem with choosing the right CCP is the lack of focus at the stage of the hazard identification, leading to an inability to focus on the urgent hazards (Taylor, 2001; Taylor, 2012). This will normally result in a huge amount of CCPs, especially in large companies. This is due to the misinterpretation of the methodology in choosing the CCPs, and it can be easily solved by training. Small companies face the same problem, but their solution needs to be through some sort of access to technical expertise. Another problem is that companies don't often understand the concept of CCP. Some, as an analogy, consider every metal detector on the same line as CCP, whereas only the last metal detector needs to be the CCP.

Similar results were found in the study done by Trafiałek et al (2015) in Germany and Poland. In Germany, seven companies had a large number of CCPs in their HACCP system with figures such as 28, 32, 42, 51, 55, 60 and 63 CCPs. Although four of these companies produce a wide range of sensitive food types – which explains the large figures – the other ones are only medium–sized and active in less sensitive areas. The number of CCPs was not always followed by

adequate critical limits. This makes controlling the hazard challenging, but even more, validation cannot occur with this lack of critical limits.

The most recent Codex guidance document provided liberation from the decision tree where it is not needed (Codex, 2014). For although some see it beneficial, many see it as a confusing tool which incorrectly indicates that the outcome of its use should always be a CCP. It is acceptable not to have a CCP in a process – when an appropriate rationale provided, i.e. where effective arrangements are in place through PRPs –. Moreover, the decision tree itself should be reviewed, its use clarified, and alternatives to the decision tree should be provided.

Europe, I. L. S. I. (1999) discusses the danger choosing many CCP, namely each step of the flow diagram. It acknowledges that although GMP is the base of every HACCP system, HACCP will fail if the GMP steps are written to be CCPs such as washing hands. Although these steps are important, CCPs need to have a HACCP plan and be monitored and records be filled about them, and this is then not possible when the CCP is a GMP.

D.8. Principle 3: Critical Limit

Critical limit is defined in the Codex (2003) as a measurable limit that must be specified and validated for each CCP. More than one limit can be mentioned, and measurements normally include temperature, time, moisture, pH and sensory parameters such as visual appearance. ISO 22000 (2005) defines critical limits as limits of the monitoring established for each CCP. However, ISO 22000 does not mention validation when describing critical limits. It mandates a rationale to be given to the respective limit without addressing as much limits as Codex (2003). It defines a critical limit as a criterion which separates acceptability from unacceptability which determines whether a CCP remains in control (ISO 22000, 2005). If a critical limit is exceeded or violated, the products affected are deemed to be potentially unsafe. Similarly, to Codex (2003), ISO 22000 says that critical limits need to be measurable, and if a sensory parameter is to be used, specifications, or instructions or trainings, must be given to carry it out.

IFS Food defines critical limits similarly to Codex (2003). It defines them as critical limits allocated for each CCP and validated in order to clearly identify when a process is out of control.

(EC) No 852/2004 defines critical limits – like ISO 22000 – as limits established at CCPs to separate acceptability from unacceptability for the sake of prevention, elimination or reduction of identified hazards. However, in the case of small businesses, EC (2004) highlights that the

requirement for establishing critical limits does not imply that it is necessary to fix a numerical limit in every case.

The problems mainly identified from critical limits by Taylor J. (2010) are that critical limits are identified as ranges instead of being specifically enumerated. Taylor et al (2012) define critical limits as absolute values in opposition to ranges. The numbers chosen for those limits need to be valid, and identified by a trusted body such as a regulatory, trade association, published scientific data, or experimental studies.

Codex guidance document considers critical limits as difficult to define for the control of a physical hazard (Codex, 2014). It recommends revising and seeking more consideration to be given to additional guidance to address these issues.

D.9. Principle 4: Monitoring

According to Codex (2003) monitoring is 'the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments' (p.26). Monitoring the process avoids any violation of the critical limits. If results show a trend towards loss of control at a CCP, adjustments should be made to curb any possible deviations. Monitoring results data must be evaluated by a knowledgeable authority who can implement corrections. CCP should be kept under control either through continuous monitoring, or through sufficiently frequent monitoring. Most CCP monitoring procedures relate to online processes and therefore need to be done fast. Since there is no time for lengthy assessment, chemical and physical measurements are preferred; they can be taken rapidly and can indicate the product's microbiological control. In short, a CCP needs to be continuously monitored in order to avoid that the process goes out of control.

ISO 22000 (2005) does not elaborate on the meaning of monitoring like the above. However, it identifies the relevant procedures, instructions and records that cover the following:

- “Measurements or observations that provide results within an adequate time frame,
- Monitoring the devices used,
- Applicable calibration methods,

- Monitoring frequency,
- Responsibility and authority related to monitoring and evaluation of monitoring results, and
- Recording requirements and methods." (p.15)

The monitoring methods and frequency should determine when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed.

IFS (2012) describes the monitoring procedure very briefly stating that 'monitoring and control of each CCP shall be demonstrated by records. The records shall specify the person responsible as well as the date and result of the monitoring activities (p.52).' (EC) No 852/2004 understands monitoring as establishing and implementing effective monitoring procedures at CCPs (EC, 2004). No further description as to how this is done is mentioned.

Taylor (2012) describes monitoring as a step that should lead to immediate feedback that the CCP is intact. This is why Codex (2003) finds that monitoring can be physical or chemical measurements. Taylor (2012) describes the frequency of monitoring as important. Frequency needs to be clearly defined especially if it is not continuous. Furthermore, Taylor talks about the importance of calibration, of considering the variability of the equipment, and of writing a procedure for monitoring so that it can be used as training material for the overall staff interchangeably.

Cusato et al (2012) relates the problems faced when implementing HACCP to the fact that HACCP is designed for big companies only. Of the reasons why HACCP is failing in small companies are because employees have little technical knowledge, high turnover, and they are unable to perform the correct hazard identification and monitoring procedures needed to control a CCP.

D.10. Principle 5: Corrective Action

Codex (2004) explains that in corrective actions, deviations from CCPs need to be brought under control, and proper care needs to be given to the affected product. ISO 22000 (2005) details two parts, corrections and corrective actions, which need to be recorded with attention to the affected products and what has been done with them, destroyed or released, and they are:

- Correction, or eliminating the nonconformity that happened due to deviation from the CCP or the OPRP and

- Corrective action or eliminating the cause of the nonconformity.

IFS (2012) has defined corrective action in paragraph 2.2.3.9 as an action to be taken in the event that monitoring indicates that a CP or CCP is not under control. However, when it describes all measurements analysis and improvements in a system, it specifically talks about management of non-conformities and nonconforming products, and defines a corrective action more analogously to ISO 22000 (ISO 22000, 2005; IFS, 2012). Moreover, there is a section in ISO 22000 (2005) dedicated to steps about corrective action in the system and how they shall be carried to as well eliminate the cause of the nonconformity. (EC) No 852/2004 stated in Article 5 (e) that the fifth principle of HACCP is establishing corrective actions when monitoring indicates that a CCP is not under control (EC, 2004). No distinction between correction and corrective action is mentioned in the regulation.

Taylor (2012) states the main problem in this principle as being 'that completed HACCP plans have very little information concerning corrective actions (in the meaning of Codex) with words like “reject”, “throw away” or “retain” (p.47). Corrective actions normally focus on getting rid of the product rather than of the cause as indicated in HACCP. This is more of an application problem rather than a standard problem because the HACCP plans are generated by business owners with the help of consultants or guidelines.

Motarjemi et al. (1998) discuss the reasons why food borne illnesses are increasing. They claim that one of the failures of food safety systems lies in the absence of appropriate corrective measures (as defined by Codex) and in not considering the full implications of a situation when the monitoring results caused loss of control at the CCP.

D.11. Principle 6: Verification and Validation

D.11.a. Definition of Verification and Validation in Regulations and Standards

Verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan (Codex, 2003). Verification needs to be done by a different person than the one monitoring. It can be done by someone from inside or outside of the company. Validation activities can be done, where possible, and should include

actions to confirm the effectivity of all HACCP system elements (Codex, 2003). In the food safety systems, validation was introduced for the first time as an additional part to verification under the optional form 'where possible'. In the definition, the annex Codex defines validation as the act of obtaining evidence that the elements of the HACCP plan are effective (Codex, 2003).

IFS (2012) defines verification similarly to Codex, and adds that it should be performed at least once a year. It shares some examples of verification activities which include internal audits, analysis, sampling, evaluations and complaints by authorities and customers. However, validation in IFS Food is viewed as a part of measurement analysis improvements and not as part of the HACCP steps. IFS Food defines validation similarly to Codex in the definition annex. However, in the document, it has a section called ‘process validation’ under measurement analysis which explains that control of process parameters – such as temperature and pressure, re-work, equipment malfunction and process deviations – should be monitored and recorded continuously and/or at appropriate intervals. Such information is to be collected and used in the validation process in order to ensure food safety.

ISO 22000 (2005) divides verification and validation into two sections. It was the first food safety standard to divide these two terms (Surak and Gombas, 2009). The first is verification and similarly to HACCP in Codex (2003), it comes after monitoring under 'verification planning'. Verification needs to be carried out for all hazards identified, control points, OPRP, and HACCP plans designed in the food safety system (ISO 22000, 2005). Then, the second is validation and is handled in a separate section under validation, verification and improvement of the food safety management system. Most importantly, ISO 22000 states that validation needs to happen *prior* to the implementation of control measures, OPRPs, the HACCP plan, and after any change in these controls. Validation checks for the ability of the selected control measures in reaching the meant control of the food safety hazards, and in verifying that the control of the food safety hazards is able and effective to getting end products with desired safety levels. If validation reveals that one or both of these elements are not realized, then either or both should be modified and re-assessed. ISO 22000 further describes that a modification is any change in control measures or raw materials or processes or packaging, or distribution methods or changing the intended use of the product.

Regulation (EC) No 178/2002 and regulation (EC) No 852/2004 which contain general principles and requirements of the food law and hygiene of foodstuff for Europe, do not mention the word validation. Only (EC) No 852/2004 speaks about verification in article 5(f). Moreover, in 2009 the

European Commission issued a guidance document to help food business implement HACCP (EC, 2009). This guidance document has explained verification and validation similarly to Codex (2003), keeping validation as optional for only when changes happen in the food business.

For the sake of this research, the definition and description for validation used is the same as ISO 22000 (2005). For details on how validation is implemented stepwise, the main reference is the Codex guidance document from Codex (2008) using the steps mentioned below.

D.11.b. Application of Validation

Whereas verification is an affirmation of the implementation of the HACCP plan, validation plays an important role prior to HACCP implementation (ISO 22000, 2005). Without validation, hazard analysis, critical limits and CCPs cannot be guaranteed to contain updated scientific methods. The importance of validation in ISO 22000 was confirmed during a study on 72 Greek dairy companies evaluating the difference between ISO 22000 certified and non-certified companies (Psomas and Kafetzopoulos, 2015). One of the results was the recommendation stating that to achieve the elements of a robust ISO 22000 system, planning and realization of safe products and validation need to be applied.

According to FSIS (2015) “validation is the process of demonstrating that the HACCP system as designed can adequately control potential hazards to produce a safe, unadulterated product. Validation encompasses activities designed to determine whether the entire HACCP system is functioning as intended" (p.4). For that to occur, the company must apply the 5 HACCP preparation steps and the 7 principles first as summarized in figure 3 below. Validation can help regulators and consumers ensure that HACCP plans are properly implemented and hazards are controlled (Scott, 2005).

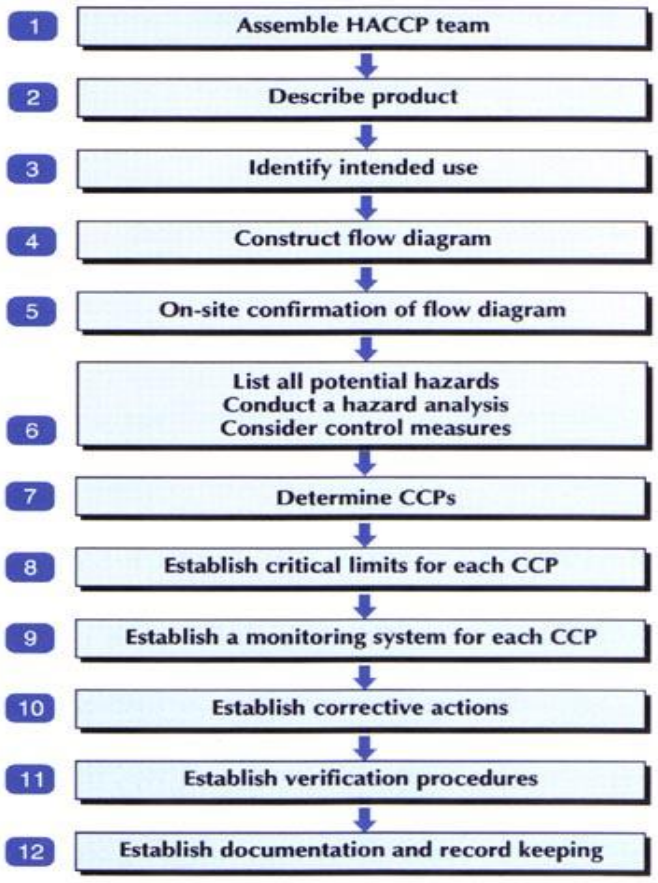


Figure 3: HACCP 12 Steps Taken from Codex 2003.

FSIS (2015) divided validation into two parts, the first part being design, and second part being execution. However, Codex issued a guidance document in 2008 outlining how to implement validation and explained it using examples (Codex, 2008). It further divides validation into 3 parts; tasks prior to validation, validation itself, and re-validation. This research uses the structure of the Codex validation guidance document to explain its aspects below:

D.11.c. Tasks Prior to Validation

Tasks prior to validation include identifying hazards, identifying needed food safety outcomes, and identifying measures that are to be validated (Codex, 2008). Prior to validation, the document defines specific steps to be prepared such as identification of hazards, definition of food safety outcomes, identification of measures to be validated – such as heat treatment –, whether the measure has been validated, and the priority of validation. The latter is based on several factors such as how dangerous the hazard is, and how possible it is to measure (Burson, 2006). To highlight the importance of the steps prior to validation, the International Life Science Institute in

Europe explains the validation of the control measures as the reconciliation or cross-checking of the HACCP data sheet and the process flow diagram (ILSI, 2001). That is done to ensure that the CCPs have been correctly identified, and that the established target values, critical limits and monitoring procedures are adequate. One of the common problems is that hazards or CCPs are not established correctly using the right descriptions. An example is provided about burger meat to be heated at 155 degrees Fahrenheit for 15 seconds (Norton, 2003). However, there was no description of the burger's thickness, the oven's heat distribution and fluctuation, or even the oven's initial setting that will lead to the 155 degrees. Without specifying such measures and defining the product controls and outcomes, validation cannot be implemented. ILSI (2001) further explains the importance of the steps prior to validation by describing the steps to a proper HACCP plan. The latter cannot be implemented without a proper hazard analysis containing the process flow diagram which includes CCPs, hazard identification, HACCP data sheet, HACCP team chart, and a description of the product and its intended use. Other factors may and should be included, but those mentioned are key for a proper HACCP preparation that is to be validated. The first key to validation in the USA is to know the food safety's purpose of what is being validated, hence the outcome needed as required by Codex (2008) validation guidance document (Scott, 2005). Defining the food safety outcomes is important and can be done through using governmental regulations. For example, meat processors in USA can refer to the stabilization guidelines by USDA for control of Salmonella in the preparation of cooked roast beef (Burson, 2006).

D.11.d. Validation

Validation can be accomplished by conducting in-plant studies, providing updated scientific literature citations, conducting pathogen inoculation studies in controlled laboratory settings, understanding process parameters, and conducting internal or in-plant observations and experiments (ISO 22000, 2005; Schmidt and Newslow, 2007; Buchanan et al, 2011). Validation steps should include choosing a scientific approach such as: published processing guidelines that help reduce bacteria or other hazards, peer-reviewed scientific or technical data that describe a process similar to the plant’s process, expert advice from processing authorities, a challenge or inoculated pack study, pathogen modeling programs, best practice guidelines, regulatory performance studies, surveys, and mathematical modeling. After choosing one or a combination of methods, one should define the parameters and decision criteria that will show control. (Codex, 2008; FSIS, 2015; González-Miret et al, 2001; Burson, 2006; Buchanan et al, 2011; Georgescu et al, 2013; Norton, 2003; Lücke and Skowyrska, 2015). Finally, one needs to collect the validation information and carry it out in the plant where needed. Analysis of the results will come

afterwards to show if these control steps are working properly or a repetition of the validation process will be needed. Buchanan et al. (2011) tells about how to validate microbial behavior by predicting patterns. Such predictive modeling can describe or predict the growth, survival or death of microorganisms in foods. It describes the challenge testing which is useful to validate process lethality against target microorganisms.

Revalidation as described by Codex is needed in 5 cases (Codex, 2008) as follows:

- Increased concentrations of hazards
- Adaptation of a hazard to a control
- Emerging new hazards
- New epidemiological findings or newly validated technologies
- A new food safety outcome

There is a need for revalidation when there is a failure in or new information about the existing system or product or plant (Scott, 2005). In a study done in Romania on the importance of new scientific information emerging, the need of revalidation and re-verification of meat products was highlighted (Georgescu et al, 2013). The revalidation study helped identify a new hazard in 'toba' meat product. The hazard was an OTA contamination which took place at the receiving stage and HPLC was used as a testing method. This is one example of how new hazards may cause the need for re-validation.

D.11.e. Challenges of Validation

Although the HACCP regulations were implemented over 10 years ago through regulation (EC) No 852/2004 in Germany and private standards such as ISO 22000 (2005) for Lebanon, food safety and inspection service has found through Food Safety Assessments (FSAs) a failure to comply with the initial validation requirement (FSIS, 2015). Moreover, in several Codex Alimentarius meetings, the topic of validation clarity is always discussed and debated (FP, 2014; Codex, 2008; Codex, 2014). The outbreaks related to sprouts in Germany, along with several other outbreaks were examples of HACCP fails in Europe during the last few years where clear validation documents were not shared (RKI, 2011; Stöcker et al, 2010). In Lebanon, the lack of validation in HACCP has also contributed to foodborne illnesses in catering companies (Hanna

et al, 2009; MOPH, 2016). In April 2015, USDA FSIS has established a recommendation document for validation because it was noticed that SMEs in specific are failing to correctly validate their systems, and that adulterated products – and even illnesses and outbreaks – are resulting from this (FSIS, 2015). Reference to process variation during validation was not discussed in such recommendations.

i. Terminology Confusion

Since Codex introduced validation as part of verification, it is often confused with verification because there is no clear distinction between the two terms (Scott, 2005). The joint FAO/ WHO committee was organized in 2014 in Peru to discuss the need for a revision of HACCP, and validation in specific (FAO/WHO, 2014). This was addressed because everyone agreed that clarity is needed to differentiate between validation and verification. It was discussed whether validation should become a new HACCP principle, whether it should be addressed as a horizontal issue in the FSMS context, or whether the verification principle should be modified into verification and validation, with both concepts being clearly defined in a single principle. More consideration was given to making specific references to the validation document in the text of the HACCP annex along with more examples of how to implement it. There is confusion between the two terms among food industry users because both words always come together (Brackett et al, 2013; FP, 2014; Codex, 2008; Codex, 2013). Several suggestions of changing the names or the order in the regulations have been suggested to avoid this problem.

ii. Scope of Validation

FSIS (2015) document discussed the consideration of PRPs under the section of validation. It justified it by considering that PRPs which control certain hazards should automatically become part of the HACCP plan and should therefore be validated. An example about this was demonstrated previously in a study about cured meat which showed that one important result of systematic revalidation for the entire HACCP system was that due to some weaknesses in GMP practices, and critical limits that limit mold count were not being met (Asefa et al, 2011). So if these GMP practices get the same validation as CCPs, hazards may be better controlled. Similarly, IFS (2012) requests that all procedures – whether PRPs or part of HACCP – to be validated to ensure control of the process. ISO 22004 (2014) on the other hand, states that where a control measure cannot be validated, it cannot be included within a HACCP plan or in OPRPs,

but it can be applied within PRPs. By this ISO 22000 allowed PRP's to be exempted from validation and limits validation only to validate CCPs and OPRPs.

iii. Hazard Names

Another challenge in validation was found to come from the inability to name hazards specifically (Trafiałek et al, 2015). This is an important challenge because the Codex validation guideline defines identifying hazards to be one of the first tasks to be completed in order to apply validation (Codex, 2008). A study covering Germany and Poland found that validation needs to work on assigned hazards and their respective controls and critical limits (Trafiałek et al, 2015). However, if companies cannot call out the hazards by name and use only non-specific terms like microbiological hazard, then applying validation cannot be possible. In fact, WHO (1998) issued a report on HACCP discussing reasons why hazards are difficult to identify. They stated that absence of infrastructure suitable for the assessment of food safety situations in general and regulatory assessment of HACCP in particular are some of the reasons making hazards difficult to identify, and therefore to validate. More reasons were due to the restricted access to technical information specific to each country and associated with that country's raw materials and appropriate control measures in specific. WHO, also linked the failure to identify hazards to the lack of access of some countries to facilities such as laboratories, equipment, and calibration facilities.

iv. Using Opinions over Science

One of the common challenges facing validation is that some companies validate based on opinions rather than proof (Comer, 2004). In a risk assessment workshop in England, one of the main difficulties found was the lack of resources for 'good data' and therefore of validating it, so the only way of some people to do it was by relying on judgments of experts as an only way to validate. A similar study in England, showed that many companies, large and small, base validation decisions on custom and practice rather than on evidence (Taylor, 2001). Taylor believes that HACCP is seen as a chance where companies can justify their choices by whatever they find possible. She believes that SME should not be given complicated methods to validate their CCP's, rather temperature and time validations can happen using simple methods.

In the FSIS document, the use of expert opinion appeared to be one of the used tools of validation, on condition that any given opinion needs to be supported by one or more peer reviewed data sets or documents. The latter provide a science-based rationale for why the different levels of the

critical operational parameter should be at least equally as effective as the one in the scientific support (FSIS, 2015). Similarly, a study done on dairies in Tanzania to evaluate the effectiveness of food safety systems, showed that very few companies conducted validation and verification activities (Kussaga et al, 2013). Those activities, however, were carried out by the people from the industry often lacking scientific knowledge or expertise, and who did not document their work. Validation and verification by external experts provide independent opinions on the performance of the system (Luning et al, 2009). A study was conducted in Japan about the performance of hazard analysis and CCPs (Sampers et al, 2012). HACCP-based food safety management systems (FSMS) in milk processing plants showed that validation of CCP and monitoring system was based on historical and/or commonly available knowledge, executed by the companies' own people on ad-hoc basis.

In England, many companies, large and small, base validation decisions on experience rather than on scientific research). This helps the company owners feel that HACCP is not being forced into their system, however this way they feel that they are shaping it by their own knowledge (Taylor, 2001).

v. Lack of Scientific Methods

Scientific data consultation and updating were found to be the most overlooked elements in a study done in Romania on rethinking validation and verification with new hazards and scientific technologies (Georgescu et al, 2013). Science is strongly connected with the hazard and the control measure, and most people tend to overlook updated scientific references and therefore, validation is weak or ineffective. Another important element missed in validation is sampling and analysis complying with government principles outlined in commission directive 98/53/EC, which refers both to official controls and to sampling and analysis carried out by food business. Moreover, laboratories selected by the food business should be accredited and should be able to comply with the requirements of regulation 401/2006. Updated scientific information for conducting validation is crucial (Norton, 2003; Lücke and Skowyrska, 2015). For example, in the past, wooden boards were not allowed for food use. However, recent studies have showed that all boards have equal risks and should be used based on their condition, unbruised, unbroken, and undamaged.

A study in Madrid about a poultry industry in 2001 started upon problems in processes or systems, where some food industries have conducted studies using validation to try and understand why a

control point is not occurring (González-Miret et al, 2001). The industry carried out a validation study using multivariate and uni-variate statistics in order to determine the best cooling conditions during the processing of chicken parts. The variation of the cooling media between 0-4 degrees in different processes phases were statistically tested using microbiological methods. Despite the short number of samples considered, statistics appear as a valuable tool for data analysis in the design and validation of HACCP systems, and can be used to explore to what extent the variables discriminate between different stages of the food elaboration process. Similarly, a study on the washing of egg shells for commercial use, showed that the process does not dominate all control measures (Srikaeo and Hourigan, 2002). The process variability or control limit was assumed as a current actual performance and therefore the actual process was not similar to the designed process.

vi. Validating without Process Variation Understanding

Process variability seems to be yet another challenge for applying validation in accordance to the validation codex document (Srikaeo and Hourigan, 2002; González-Miret et al, 2001). Process variation studies are needed because a process is likely to encounter sources of variation that were not previously detected or to which the process was not previously exposed. Variation can be depicted through the prompt assessment of 'defect complaints, out-of-specification findings, process deviation reports, process yield variations, batch records, incoming raw material records, and adverse event reports' (FDA, 2011b) (p.3). The information gathered at this phase suggests how to improve the process through the modification of certain aspects of the process or product, like process controls, operating conditions, or in-process material characteristics. In food safety standards such as ISO 22000, IFS, or Codex, process variation is not part of the clause of validation. Looking into pharmaceutical standards, the impact of validation on the quality of the product and the reasons behind such quality are detailed (Pharmaceutical CGMP, 2004). Accordingly, it is explained that a focus on process understanding reduces the burden of validation. "That is done by providing more options for justifying and qualifying systems intended to monitor and control biological, physical, and/or chemical attributes of materials and processes" (Pharmaceutical CGMP, 2004). This can happen through multivariate statistical process control to understand process variation, and predict different product and process attributes (FDA, 2004; EMA 2014). Pharmaceuticals perform process validation testing using an experimental approach which tests the control of process parameters, challenge testing simulation process trials and surely extensive product testing (Jatto and Okhamafe, 2002; EC, 2014). Almost no food safety

standard or recent publication discusses at length the importance of process variation and limit testing during the validation for the success of HACCP in specific.

Process variability affects decisions that are to be made about the process settings (Buchanan et al, 2011). Some examples can be shared from the industry. When using a sanitizing agent, logs of the bacteria, *listeria monocytogenes*, would need lowering in order to meet the limits inside the legal standards. However, with certain process parameters, the prediction levels can be tested and include variations that go above the standards. Such a study is needed and helps make decisions such as using alternative sanitizing wash methods to lower the log by using process methods. Moreover, process validation is considered as part of quality management manuals such as ISO 9001 (2015). Its clause No. 7.5.2 tells of 'validation of processes for production and service provision' (p.24) ISO 9001 (2015), and other quality related standards that are not necessarily related to food. ISO 22004 (2014) mentions that companies cannot depend on laboratory or pilot testing only to validate a system. They should rather scale up the test to the real process to reflect true parameters and numbers. This is another process related challenge since companies can test their new products on a small scale to validate them, and later face problems with the ongoing validated process without solving this problem.

Therefore, this research was designed to identify factors that influence the success or fail of HACCP through validation and comparing countries such as Germany, Poland and Lebanon.

vii. Verification and Validation differences in Food Safety Systems

Codex (2003) names this step as establishing verification procedures. It describes it as the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine its compliance with the HACCP plan. It says that verification needs to be done by a different person than the one monitoring, and it can be done by someone in house or external where needed. Furthermore, it states that validation activities can be done, where possible, and should include actions to confirm the efficiency of all elements of the HACCP system. Therefore, validation started out as a concept that was introduced in the HACCP section of Codex at the end of the section of verification in 2003. The form used in the section of verification is an optional form stating “where possible” (p.27), all in the purpose of having actions confirming the efficacy of all HACCP system elements. Since Codex introduced validation as part of verification, it is often confused with verification because there is no clear distinction between the two terms (Scott, 2005).

ISO 22000 (2005) has a different placement for verification and validation. Verification is placed independently from the HACCP plan under verification planning. It describes that verification needs to be carried out for all identified hazards, CPs, OPRPs, and HACCP plans designed in the food safety system. ISO 22000 also has a separate part about verification under validation and verification of the whole system saying that monitoring and auditing are also forms of verification. Validation of the other processes, however, is written separately. At the beginning of the validation section, ISO 22000 states that validation needs to happen prior to the implementation of control measures in OPRPs and the HACCP plan, and after any changes in these controls. Validation needs to ensure that the control measures eliminate the specified hazards, and that they are effective within the existing process and limits defined.

IFS (2012) follows the Codex (2003) order by putting verification as the 6th step in the HACCP model. Verification is applied using procedures that confirm that the HACCP system is effective. Verification of the HACCP system is performed at least once a year. Examples of verification activities include: internal audits, analysis, sampling, evaluations and complaints by authorities and customers. However, validation in IFS (2012), is viewed as part of measurement analysis improvements and not as part of the HACCP steps. It requests that all procedures whether PRPs or part of HACCP to be validated. It does not describe a specific process for how to do validation.

Regulation (EC) No 178/2002 lays down general principles and requirements of the food law, and yet does not mention verification or validation (EC, 2002). On the other hand, regulation (EC) No 852/2004 on the hygiene of foodstuff refers food handlers to the HACCP principles of Codex without mentioning specific verification or validation procedures (EC, 2004).

viii. Guidance Documents and Guidelines

European commission issued a guidance document subsequent to Article 5 of regulation EC No 852/2004 to help food business implement HACCP (EC, 2004). This guidance document has explained verification in depth and included that it is made with the aim of specifying the methods and procedures to be used in determining if the HACCP is working correctly. These methods include audits, inspections, validation of critical limits and review of deviations. Validation, on the other hand is a section under verification in this document, having activities including actions to confirm the efficacy of all elements of the HACCP plan. In this document, validation is optional and comes only when changes happen in raw material, packaging, consumer use, or new hazard.

It also suggested using legislation for microbiological criteria to validate and verify HACCP based procedures and other food hygiene controls (EC, 2009).

Another guidance document written by the European commission for Asian use categorizes verification in a section alone, where the first step is validation through sampling and micro tests and the final step is verification on the field by reviewers and audits all under the major title of establishing verification procedures (Bonne et al, 2005). In this document, validation takes up a section where good hygiene practices are described and how to test their effectiveness outside HACCP plan.

Codex Alimentarius Commission issued a guidance document in 2008 outlining how to implement a validation (Codex, 2008). It draws a major difference between verification and validation by explaining that validation is obtaining evidence that control measures which, if properly implemented, are capable of eliminating a hazard; whereas verification is using tests to verify that controls have been operating as planned. The timing of validation was also specified in the design of a control system and upon change. Verification is an ongoing activity occurring during or after operation of a control measure through a variety of activities to confirm that the implementation of control measures is taking place according to design.

Prior to validation, the document defines specific steps to be prepared such as identification of hazards, definition of needed food safety outcome, identification of measures to be validated – such as heat treatment –, whether the measure has been validated, and the priority of validation based on several factors – such as how dangerous and measurable the hazard is (Codex, 2008). Once these points have been considered, the validation process can be initiated with the following options:

- “Reference to scientific or technical literature, previous validation studies or historical knowledge of the performance of the control measure.
- Scientifically valid experimental data that demonstrates the adequacy of the control measure. Laboratory challenge testing designed to mimic process conditions and industrial or pilot plant trials.
- Collection of data during operating conditions in the whole food operation. When this approach is used, biological, chemical or physical data relating to the hazards of concern are collected for a specified period.

- Mathematical modeling which is a means of mathematically integrating scientific data to how factors affecting the performance of a control measure or combination of control measures affect their ability to achieve the intended food safety outcome.

- Surveys can be used to validate control measures, as appropriate, in conjunction with other approaches to demonstrate the expected level of hazards control that can be achieved." (Codex, 2008)

Once one or more of the steps above must be used to validate a control measure. The data after that, is collected and analyzed to prove that the method can have effective control. In case control was not accomplished, the steps need to be repeated. In the end, records must be kept in case changes happen. (Codex, 2008)

The guidelines for the validation of food safety control measures (Codex, 2008) were elaborated subsequently to the last revisions to the GPFH and its HACCP Annex. In revising the GPFH text and the HACCP annex, validation document should be considered so that it gains more acknowledgment and be used effectively (Codex, 2008). There is a need to clearly distinguish validation from verification. Moreover, it should be studied to confirm whether validation should become a new HACCP principle, whether it should be addressed as a horizontal issue in the FSMS context, or whether the verification principle should be modified. (Codex, 2008)

D.12. Principle 7: Records

The last principle of HACCP is to establish documentation which concerns all procedures and records appropriate to these principles and to their application (Codex, 2003). An example of this is a hazard analysis plan or CCP determination plan. "One of the criticisms made by small businesses trying to operate the HACCP system is because of its requirement for documentation. For many, especially micro–businesses, paperwork of any kind is a burden with verbal communication playing a major role in the successful management of their businesses." (Taylor, 2001).

Some literature has shown that inappropriate development of documents leads to their excess no matter the size of the company (Motarjemi et al, 1998; Taylor, 2001). This highlights the need for effective training in HACCP methodology. "One way to cut down on the paperwork that is a part of HACCP system is to control all products in the same process category using a single HACCP plan" states an FSIS report from 2015). This is for the benefit of very small establishments having

products which differ only in characteristics that would not affect safety rather affecting quality or taste.

Taylor E. (2008) designed the Salford model aiming to improve HACCP implementation. The creation of the Salford model was done through focusing on describing processes using simple details, following them up closely, and having management linked to supervision. Cusato et al (2012) described a difficulty in record keeping due to lack of training and limited knowledge of the staff in small companies.

A report prepared from the European commission to the council and the parliament with the aim of sharing the experience gained from the application of the hygiene Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 highlighted that one of the difficulties faced in HACCP was record keeping (EC, 2009). The report said: "It is sometimes perceived as an administrative burden by small food businesses. Member states have taken initiatives to simplify this step and minimize the documentation to be kept according to their own perspectives." However, the problem arises from how competent authorities tend to have different expectations for documentations and record keeping, and sometimes exaggerate documentary requirements. However, other member states did not face the same problem because authorities required different amounts of documentation based on the different business sizes and natures.

Terminologies in HACCP

During the joint FAO/WHO committee in 2014 in Peru, the first point of concern brought up was the clarity on the relationship between the annex with the HACCP principles, and on the good hygiene and manufacturing practices (Codex, 2014). This came from the fact that HACCP and GMPs have interrelationships to control hazards. The committee has envisioned that revising the document could result in a 'more generic and all-embracing document ... that makes the relationship more explicit to aid regulatory control and to avoid businesses developing unnecessarily complex control arrangements' (p.2). In the same document, advice was given to check Codex (2003) texts for alignment of terminology with food safety management guidance or systems, and to agree on terms such CPs or OPRPs.

E. Guidelines

Regulation (EC) No 852/2004 recommends using guidelines for the implementation of HACCP (Trafiałek et al, 2015). Based on that, a lot of companies in Germany and Poland use guidelines

as a form of consultation. Therefore, some guidelines were analyzed for this research to explore how they interpret the HACCP steps. This study was able to identify two types of guidelines described below, generic and simple guidelines, or detail-oriented guidelines.

Examples of simple generic guideline were found in DEHOGA (2012), and IHK (2012). These guidelines were based on the 7 principles of HACCP. They have presented fixed flow diagrams for catering that have defined places such as: receiving, storage, preparation warm kitchen, cold kitchen and finished product.

Hazards in these guidelines are generally named. The receiving and the warm kitchen are always considered CCP's or "kritische Kontrollpunkte". For example, for the warm kitchen, the heating should always be 80 C and above for 3 minutes. There is no mention of which bacteria is being controlled in specific. For the cold kitchen, this step is not a CCP, so any cooling down activity does not have to be closely monitored.

The CCP for receiving is controlled by checking the temperature of any received good and rejecting anything that is above 4 degrees with written forms and documentation examples. There were no defined directions for using a thermometer and in which thickness of the food to use it. There was no mention of a hazard assessment step, a use of a CCP decision tree, or validation. Corrective action is defined as re–cooking the food if undercooked, or returning the raw material if it doesn't meet the temperature requested. Verification step exists and it is done by external parties.

Examples of detail-oriented guidelines were such as: Azevedo and Joh (2010), Dirschauer et al, (2014) DGQ (2009), and BVL (2013). These guidelines draw a comparison between critical control point as written in German "kritische Kontrollpunkte" to call it "Lenkungspunkte" (p. 2) because the process is to be controlled. They follow the directive 93/43 and (EC) No 852/2004 and state that because the regulations and directives do not include examples about specific food sectors, they provide those needed examples inside their guidelines.

Generally, the hazard analysis part of these guidelines provides and identifies the names of the hazards. Some even identify whether the biological hazard produces toxins. They also explain that not all hazards are significant and they provide matrices for the hazard assessment. They ask to evaluate the likelihood and severity of hazards. Some give examples of where the most critical hazards come from and say that they come from raw materials such as raw meat or raw mussels.

Afterwards they recommend using the decision tree to identify if the step is a CCP or not. Some guidelines link the decision tree the vulnerability of the audience. For example, if it's a children's day care or a hospital, the risk is very high, so this is taken into consideration in the choice of a CCP (Azevedo and Joh, 2010).

Those detailed guidelines have some differences among them. For example, the guideline written by DGE focusing on catering elaborates on hazards and differentiation between toxins and infectious hazards. However, it also has defined CCP's and does not include a step of hazard assessment. Even more with corrective actions, it includes a step to eliminate the cause rather than mere correcting the current mistake by alternating the procedure of cooking for example. These guidelines do not mention HACCP preliminary steps, however on the 7 principles. In verification it also does not include any validation terminology or activity. (Dirschauer et al., 2014)

DGQ is a guideline which helps implementing HACCP and EU regulation. This guideline has the defined CCPs wherever there is a temperature step or a metal detector installed. This means that it teaches its users that any temperature step is automatically a critical control point regardless of further analysis. Although specific hazards are identified, the control steps are defined to be 4 degrees cooling, or 70 degrees heating. However, this guideline was the only guideline that mentions validation and that it should be done prior to the implementation of HACCP. Further details on how to implement validation were not clearly defined. (DGQ, 2009)

Bayerisches Staatsministerium für Umwelt und Verbraucherschutz issued a handbook used by governments to use for different food types. It contains procedures and checklists to control all food hazards of all types. It does not include HACCP inside it however it combines both HACCP steps and GMP steps into unified controls.

F. Role of Governmental Inspectors, Auditors, or Consultants:

Germany has 16 federal states which are all independently responsible for the implementation of the law for food and feed safety. This happens through local inspectors and activities within their area (BfR, 2014). Poland has the similar arrangement with official control (Trafiałek and Kołożyn-Krajewska, 2011). However, official control is set up to check on HACCP principles in Poland through a defined system based on the (EC) No 852/2004 called "hygiene packet". Lebanon has no literature reviews or publications about how inspectors work specifically for food safety. However, there are five different ministries that are involved in food safety (El-Jardali, et al, 2014). The ministry of Economy and Trade, the ministry of Public Health, the ministry of Agriculture, the

ministry of Industry, and the ministry of tourism, all care for food safety by sending inspectors to the different food companies. In addition to that, the local municipalities also send inspectors to food retailers. Studies on roles of inspectors show that they have a monitoring and assessing role for the implementation of HACCP (Ababouch, 2000). FAO (2016) have developed a training for food inspectors which include the harmonization of GMP and HACCP. The training should help develop the skills of the inspectors and should be tailored to different countries based on their infrastructure available and cultural differences.

The European commission issued in 2015 a report on the state of HACCP application in European countries where one of the outcomes was related with the official control understanding of HACCP. (EC, 2015) The study showed that inspectors often lacked the needed training for HACCP and examples were given about the lack of ability to know and find CCPs. Moreover, inspectors didn't all have sector specialization or training that would allow them to understand the different technologies encountered in the food field. A survey about the implementation of HACCP in 2001 in Ireland showed that one of the barriers to implementing HACCP is that the food safety authority does not perform enough checks and follow-ups about HACCP systems due to the limited number of inspectors (FSAI, 2001). Taylor and Taylor (2004) recounted from the interviews with small SMEs like bakeries how the presence of the inspector in the UK was the first step for bakeries to ever hear and know about HACCP. And from that time on, they were curious to learn more and therefore took some specific courses to achieve more knowledge on how to implement HACCP. Some SMEs are hesitant to hire consultants because they have the perception that consultants only care about getting paid.

Auditors on the other hand are hired by private companies with the aim of certifying the company with the private food standard it is applying (Surak and Wilson, 2014). Auditors' qualifications should include a good knowledge of HACCP, PRP and food safety, a specialization in the area audited, knowledge about systems, work experience, and auditing experience (Surak, 2009). Mortimore and Wallace (2013) discuss how auditors remain a challenge sometimes in HACCP due to the limited competency. ISO 22003, a standard for auditors, attempted to add qualifications for auditor in order that they carry out an effective audit (ISO 22003, 2013). Some of these qualifications were having a post-secondary knowledge of chemistry and microbiology in addition to post-secondary knowledge in auditing in the specific field of target.

Consultants' role in food safety was defined by Surak and Wilson (2007) as someone who is a trainer and will be able to develop leaders in order to use HACCP. A consultant should have the

proper awareness of the 7 HACCP principles, the GMP's, a scientific background, updates on new food safety laws and should be to be a good auditor as well.

A report prepared by the European commission to the council and the parliament with the aim of sharing the experience gained from the application of the hygiene regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 speaks about the challenges resulting from consultants (EC,2009). The report found that consultants tend to use generic systems and give them to businesses for use. This does not always apply to the specific company they are consulting and will cause that place more paper work than is needed. Such consultancy is causing the companies to pay more money and be less efficient. The same report showed difficulties regarding competent authorities' capability in adequate assessing of HACCP-based procedures (EC, 2009). Specific reasons were not given as to why this problem persisted but it was concluded that despite some established improvements, there is still room for improvement.

VII. Research Methodology

A. Reason for Changing Methods

In the primary planning of this research study, 'mixed methods' were chosen for the methodology. 'Mixed methods' is a philosophical approach that guides the direction of data collection and analysis in a mixture of qualitative and quantitative approaches at many research phases (Creswell and Clark, 2007). This method was chosen because the initial thinking was that in order to develop a hypothesis indicating reasons why food safety systems succeed or fail at the HA and CCP level, qualitative research is needed to collect data as a primary step. Moreover, a close ended method of quantitative research is needed in order to test those attitudes, behaviors or performance variables and measure them statistically (Creswell, 2009). Furthermore, after conducting the trial qualitative interviews with food safety experts, the following observation was made: qualitative interviews were not only generating a hypothesis based on the literature study done for why steps in HACCP are not always correctly implemented, but they were also giving answers as to why these problems are happening when people use HACCP or other systems. The answers received to these open-ended interview questions provided an explanation for the failure and success of HACCP in certain premises, especially with the focus on HA and CCP. These results have therefore eliminated the need for a quantitative method to numerically confirm the hypothesis of the qualitative study, i.e. interviews. However, the initial interviews led to having

extensive qualitative data which encouraged further interviews, and the development of more qualitative work.

B. Why Qualitative Research?

Oevermann et al (1979) stated that 'quantitative methods´ are only research economic shortcuts of the data generating process, whereas only qualitative methods…are able to provide the actual scientific explanations of facts' (p. 352). The qualitative methodology used for this research is derived from the book 'An Introduction to Qualitative Research' by Flick (2009). In order to understand why industries and caterers are not able to implement the correct HA steps, and choose the right CCPS, one has to understand the thought process that experts undertake to choose HACCP as a system, and then the ways they learn the steps to implement it. Qualitative interviews generated a set of reasons describing the science that experts believe is true, and which they have adopted to work with practice. It helps to understand the nature and roots of the human behavior and of their choices towards food safety. This creates a deeper understanding of the reasons and the circumstances leading to the concepts found in the existing literature summary, and helps derive new correlations as to why these observations are still happening. This was done through the administration of a thorough qualitative questionnaire continued by a thorough analysis process. Flick (2009) explains that, due to their complexity, qualitative methods are superior to quantitative methods in the cases of public health issues at the level of socio-political topics, and their relationships (p. 25).

Primarily, HACCP is a food safety system which though it must follow a purely scientific approach, it needs to be adopted and implemented by human beings to make it work (Taylor, 2004). This adoption and application of HACCP is a social study which normally belongs to qualitative research (Flick, 2009). Moreover, new methods are needed to understand the vast changes in social evolution and interpretations are crucial to understand reasons behind the adoption of certain systems. These methods are based on deriving research questions and hypotheses from hypothetical simulations which need to be tested with the aim of directing researchers towards new inductive strategies. “These strategies and concepts are themselves influenced by previous theoretical knowledge with one difference being that the theories here are developed from empirical studies” (Flick, 2009) (p.12). For this reason, the qualitative method was followed in this research, based on inductive methodologies which start by looking at the literature review to form an idea about the realities and challenges that food safety experts are facing. This information

was placed in the questionnaire, and the results of this questionnaire constituted answers that revealed the new information or theories, from the various experts' points of view.

Qualitative interviewing is usually a conversation (Kvale, 1996), with questions being posed by researchers, then listening to the respondents' answers (Rubin and Rubin, 1995). The purpose of most qualitative interviewing is to derive interpretations, not facts or laws, from respondent talk (Gubrium and Holstein, 2002). This qualitative research was conducted with experts from the food safety field in order to understand which systems are implemented, how the HACCP steps are specifically implemented – by the companies, and the consultancy and training sides –, and how the official control contributes to maintaining these systems. The focus will be on three chosen regions: Lebanon, Germany and Poland.

C. Step 1: Literature Review

Flick (2009) pronounces it naïve to start a study without collecting existing literature because there is no field that has not been primarily explored yet. It is rather important to familiarize oneself with the nature of the experts one wants to interview so that any questions posed may be relevant and adequate to the situation (p. 49). It is important to focus on what has been already studied and discussed and derive what is still unknown and under-researched in order to further investigate a topic. Extensive literature collection was primarily done to build the base of the research questions. By nature, it required references and resources to be considered ahead of making the field search (Creswell, 2009). This has been dealt with at an early phase where the literature review earlier was done for the purpose of accumulating of the needed data.

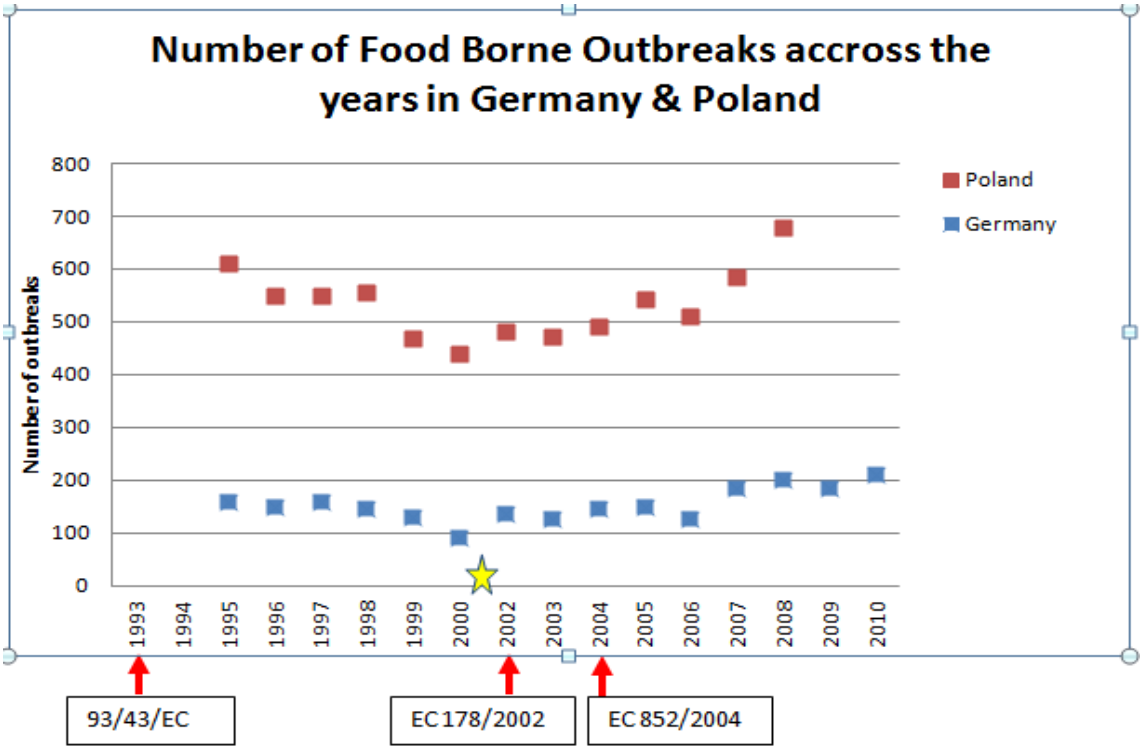
C.1. Why Collect Literature?

Strauss and Corbin (1998) list several ways of using the literature (p. 49-52). They list a set of questions that the literature must answer and help clear out before the initiation of the empirical collection of data.

The first aim from the literature research done is to understand the current state of the art in the food safety field. If the primary theory is showing that HACCP steps are not well implemented in Germany, Poland and Lebanon, then, it is important to check the existing studies about this topic by other researchers. It is also pivotal to consult the data proving the failing of the systems of interest, such as the occurrence of outbreaks in countries and companies applying HACCP. Moreover, there was a need to scan systems embedding HACCP such as IFS (2012) and ISO

22000 (2005), in relation to which countries adopt which systems in order to build the entire food safety status picture. The theories subject to this literature are called substantive theories which are known and defined as basic theories that direct the initial research (Flick, 2009; p. 50).

The second aim from literature research is to search for contradictory results or findings that can be used as a starting point for this research (Flick, 2009) (p. 50). For instance, the level of outbreaks was increasing in Germany and Poland in spite of the increase in the use of food safety regulations and systems. Such an observation posed a clear paradox that asks for more research as to why outbreaks are increasing. (Refer to figure 2 below). The statistics show that the number of outbreaks in Germany has dropped from 160 cases in 1995 to 90 cases in 2000 (WHO, 2000). This came after the food hygiene directive 93/43/EEC that was mandated to the European countries in the year 1993 to transfer into a national law (EC, 1993). However, since 2000 until today, and in spite of the introduction and proliferation of new food safety regulations like (EC) No 178/2002 and (EC) No 852/2004, and other private standard systems like ISO 22000, BRC, or IFS, food-borne outbreaks have been increasing in line with the increased regulation spread and awareness (BfR, 2007; BfR, 2008; 2009) (Figure 2). In Poland, a similar trend can be observed with a generally higher number of outbreaks; 450 outbreaks in 1993, and 350 in year 2000. Between years 2001 and 2004, the ascension of Poland into the European Union occurred and resulted in Poland's compliance to (EC) No 852/2004 whereby all food related sectors needed to implement HACCP (Trafiałek and Kołożyn-Krajewska, 2011; Baumann-Popczyk and Sadkowska-Todys, 2010). In spite of this ascension into the EU and adoption of EU regulations, food outbreaks kept increasing to date as the figure below shows.



N= Number of Outbreaks in Germany and Poland between years 1993 and 2010

Graph1: Number of Food borne Outbreaks in Germany and Poland (WHO,2000); (RKI,2011); (Baumann-Popczyk et al, 2009)

Figure 2: Number of Food Borne Outbreaks in Germany and Poland (WHO, 2000, RKI, 2011, Baumann-Popczyk and Sadkowska-Todys, 2010)

In several countries like USA, France, and New Zealand, a similar trend of increasing levels of food-borne outbreaks is seen especially in 2008-2009 in spite of the increase in awareness and the spread of food safety laws and systems (CDC, 2012; Gallay et al, 2005; Gadiel and Abelson, 2010). In the case of the different existing systems containing HACCP, literature research has helped compare the different systems, and figure out the differences between them that are potentially a huge factor in causing misconceptions and misunderstanding about the implementation of HACCP.

A third aim of the literature research is to look for existing studies and avoid repetition of existing studies (Flick, 2009; p. 51). Going through existing studies should ensure that the scope of the current study is narrowed down to topics that have not been answered in previous studies. It is also important to learn from the successful methodologies they have used for their studies which can be applied to this study as well. Some of the methodologies used, especially the qualitative research, were highlighted by Taylor and Taylor (2004).

D. Step 2: Deriving the Questionnaire

Literature research should help derive new open-ended questions that have not been answered before by previously published literatures (Jacob and Furgerson, 2012). This was exactly how the questionnaire was derived, through asking questions about areas that literature research did not find answers for. Strauss and Corbin (1998) (p. 49-52) suggest four areas that literature review is helpful in:

- "The literature can be used beforehand to formulate questions that help as a springboard in early interviews and observations,
- The literature may stimulate questions while one analyzes material,
- The literature can suggest areas for theoretical sampling, and
- The literature can be used for confirming findings or can be challenged by new findings."

Accordingly, questions were derived for this study (Questionnaire attached in Annex 2). Now for the sake of consistency and minimization of variables, the researcher supervised and carried out both field research phases personally in both Lebanon and Germany, starting with qualitative field research, and following it up with online quantitative research. This was later changed and the quantitative part was replaced by an extension of the qualitative research as explained in chapter 3.5.1. For the case of Poland, Dr. Joanna Trafiałek, a professor in Food Hygiene and Quality Management at Warsaw University of Life Science, was delegated to do the qualitative work due to language restrictions of the PhD candidate. This was also eliminated from the scope of this research as is explained in chapter 3.11.5.

E. Step 3: Testing the Questionnaire

The initial interviews were conducted with experts from the Middle East and Europe during the time frame of April/May 2014. It was a mixture of 5 experts consisting of consultants, government officials, government inspectors, experts who contribute to writing food laws for Europe and the Middle East, and HACCP experts. The aim of the primary interviews was to confirm the validity and relativity of the questions of the interview, and to assure the need of researching such a topic. The aim was also to understand which topics to focus on during the interview and therefore ask more open questions regarding those specific ones.

E.1. Refocusing the Research Question

At the beginning of the expert interviews, the aim of the study was explained to the interviewees. It was clarified that the research is looking into how companies understand and implement HACCP systems, and why in spite of that, food-borne outbreaks keep happening. It was explained that focus is on small to medium sized companies who already implement HACCP, on understanding the main steps of HA and CCP, and to know where the strengths and weaknesses lay in applying those steps. The general reaction was that this important topic has not been studied before, and that the investigated problem need to be answered. Moreover, it was derived that this is not a problem at SMEs only, but also in huge companies. Due to many reasons and mainly due to making generic generalizations of processes, huge companies are also not always able to carry out a successful HACCP system.

This insight drove the research to a wider scope to include all company sizes implementing HACCP rather than only SMEs. This way one variable - which is size of company - was omitted, and the research refocused the target more on the system itself and defects within it.

The PhD Candidate was advised by some interviewees to focus on qualitative interviews, and to emphasize the scope of the research on the qualitative interviews rather than on the quantitative surveys. The disadvantage in quantitative research is that for HACCP itself, they can indicate the size of the problem but not tell about the problem itself (Creswell and Clark, 2007). Moreover, people may fill in surveys very quickly online and inaccurately in most of the answers, especially when it is a sensitive topic like system implementation for food safety. They would tend to give some idealistic perfect answers about HACCP. The scientific assessments resulting from these surveys are not very sound since they would be based on subjective opinion, rather than company facts. In contrast to that, the interview composed was asked in a manner to assure the expert's knowledge or implementation skills are not being tested (Flick, 2009) (p. 266). Moreover, their professional input was encouraged about the HACCP system and implementations as practices in industries. The researcher was able to check the system itself on the floor and see specific practices that were of benefit to the research. This method gave a clearer, more grounded, picture of the problem and of its potential solutions.

Therefore, the time initially allocated for surveys (6 months) was shifted towards qualitative research. And thus, the number of qualitative interviews increased from 15 to 45 interviews, 15 for each country. The information from the interviews was assessed using a software called NVivo

and correlations were derived, analyzed, and suggested through this software (Bazeley and Jackson, 2013).

E.2. Interview Structure

It was important to stick to the constructed questions. When there is a need to explain further, careful attention was given so that the explanation does not reflect any expectations or perspectives (Jacob and Furgerson, 2012). The questions were spoken slowly in the language that the interviewee is most comfortable with generally English or German or Polish.

It was important not to write down any notes during the interview as this proved to make the interviewee tense and anxious about what was being written at that specific moment. It was sufficient to record the interview and later transcribe it remembering mental notes or making a recording of all the collected observations right after the interview.

E.3. Interview Content Focus

The topic of hazard analysis is ambiguous since experts have different perspectives and definitions about it. There was a special focus on hazard analysis since it constitutes the core of the research questions. It was asked about at the beginning of the interviews because the experts had more energy and motivation to share examples about it. All papers carried on the interview were kept as anonymous so that each company cannot tell which other companies are part of the research.

The order of questions was reshuffled according to the answers. For instance, if an example was given about one of the last questions in the interview like corrective action, there was no need to ask the question again.

F. Step 4: Reformulating the Research Question at Several Intervals

According to Flick (2009), the research question needs to be revised at different intervals of the study. The aim of this is to clarify what the field contacts are supposed to reveal as time progresses. 'Reflecting on and reformulating the research question are central points of reference for assessing the appropriateness of the decisions you take at several points' (p.98). The research question was redefined after two intervals.

The first time was, after the literature review was finalized. The research question was narrowed down. Initially, it said: identifying the decisive factors causing the small to medium enterprises (SMES) to succeed and fail while implementing the first step in HACCP, leading to either better systems or contamination and outbreaks. The narrower research question became: Gain understanding for the reasons behind companies (industries, caterers) inability to apply the first two principles in HACCP being, hazard analysis and choosing critical control points correctly. Relate this answer to consultants, auditors, and governmental authorities and their personal understanding of HACCP and its application and their way of influencing the companies. Moreover, relate the above to question to the way different regulations and standards are designed and written.

After the first round of interviews, and based on what was explained in step 3 above, the research question was reformulated and narrowed down a second time into: understanding the way decisions are taken to choose hazards and critical control points from team leaders in light of: choice of HACCP team members, flow diagrams, risk assessment methods and validation procedures and updating hazard identification systems. Understanding of these facts depending on the nature and qualifications of the experts interviewed will reflect as well the interpretation of the standards and the method of spreading of those interpretations.

Moreover, the interviews have provided a means of detailed facts collected from interviewees in addition to the justification of the given facts. This has eliminated the initial need for carrying on a quantitative research following the qualitative research in order to justify correlations between factors. It was due to the fact that the interviewees themselves are offering clear explanations as to why those systems and factors are being carried out the way they do. A simple example is the choice of ISO 22000 in Lebanon due to a grand project offered for free to all companies called QUALEB. This, in return, justifies why the complete HACCP system is carried out in the methodology of ISO 22000 and not in the methodology of HACCP from Codex (2003) (Hatab, 2013). Such data cleared out in interviews presented the opportunity to raise the number of qualitative interviews to have a more comprehensive amount of data to confirm such correlations. The final questionnaire can be found in Annex 2.

G. Step 5: Entering the Field

To enter an institution and perform interviews, there are defined processes by Lau and Wolff (1983) (p. 419) summarized in Flick (2009) (p. 108). These processes were used to carry out the

research interviews. The process starts by defining that an interviewer is known as the client who needs to make a formal request for the interview. In cases of food safety, a phone call or an email needs to be sent to institutions like food industries, hotels, caterers or restaurants explaining the research question and the aim of the interview. Lau and Wolff (1983) point out an important watch out saying that coming from an official institute like a university may produce distrust in the people interviewing. However, being referred into this institution by other people, may facilitate the process. And this is exactly how all interviews were carried out in Lebanon, Germany, and Poland. In Lebanon and in Germany, many references were given to the researcher through common colleagues from university, and the formal interview request was later carried out by phone or email. This facilitated the grounds and removed some anxiety from the interviewees since they regarded it as an activity to help a friend's friend on a scientific project.

Unlike quantitative interviews, qualitative interviews have a special role in terms of competency in communication (Flick, 2009) (p.106). In order to gather the needed data, a certain familiarity with the interviewee needs to be achieved. The qualitative interviews planned for this research are with experts in the food safety field. Based on advice given by one interviewee, the way to receive reliable information from these people is to formulate the questions in a non-intimidating manner. That is primarily done through making sure to clarify that the aim of the interview is purely to collect data about the food safety activities in their work field rather than presenting the interview as being a test to their knowledge. And secondly, it is done by clarifying the summary of the literature research done in the first year of research showing that due to multiple food safety systems, and direction, the people implementing these systems are confused by this high variation, and that the current research attempts to better understand this confusion. A confidentiality agreement was also signed between the two parties ensuring anonymity of identity of the company and the expert (Flick, 2009). It also provided permission to use the information recorded for the research sake. The agreements are found in Annex 3.

H. Step 6: Sample Quality and Sample Size

Sampling in Lebanon is limited by the amount of companies who are certified for HACCP or its systems like ISO 22000. The sampling criterion is: a food producing company who has adopted HACCP over the last 2 years from the interview date. This HACCP can be applied through any identified standard being: ISO 22000, IFS Food, BRC, or HACCP from Codex (2003). Included in the scope are consultants, auditors, and governmental inspectors who are actively advising and visiting food companies in the chosen country about HACCP or HACCP-based systems.

In order to choose the number of the interviews, literature was collected about the saturation theory. Saturation is when there is no additional data found about a topic researched (Guest et al, 2006). As the researcher inquires more information about the same topic, eventually this topic gets saturated and another topic can then be researched. There is no defined number for how many qualitative interviews are needed to reach saturation. Byrman, in a study about saturation, found that it is impossible to know the number of interviews needed from the beginning, rather the researcher shall collect data, combine sampling, and analyze data as he goes through the interview processes (Baker et al, 2012). Some studies show that 12 interviews are fair even when incorporating interviews from more than one country (Guest et al, 2006). Other studies show that depending on which type of qualitative research is carried out, the number of interviews can be chosen (Marshall, et al, 2013). In the case of this study, being qualitative 30 interviews should be sufficient.

The number of HACCP certified companies in Lebanon is limited, and based on the saturation theory 15 interviews in total were possible to be attained and would be sufficient. Similar numbers were chosen for Germany and Poland. The experts included came from: meat or poultry industries, canned food, potatoes, sweets, drinks, hotels, catering companies, consultants, auditors, and governmental inspectors. Thirty-three interviews conducted between Germany and Lebanon. The list of interviewees and their relative field are attached in Annex 4 of transcripts. The names are not mentioned due to the confidentiality agreement.

I. Step 7: Qualitative Interview

Qualitative interviewing is based on conversation (Kvale, 1996), with the emphasis on researchers asking questions and listening, and respondents answering (Rubin and Rubin, 1995). The qualitative research was with experts from the food safety field in order to understand the following points:

1. Whether experts were familiar with the 5 steps preparation for HACCP and if they consider them as major steps,

2. Asking experts to explain how they think they should implement HACCP with onsite examples,

3. Whether experts understood differences in terminologies such as hazard analysis risk analysis, validation and verification, and correction corrective action,

4. The impact of official control and consultants and auditors on how HACCP is implemented.

The focus was on three chosen regions: Lebanon, Germany, and Poland.

In depth one-on-one semi-structured interviews were used because they provide detailed information more than what is available through other data collection methods, such as surveys (Boyatzis, 1998). Semi-structured interviews allow the standardization of the questions, which increases data reliability. It also leaves room to ask spontaneous questions which may be sensitive to some participants. Moreover, it provides a relaxed atmosphere in which to collect information where people feel more relaxed in a conversation-like form. The in-depth interviews that can be particularly effective are the ones where the study involves an investigation of complex behavior or decision-making processes (FAO, 1997).

The interviews were saved using a telephone software called: IPhone 4s Voice memo recorder. Flick (2006) (p. 294) says that using a machine to record data helps this data become independent of perspective because it shows a natural representation of the events. The IPhone 4 s recorder can save an unlimited number of hours of interviews, and can be saved on the computer and sent via email for having 2 backups (Brown et al, 2014).

After exiting an interview, specific field notes were written by describing specific observations that took place (transcript protocol). This is because one of the questions of the interviews asks to see the flow diagrams and hazard analysis of companies. Since writing down in front of the interviewees would trigger a negative and nervous impression on their end – as mentioned above in the section of testing the questionnaire –, field notes were recorded or written down after leaving the company. These field notes contain facts about what was in the papers that were shown to the researcher over the interview, and any further observations made during the visit. Lofland and Lofland, as cited in Flick (2006), have said that it is better not to delay taking these notes too late after the interview so that one does not lose the artificiality in the relationships (Flick, 2006) (p. 280).

J. Step 8: Transcription Method

The first step needed is the transcription of the data as a form of basic description (Kvale, 1996). One limitation of transcription is that it automatically results in reduction of the original tape data, because by default it cannot contain the full set of data. As Kvale (1996) pointed out, transcripts 'are not the rock-bottom data of interview research, but are artificial constructions from an oral to written mode of communication' (p.163).

The method of transcription needs to be in line with the level of analysis (McLellan et al, 2003). In this research, the exploration of general themes and patterns is used as opposed to the use of an in-depth description of the knowledge, attitudes, values, beliefs, or experiences of an individual. This can be transcribed using less text and yet more focused on the answers of specific questions through facts given by the interviewee. Since the focus in this research is on the factors leading to incorrect HA and CCPs, scientific restrictions and events were collected from the interviewees. Unlike narrative interviews, semi-structured interviews are based on facts through semi-guided questions with interviewees answering using facts and data known and owned by these experts (Taylor-Powell and Renner, 2003).

Since the need focuses on concrete data, the transcription method used excluded any references to nonlinguistic observations such as facial expressions, body language, or setting descriptions (McLellan et al, 2003). There was no need to use transcribed verbatim nor there was a need to identify specific speech patterns, vernacular expressions, intonations, or emotions.

The transcript protocol was such that each transcript needs to include a header and a summary about the interview in order to keep the context of each interview intact. McLellan et al, (2003) points out that labeling interviewees is important in order to facilitate the comparison between them as groups. Thus, the transcription header could include a profile or set of personal characteristics such as gender and age which might be relevant to the analysis.

In order to unify and simplify the transcription, one must create a standard or template by which all transcripts can follow a specific pattern. The advantage is that instead of transcribing each interview alone, one can organize the approach holistically. Another advantage is that by such systematic transcription, codes and categories would emerge naturally, and make it easier for later analysis. So, instead of wasting time on looking at each text alone, this method will help focus the attention on analyzing and interpreting the text. A back-up system needs to be made for all written data. The way the data is inputted and analyzed should be easily retrievable. This

transcription form leading to automatic categorization could take the form of a table or Excel chart, or matrix based on the software used (Adams et al, 2007).

Strauss, as cited in Flick (2009) said that it seems more reasonable to transcribe only as much and only as exactly as is required by the research question. His reasoning was that precise transcription of data absorbs time and energy, which could be invested more reasonably in their interpretation instead. The second reason is that he believes that the looked-for answer is often found hidden between the words rather than in the words itself (Flick, 2009) (p. 300).

The transcription used the rules given by Drew (1995) from the book by Flick (2009) (p. 78). Drew provides a glossary of transcription conventions which was used for the transcription of all qualitative interviews conducted as illustrated in the figure below.

Box **22.3** **Transcription Conventions**

[	Overlapping speech: the precise point at which one person begins speaking while the other is still talking, or at which both begin speaking simultaneously, resulting in overlapping speech.
(0.2)	Pauses: within and between speaker turns, in seconds.
"Aw:::":	Extended sounds: sound stretches shown by colons, in proportion to the length of the stretch.
Word:	Underlining shows stress or emphasis.
"fishi-":	A hyphen indicates that a word/sound is broken off.
".hhhh":	Audible intakes of breath are transcribed as ".hhhh" (the number of h's is proportional to the length of the breath).
WORD:	Increase in amplitude is shown by capital letters.
(words...)	Brackets bound uncertain transcription, including the transcriber's "best guess."

Source: Adapted from Drew (1995, p. 78)

Figure 4: Transcription Conventions, Taken from Flick (2009)

K. Step 9: Coding, Categorization and Analysis

After transcription, the information needed to be coded and categorized in order to understand correlation and reasoning between the experts and the relative answers (Jones, 2007). A software was used to initiate this step.

K.1. Software Program

In order to understand the collected qualitative data, it is important to break down the answers of the questionnaire in a scientific manner and to derive the hypotheses needed (Jones, 2007). In order to use a systematic and consistent method of analysis, a software program was used to help along the process. The fundamental need of such a program is to assist in the retrieval of text from data, allow the coding of that data, and development of a system which relates codes to each other using a tree structure or other structures. NVivo, used in this research, is qualitative data analysis Software from QSR International Pty Ltd. Version 10. It is described as a retrieve, code, and theory building tool. Jones (2007) in his paper on software analysis described the process as such: 'the software utilizes rich text which allows integrated emphasis through color, font and character style'. 'Once imported, the text can continue to be emphasized through the internal rich text editor for the manipulation of color, font and character style' states Blismas and Dainty, (2003). Richards, (2002) states that 'selected data can be coded both *in vivo* and through an accumulated tree structure. Editing is dynamic, in that text can be edited while it is coded, and memos and comments can be added throughout. This allows for easy and progressive reflection and conceptualization.'

K.2. Why Use Qualitative Content Analysis?

The procedure of analysis used for this research is the qualitative content analysis, which is defined as: 'a research method for the subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns' (Hsieh and Shannon, 2005) (p. 1278). There are multiple reasons for choosing this type of analysis for this specific research. First of all, content analysis allows researchers to interpret the text in a scientific manner as it was primarily developed in anthropology, qualitative sociology and psychology in order to explore the meanings underlying physical messages (Zhang & Wildemuth, 2009) (p.1-2). Since the research conducts interviews asking experts about how HACCP works for them, how they understand it and which methods they use to implement it, a scientific method is needed to lay down the facts collected in a systematic manner. Although the expected answers are mere facts, underlying messages need to be understood, for example, reasons behind experts adopting a certain view. Content analysis is the ideal method to interpret this data. Zhang & Wildemuth (2009) (p. 2) add that 'qualitative content analysis is mainly inductive, grounding the examination of topics and themes, as well as the inferences drawn from them, in the data.' Zhang & Wildemuth (2009) continue to say that: 'unlike quantitative content analysis that chooses a random selection

of texts, qualitative content analysis usually consists of purposively selected texts which can inform the research questions being investigated. The qualitative approach usually produces descriptions or typologies, along with expressions from subjects reflecting how they view the social world (p.2).' This way the researchers results will reflect his perspective through the text presented (Berg, 2004). Qualitative content analysis focuses on themes reflecting the meaning of a seen phenomenon rather than statistical accounts of texts.

K.3. Defining Unit of Analysis: Category or Theme

A unit of analysis is a theme assigned to the transcribed research material (Zhang & Wildemuth, 2009). The aim of it is to have the messages in the text unified through a theme. Only when themes are chosen, can we later start a coding system.

Robson (2002) clarified the need for themes. He says that themes are identified, and after that, the researcher can focus on the way and frequency these themes are occurring. The analysis is then of both the content and the context, as it is linked to outside variables, such as the gender. This category in the NVivo system is named a node (NVivo, 2014). Nodes allow the gathering of related material in one place so that emerging patterns and ideas become visible. The nodes evolve from the transcribed interviews if they highlight the following:

- Repeated words in several places,
- Information that was not found in the literature review,
- Interviewee states that it is important,
- Information highlighted during the literature research,
- Agrees with a theory from the literature research,
- Agrees with a theory formulated during this research.

Bryman (2001) states that a coding manual needs to be assigned. This manual involves category names, definitions or rules for assigning codes, and examples (Weber, 1990). This manual evolves over the process of data analysis. The Software NVivo allows this through the classification of nodes according to descriptions and attributes that they have (NVivo, 2014).

K.4. Coding Hierarchy and Analysis

The method chosen for use is the cross-sectional code and retrieve method (Ritchie et al, 2013). A system of categories was retrieved through a computer program in order to search for and retrieve parts of labeled data after the general themes or nodes were assigned. These categories were coded in systematic ways using this software and based on similarities in topics, repetitions, linking words, and other important observations (Ritchie et al, 2013). These categories or nodes have sub-categories which divide them further into options according to the answers received. This hierarchy has child nodes which were added under parent nodes. During analysis, it is possible to see the parent nodes with the different references from the child nodes underneath (NVivo, 2014).

Example of parents´ nodes are: expert role, First HACCP step, Flow diagram, GMP vs HACCP, HACCP safer, HACCP team, Hazard analysis, Info-sources, Scope of HACCP, many systems, Successful HACCP, System used, Updates, Verification and Validation. The interview transcripts divided into these nodes can be found in Annex 3. An example from nodes can be seen in Annex 4. The results are referenced with acronyms to be traced back from the transcripts as such:

a. Consultant Inspector Auditor: CIA
b. First Step HACCP: FSH
c. Flow diagram: FC
d. GMP vs HACCP: GVH
e. HACCP Team: HT
f. Hazard Analysis: HA
g. Info-sources: IS
h. HACCP makes safer: HS
i. System used: SU
j. Many Systems: MS
k. Raw Material: RM

l. Scope of System: SC

m. Successful system: SS

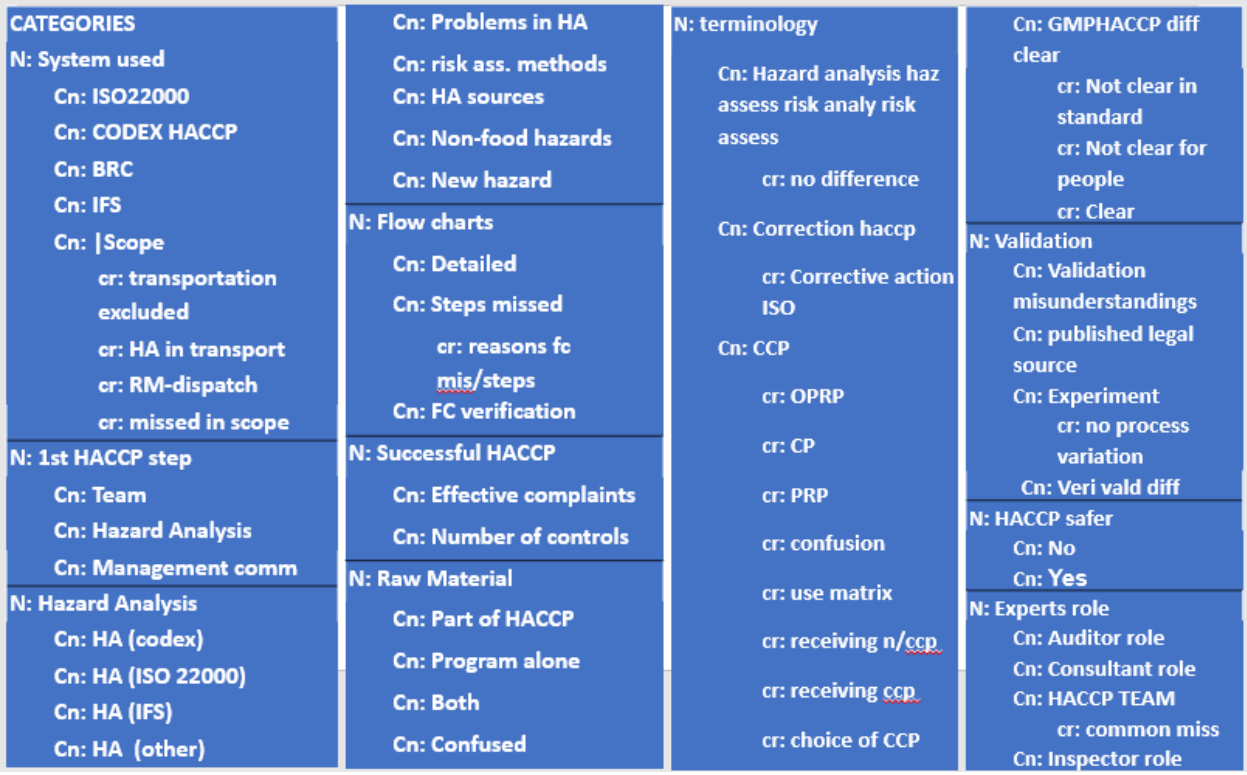
n. Terminology Confusion: TC

o. Update System: US

p. Validation: V

Examples of child nodes are subcategories derived from each parent node and comprise the titles of the chapters of results. Examples are for the parent node, first step of HACCP are: Auditors' role, consultants' role, inspectors' role and company experts' role. Details of nodes and child nodes further correlations and reasons for them are portrayed in Table 1 below as 'N' for Nodes, 'Cn' for child nodes and 'cr' for correlations and reasons. Further examples of child nodes inside the NVivo program are demonstrated in Annex 4.

Table 1: Nodes and Child Nodes as Extracted from NVivo



After setting categories, relationships between categories need to be monitored and revised. This is an important step in the analysis process because it moves the questions posed away from the presented facts, and clarifies why those facts have taken place and what have caused them (Adams et al, 2007). Using relationships in this research to draw correlations between specific food regulations used for example, and the success of specific HACCP steps, explain why those steps have succeeded. Themes, categories and codes form a matrix which condenses data into simple categories, reflecting further analysis of the data to identify the degree of support, and provide a multidimensional summary that facilitates subsequent, more intensive analysis (Schutt, 2012). Examples of correlations were between Auditors and HACCP or Consultants and verification, were one could how the results of choosing critical control points depending on the consultation of a consultant or an auditor. These correlations happen through the NVivo program using queries (NVivo, 2014)**.** Queries find and analyze the words or phrases in the sources, annotations and nodes. It can help find specific words that occur most frequently. Queries help ask questions and find patterns based on the coding and it can check for coding consistencies. This can happen using matrix coding queries which ask a wide range of questions about patterns in the data and gain access to the content that shows those patterns. More examples such as comparing different auditors' opinion regarding different validation approaches from different standards, or comparing terms used in different contexts or comparing definitions of the same

terms coming from different experts can we found in Annex 4. The results of the nodes and child nodes and how they were coded and analyzed is reflected in the titles of the results and then correlations are reflected in the discussion.

K.5. Changes and Omissions:

After the interviews in Poland were executed by Dr. Joanna Trafiałek in Warsaw, the results were sent in the Polish language and an adequate translation of the transcript could not be realized. This has led to lose a lot of the detailed information that reflects the perception of the different experts especially in relationship to questions are terminologies and wording (Squires, 2009). Due to this limitation, and due to the saturation theory that shows that after 12 interviews about the same topic no new information can be attained (Guest et al 2006), and due to the shortage of time, the interviews from Poland were not analyzed using the NVivo system as the rest of the data. The study will continue to focus its results on Germany and Lebanon. Further analysis may be conducted in relationship to Poland on the basis of these interviews collected at a later time.

VIII. Results

A. Systems Used

The first question that was addressed to the experts was about the type of systems they were using in their companies and the reasons behind choosing these systems in particular:

- For enterprise: what food safety system are you implementing and why did choose it?
    a. What made you choose these specific systems?

    b. What do you think is the scope of HACCP? Does it cover your transportation after production? And shipping over sees?

    c. If their enterprise is using more than one standard (IFS and ISO 22000 for example), according to which standard do you conduct the hazard analysis?

The food industries and caterers were mainly using ISO 22000, ISO 9001 and FSSC 22000 (579SU, 518SU, 430SU, 424SU, 353SU, 291SU, 164SU). Few other companies said they use other systems, but not in particular for food safety, in addition to the mentioned above systems such as HACCP (76SU), FDA (353SU), 15593 Norm for packaging (205SU), ISO 9001 and 14001 (172SU).

Consultants and auditors had a wider variety of systems that they were trained and certified on. Those systems included Codex (2003), BRC, ISO 22000, ISO 9001, BRC, GMPs, IFS, and FSSC 22000 (586SU, 567SU, 560SU, 553SU, 510SU, 497SU, 480SU, 470SU, 463SU, 456SU, 221SU). Different consultants specialized in different national laws such as EU regulations or the English law (437SU). Other consultants were specialized in private types of HACCP-based systems such as Gütenachweis für Kleinbetriebe or Menu-Safe HACCP which was created by the Taylors (490SU), which is a HACCP customized for small companies created by a consultancy agency (82SU) and other HACCP based or other than HACCP based systems such as ISO 50001 (65SU, 119SU).

Governments on the other hand, whether in Germany or Lebanon were all relying on HACCP from the Codex Alimentarius standard that was updated in 2003 (543SU, 250SU, 2SU, 140SU). Exceptionally among both governments in Germany and Lebanon, one ministry in Lebanon uses ISO 22000 (2005) and trains companies and helps them to implement it. They are funded by the European Union through a program called QUALEB (470SU). Other governmental inspectors rely

on national laws or European laws such as Verordnung 852, DIN Norm 369, EU-Leitlinien / Leitfaden für die Umsetzung von HACCP, SANCO/1955/2005, and Leitfaden zur Grundlage für die Schulung in addition to the Codex (2003) (18SU).

When experts were asked why they have chosen these specific systems, there was a difference in answers from each country. The answer from the German experts was that they use these systems because it is a legal obligation to have HACCP. The answer from Lebanese experts, however, was that they use these systems because it is a trend to use food safety systems nowadays especially ISO 22000 (2005). They also believe that it helps export products to different countries (800SU, 814SU, 779SU, 766SU, 759SU, 726SU, 710SU, 718SU). None of the answers were country specific. The experts' answers and the reasons for them were independent of which country they came from. This same observation was seen for all of the answers below. The country type and its influence was minimal to negligible as will be seen below (1HA-2481HA).

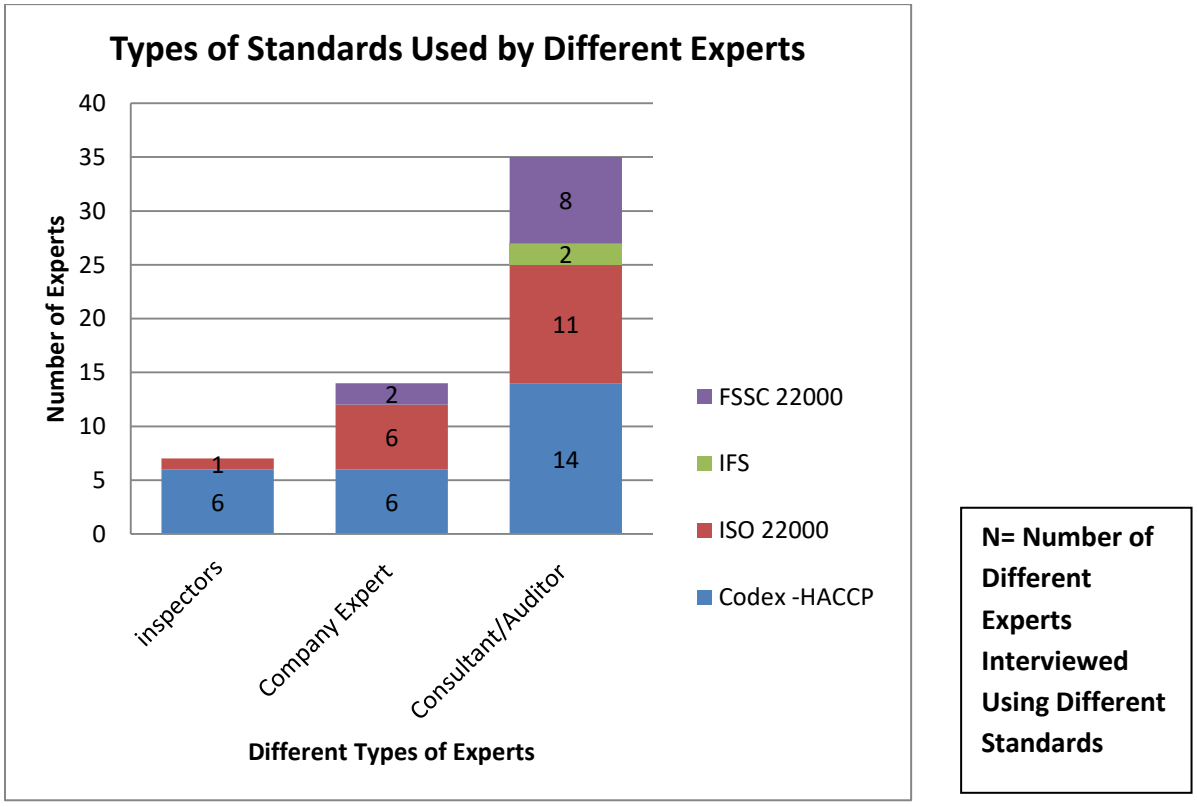


Figure 5: The Types of Standards Used by Different Experts

A.1. Several Systems Used

After knowing the variety of systems used, and still under the first question, experts were asked to identify according to which system they would conduct their hazard analysis when they were using more than one food safety system.

The answers were spread sporadically and almost each expert using more than one system gave a different answer. Some would conduct hazard analysis according to HACCP Codex (118MS), whereas others would do hazard analysis according to ISO 22000 (2005) (128MS, 96MS). Some said they would do it according to the standard they would be getting certified on ISO, or IFS or BRC or Codex (86MS, 44MS). Some would follow the rules or the requests that their customer wants, or that the government would ask for (68MS).

Some did not believe there is a difference in how hazard analysis is conducted across different systems, so it is all the same to them (57MS). Whereas another expert, namely an auditor said it did not matter how hazard analysis was done as long as it was conducted logically (19MS).

Government inspectors based their inspections on Codex (2003), and therefore always understood hazard analysis from the Codex perspective (1MS, 795CIA, 499CIA, 1CIA, 65CIA, 278CIA, 572CIA, 607CIA, 171CIA, 178CIA).

B. Scope of HACCP

The next question asked to the experts was about the scope of HACCP and what they believe HACCP covers:

What do you think is the scope of HACCP? Does it cover your transportation after production? And shipping over sees?

Their answers were similar depending on whether they were using ISO 22000 (2005) or just HACCP from Codex Alimentarius.

B.1. ISO 22000 (2005)/IFS Experts in Food Industry

ISO 22000 (2005), or IFS experts supported the idea that the scope is covering steps from raw material receiving until dispatch from the plant. These would include all the steps within these steps such as preparation, production, holding time and storage. Transportation was the point of highlight and confusion in terms of scope. Several ISO 22000 (2005) experts deemed

transportation as optional depending on several factors. One factor was if vehicles belong to the company or not. Another was if the product is produced in different locations, and thus transportation would be considered part of the scope as well (670SC, 636SC, 610SC, 445SC, 296SC, 163SC, 47SC). Another controversy over transportation was whether the product needed freezing or the use of a fridge; otherwise, transportation could be excluded (652SC, 332SC). Other reasons for the exclusion of transportation from the scope were that frequently, transportation is sub-contracted, and thus what happens generally is that goods leave the gates and then they stop being the responsibility of the production plant (359SC). Other ISO 22000 experts did not include transportation although they have high risk products such as sweets and cakes because the auditor never said that they needed to include it (536SC). Some experts noticed that when the customer covers transportation – for example by monitoring the temperature – he or she often does it for money gain or to avoid the loss of damaged products, rather than for food safety (598SC, 400SC).

B.2. ISO 22000 / IFS experts in Catering, Packaging plants, and Farms

Some ISO 22000 experts found this question challenging for catering, agriculture and packaging companies in specific (598SC, 400SC, 523SC). In catering, for example, several experts said that their satellite locations were not covered in the scope since it is hard to control them and only the main kitchen is considered in the scope. This means that different branches or wedding locations are not considered for HACCP analysis (523SC). Farms and suppliers were not covered either although they sometimes cause problems, but again the experts said they were out of their control (490SC, 342SC). For example, for the meat or chicken industries interviewed, the premises and industry were covered but the farms are excluded (490SC, 342SC). Some had a theory that the scope of HACCP must end after selling it to the customer, because of the inability to conduct traceability afterwards (536SC). This differs between HACCP and ISO 22000 because in ISO 22000, traceability is of high importance and has a separate clause dedicated to it. However, an expert has told about his experiences with the scope of HACCP and said that no one asks about it in audits (536SC).

B.3. HACCP Experts

HACCP experts, whether from industry, catering, or whether from consultancy agencies or the government sector, whether from Germany or Lebanon, all had a similar answer (473SC, 308SC, 226SC, 274SC, 186SC, 128SC, 80SC). The answer was that HACCP should cover all the supply

chain from farm to fork and this means that it should cover transportation as well, although they often do not see that happening (473SC, 308SC, 226SC, 274SC, 186SC, 128SC, 80SC). They noticed that transportation was included mostly when they have IFS logistics or IFS broker taking care of it (98SC). According to experts, HACCP covers sections separately without combining them all under one plant or company, so that production and raw material at suppliers are covered alone. Experts saw that it would be easier if it was all merged under one system together (257SC, 2SC, 26SC).

When asked for reasons why HACCP is not always covering the whole chain, answers were that this step was not always practical. This means that often industries did not have control over certain places such as suppliers or transportation or even some lines inside their plants. Therefore, they would exclude it from the scope so that they would not fail to get the certificate. Narrowing the scope of HACCP gives them a bigger chance at passing the audit and getting certified (426SC).

Another major reason why the answers varied between different experts was that the standard itself, whether HACCP or ISO 22000 or IFS, allows the enterprise to specify what they want to cover under the scope they want to be audited on (420SC). Therefore, it gives the freedom to choose if they want the standard to cover the product, the main kitchen, or other parts of the supply chain.

C. First Step of HACCP

Different experts were asked about the first thing they think about when asked to start a HACCP system:

- What's the first thing you/business should do when starting a HACCP study?

The experts had completely different points of view based on their experiences and their concerns. Not all of their answers matched the first step of HACCP which is to "assemble the HACCP team". The results were divided based on whether the experts were caterers, auditors, consultants, inspectors or industries.

C.1. Industries and Caterers

Companies had different answers depending on the size of the company. Bigger companies that have ISO 22000 and IFS certificates thought of hazard analysis first when starting a HACCP study

(342FSH). Big companies seemed to focus on the commitment aspect from both management and team members as a first step to have HACCP in place. Without commitment, they saw that people cannot offer the right information and resources to help make HACCP happen (199FSH). Industries thought first about the availability of the resources and about who can do HACCP in terms of personnel (99FSH). Smaller companies also thought of personnel in terms of hiring qualified experts to do HACCP (295FSH). They considered infrastructure and good manufacturing practices GMPs as crucial to have in place ahead of implementing HACCP (241FSH, 231FSH).

The first step in HACCP for a catering company that has a HACCP certificate was the hazard analysis step to look at the raw materials first and analyze where the hazards are and how high the risk is (189FSH). One of the packaging suppliers, who is HACCP certified, saw that the first driver to implement HACCP was when the customers ask the supplier to implement HACCP (154FSH). Another HACCP certified caterer thought that the first step of HACCP is having a lot of work to do, which is why after finding a system that is already in place, this caterer hires a nutrition student to reapply it to the products that she has (62FSH).

C.2. Auditors

Auditors mainly saw the first thing to think of when implementing HACCP is related to management commitment. Auditors thought that the first step of HACCP needs to be a management meeting inviting all functions to show their full support and commitment for HACCP (331FSH, 248FSH). Similarly, other auditors believed that without management commitment as a first step the system would stay weak, and where there is management commitment the system would take off (331FSH, 248FSH). Some auditors that audit mainly ISO 22000 (2005) and IFS systems have answered that when they think of the first steps of HACCP, they think of pre-requisite programs because 90% of the companies in Lebanon have most of the ISO 22000 non-conformities from PRPs (355FSH).

C.3. Consultants

Consultants thought that training the team is the first main step that needs to be considered. Some consultants that usually follow ISO 22000 and IFS systems observed that the first step to do HACCP should be training the people in the plant on HACCP. The second step should be choosing the HACCP team from the company itself and not relying on a consultant to do HACCP for the company (317FSH, 42FSH). A highly experienced consultant believed that the first step in HACCP is training the team that will be working on it through using the right terms and systems

of HACCP (42FSH). If there was no team to be trained, and they were to bring a consultant, then the first step is to ensure that the consultants gave the needed knowledge and training to the people working there. That is so that when this consultant leaves, they would be equipped to continue HACCP and avoid the failing of the system (42FSH).

Four other consultants gave different single answers. A consultant believed that management commitment needs to be the first step in order to ensure that the system will be efficient and effective (275FSH, 258FSH, 283FSH, 74FSH). Reviewing the GMPs was another suggestion for what the first step in HACCP is (258FSH). A Codex (2003) consultant believed that the first thing one should think of is the scope of HACCP in order to evaluate if it is a big job or a small one, and then one should evaluate the time needed to invest in this study (283FSH). Another Codex (2003) consultant thought of the documented procedures as a first step to implement HACCP (74FSH).

C.4. Inspectors

A Lebanese governmental official believed that the first step in HACCP is the mindset of the company which needs to be convinced about the importance of HACCP (309FSH). Another believed that a research about the product is needed first in order to be ready to conduct hazard analysis as the study starts (266FSH).

The first thing some German inspectors looked for is the HACCP team and who is represented on it (212FSH, 84FSH, 16FSH). They looked for specific functions to be present such as production, warehouse and quality management. They also sought to check if the persons on the team know their responsibilities well. 'When thinking of HACCP, the first idea to come to mind is finding the right people to do that job' is what a group of German inspectors think of (212FSH, 84FSH, 16FSH). Another inspector thought of the documentation of the whole HACCP plan to be needed in place from beginning to end as a first step she looks for when inspecting a company for HACCP (1FSH).

D. HACCP Team

Experts were asked who they recommend on the HACCP teams and who do they see on the teams in different companies or on their own:

- Who do you recommend to have on the HACCP team? How do you choose specifically? In catering?

The answers were separated again based on roles because the influence of each role must show due to their different understanding of the importance of a HACCP team.

D.1. Industry and Caterer Opinion on Teams

Companies differ in their opinion about who needs to be on the HACCP team. They all believed it should be according to the standard, a multidisciplinary team. However, the interpretation of what that means in reality differed in each company. A company implementing ISO 22000 (2005) believed that the team should have a quality manager, maintenance, and warehouse on their team (559HT). However, they did not believe that marketing needs to be part of it because they only care about selling, and they would get bored during meetings. Such people also do not believe that production needs to be on the team, because of conflict of interest: production wants to make the biggest amount of products in the fastest way, and has the perception that food safety would be slowing it down. Other companies had a big team made of a laboratory manager, food process manager, R&D, production manager, maintenance, marketing manager, and human resource manager (464HT, 320HT, 329HT, 169HT). They said that human resource is important because if a change of employees happens, new persons would need training. Furthermore, they thought that purchasing is also important because a change of supplier needs to be communicated so that food safety procedures would be changed accordingly. In big companies, some teams would invite different people from the plant as needed in order to better understand some parts of the production processes (251HT). Other companies have a legal department involved in the food safety team so that they can inform and help with new food safety regulations (153HT). R&D is also part of the team because they need to inform the HACCP team of new initiatives.

Some caterers emphasized that the importance of who is on the HACCP team lies in their level of qualifications no matter which positions they occupied (478HT, 103HT). They blamed the lack of qualifications on how people often get positions out of cronyism and favoritism in Lebanon. Diversification in the team such as including maintenance, head chefs, production manager, and dieticians are also important inside a catering company according to these experts.

Along with the mentioned departments, one of the caterers interviewed talked at length about the importance of having the transportation department in the team or at least have the delivery personnel as part of the HACCP team (488HT). This is because a lot of the delivered food in this company is of high risk and a customer often asks the person in which conditions to store the

products. From experience, the delivery personnel often offer wrong answers due to the lack of food safety awareness about the product at a given place and temperature. A smaller catering company has the team made of themselves, the product supervisor and the consultant helping her put the system in place (56HT). This is because she believes every staff member is responsible for the implementation of HACCP, and not only the HACCP team members. Other catering examples show a trend of separation between administrative and working staff. This company, for example, has two as hygiene officers who plan and follow HACCP all by themselves without asking the people on the ground because they claim to know the process well. After they make the HACCP plan, they would teach the plan to the working staff in the kitchen and explain to them where the hazards are and what they must change in their implementation steps (56HT).

D.2. Auditors Observation of Teams

Some auditors saw a difference in the HACCP team personnel depending on whether they were implementing HACCP or ISO 22000 (576US, 356HT, 80HT). They believed that the team can be smaller when doing HACCP. In ISO 22000 however, the team needs to be bigger. Some recommended having the following departments represented on the ISO team: raw material, maintenance, quality assurance, food safety, production, and the laboratory. Others recommended having the following departments represented on the HACCP team: production, maintenance, and dietician or chef depending on whether it was an industry or a food service establishment. In both HACCP and ISO, auditors recommended that upper management be represented to ensure management commitment and ownership of the food safety plan (576HT). Their presence is also important to understand of the different terminologies such as CCPs and other needed clarifications (576HT).

Some auditors said that the choice of the team not only depends also on the scope of the product, whether food or packaging for food or something else (356HT, 80HT). Another important point is that auditors check to ensure that the food safety team leader is not reporting to production in the organizational chart so that he is able to conduct an objective internal audit (356HT). German auditors make sure that the team has someone to look after regulatory affairs to ensure that companies comply with legal requirements in terms of food safety (80HT). An auditor of SMEs said that he sees a lot of systems made by administration rather than the production departments, and the latter accepts it if the awareness of HACCP is available or otherwise asks the administration to correct the mistakes and repeat the audit.

D.3. Consultants' Recommendations for Teams

Consultants working with industries recommended members from production, quality, maintenance, and purchasing because normally they are often the ones causing changes quoted as 'making problems such as changing raw material sources without telling the team' (534HT). Since they are usually not on the HACCP team, they do not know about procedures leading to food safety breaches such as the need to validate any new material. Some consultants added that engineering is important to be part of the team, and that R&D can be part of it; however, the latter are known to 'not excelling at hazard analysis' (342HT). The stress needs to always be on training the team efficiently and on qualified HACCP personnel.

Consultants that work with caterers usually prefer to have a dietician on the team along with a sous-chef because they believe that the head-chefs do not care much about food safety (547HT). Thus, consultants would rather train the younger ones who work more with their hands and are in the work field. They also recommended having housekeeping and maintenance on the team. It is of upmost importance in the team to have a manager that can coordinate the HACCP plan among departments and drive it to execution (180HT).

'The reason the HACCP team became a multidisciplinary team in reality is related to standards such as IFS or BRC, who set up in their standards some requirements of who should be in the HACCP team', commented one of the high caliber consultants in Europe (38HT). This caused a lot of companies to get their teams right nowadays. Moreover, 10 years ago university graduates did not hear about HACCP, however, nowadays it is being taught at universities although only theoretically. This does not help the students of food science learn much about the practical problems in setting up a HACCP system. Thus, a better education on HACCP is needed in the future on a university level. (38HT)

D.4. Struggles in Teams According to Consultants

A consultant working with SMEs saw that a major problem in teams is the level of qualification the quality manager has versus the other functions such as warehouse maintenance and supplier supervisors (398HT). This consultant, like other consultants, found it crucial that management is represented so that commitment can happen. Such a mentality comes from consultants who are rather ISO 22000 oriented. This consultant in specific highlights that the food safety team leader needs to be the quality manager. Other consultants similarly stress on the need of a consultant

who can well understand the company because SMEs in Lebanon usually run on a minimum of 2 to 6 persons who would not have time or expertise to understand HACCP (372HT).

A European HACCP specialist and consultant sees that struggles with HACCP are more related to the culture and attitude rather than merely the function (414HT). He states that it does not matter who is on the HACCP team as long as they are the people who are directly involved in the production or the cooking of the product. The second aspect is about their attitude during the meeting. Some managers or supervisors tend to use those meetings to defend their functions rather than add input to food safety. That is why attitude is important to make sure that the HACCP team discusses relevant food safety topics. He further stresses on the importance of having a handpicked team who understands operations from firsthand experience and know how machines work. This consultant talks about the major roles needed in the team: a management type of person who can help make things happen, a HACCP knowledgeable person, and someone who works directly on the product. Barriers are often seen with these interdisciplinary roles which is why through training they can open up to each other. The trainer or the HACCP expert should have the right knowledge and definition of what HACCP really is. From this consultant's experience, when HACCP is taught incorrectly and later corrected through other people or trainings, the team gets very confused, disappointed, and demotivated.

D.5. Governmental Inspectors

Governmental inspectors look for a multidisciplinary team with people who are heavily involved in the production, and for a person who can coordinate tasks between different parts of the company (5HT, 19HT, 103HT). They check if all the staff is trained well at all functions such as hygiene and driving to deliver foods. The hygiene department is crucial, in particular, in preventing chemical and micro biological contamination. The departments they look for are purchasing, sales, product development, quality assurance, production, and technical expertise (5HT, 19HT, 103HT). They also look for people in charge of pest control. They find these functions involved in the team in big companies, but limited resources in smaller companies. It is key to differentiate between a big company and small, insists a group of inspectors (5HT, 19HT, 103HT). Small companies would need a consultant on the team to help them understand the risks. Big companies should have several functions namely the legal department to make sure all the requirements are covered. When asked if an inspector found these requirements in reality at companies, he admitted to finding the companies abiding with half of the requirements or keeping the minimum asked (211HT, 262HT). He viewed that in reality few establishments consistently follow HACCP. Another

governmental inspector, when asked about teams, expected warehousing and sales to be heavily involved in food safety so that if a product is spoiled they can stop it from being sold (518HT). Another governmental inspector requires that functions such as production, maintenance, quality, laboratory, top management, warehouse, sales, and IT be part of the team to help in traceability (387HT).

E. Flow Diagrams

Experts were asked to show some of their flow diagrams and were asked how they recommend others to construct them:

- Can I see a flow diagram that you have done? Can you talk me through how you develop a flow diagram?

They were also asked if they often miss steps, or see steps missing in the flow diagrams. Answers were categorized based on the type of flow diagrams presented and the offered reasons as leading to the choice of flow diagram. For a summary of the most important results refer to table 2 below.

Table 2: SUMMARY OF ALL THE RESULTS

It is divided into two parts, the first is based on experts from the industry and their view of flow diagrams, hazard analysis, critical control points and validation. The second part is based on the other experts interviewed such as consultant, Auditors and Inspectors and how they influence the latter 4 points mentioned.

Experts in Industry in Lebanon and Germany					Flow Diagram-HA-CCP-Validation as perceived in both countries by:		
Problems with Flow Diagrams Section: 4.5	**Problems with Hazard Analysis** Section: 4.6-4.7	**Problems with Hazard Assessment** Section: 4.7.3	**Problems with Critical Control points** Section: 4.7.4	**Problems with Validation** Section: 4.12	**Consultants** Section: 4.9	**Auditors** Section: 4.8	**Inspectors** Section: 4.10
Lack of flow diagrams in SME's mainly	Raw materials sometimes are not analyzed as part of hazard analysis	11 experts applied the matrix then decision tree They are mainly ISO22000 users	Lack of understanding if choosing a CCP means controlling it or it can't be controlled there for it is critical	Confusion between definition of validation, verification, and monitoring by experts and guidance documents	Some consultant sell HACCP plans without training teams how they designed it	Auditors understand terminology differently based on their companies' training	Both inspectors depended on HACCP Codex 2003 and were not up to date with other systems
Very detailed flow diagrams	Not naming the hazard or naming every single hazard for a step	Others use tree only to assess which hazard is significant	Choosing many additional yet wrong steps to be CCP's just to have extra control	Only 2 experts understood the concept of process variation in validation	Other consultant is hired only to solve problems and don't get the chance of follow up with companies or update their hazards and systems	Auditors influence the HACCP system of companies to be in a way they approve it even if different than consultant or guidance document	They were not familiar with terminologies different than in HACCP
Missing items in flow diagrams such as important hazardous raw material, timings, water and gas inlets	Use of Generic HACCP plans from different countries and lack of updating hazard analysis	Others use matrix only to assess which hazard is significant	Choosing a CCP based on the equipment availability or lack of it	Only 3 companies applied validation according to Codex validation document CAC/GL 69-2008	Other consultant follows their own methodology which is not always in accordance to standards and teach terminologies differently based on their understanding	Choosing and testing hazard is justified whether auditor asks for it or not	They expressed their distance from updated hazard outbreaks until after the outbreak occurs
	Lack of understanding how to do hazard analysis from company expert or consultant auditor or inspector	Others flip the order of using tree before matrix so assess hazards	Confusion between OPRP and CCP use and choice and switching simultaneously between them	An auditor expressed confusion about what it means, and 3 consultants explained not in accordance to Codex.	Consultants were not specialized in the field where they advise	Auditors were not specialized in the field where they audited	Companies complained that inspectors focus on what they see and the hygiene aspect rather than help with the HACCP aspect
	Inability to detect emerging hazards/limited laboratories in Lebanon/limite			Many interviewed conducted validation based on opinion rather			

E.1. Lack of Flow Diagrams

A consultant in Germany for SMEs observed that most of the times companies do not have flow diagrams at all (146FC). This depends on the company size, and education of food safety. Generally, smaller companies are the ones having almost no flow diagrams. An example was given about the adhesion bakery where one would not find any flow diagrams in such small shops.

E.2. Non-Detailed Flow Diagrams

A high-level consultant does not like detailed flow charts and likes detailed hazard analysis instead (594FC). Reasons for that mentality is laziness and avoiding writing twice, once in the flow diagram and once in hazard analysis.

An auditor believed that if a flow diagram is too detailed, one cannot do hazard analysis because it would be too complicated (804FC). He recommended that it is better to divide the flow diagram into several small flow diagrams so that hazard analysis can be done correctly with the right amount of CCPs. However, detailed flow diagrams lead to complications of ending up with 40 CCPs. Some consultants said that they write the flow diagram for the company without teaching them how to do it (856FC, 545FC, 217FC). The flow chart is brief because they have descriptive SOP for every step in the flow diagram placed in another file. For example, details about receiving and storage are described and the flow diagram is only the summary of their descriptions.

A major cause of confusion for a company is having two consultants, one asking for detailed flow diagrams and the other one asking for brief flow diagrams (897FC, 718FC, 658FC). An expert prefers brief diagrams because they are easier to write. This preference is due to the limited time the experts have at work due to carrying out several responsibilities aside from food safety. So, flow diagrams would look like 3 to 4 steps only containing purchasing, receiving, cooking and cooling. This type of brief flow diagrams is mostly seen in catering where most processes include receiving, and hot and cold kitchens.

E.3. Detailed Flow Diagrams

Detailed flow diagrams are encouraged and seen mostly in industries which entail several steps to produce a product (658FC, 508FC, 497FC, 449FC, 638FC). Samples of detailed flow diagrams include water supply, reasons for rejection and acceptability of products, raw materials, finished products, temperature control, delivery time to customer, shelf life control steps, packaging material, or gaz. The reason some companies make it detailed is so that new or changing

employees understand the process, machinery, how they are used, and what they are used for in detail (449FC).

Quoted here is an example of a detailed flow diagram that includes little details (697FC). It is done by writing a big general flow diagram and then dividing it into little flow diagrams. The expert said:

> "I show you something recent…Let us choose nuggets because it is common. Receiving has a FC before it from the cutting department and in cutting there is a flow diagram just for cutting the product. Then we say transfer to sorting ingredient and trimming by knife. We also have the 'waste part' reversing the trolleys, also we mention the grinding and its description, the mixing also, dry ingredients have its own flow diagram and each raw material that we have is mentioned, and here I just write a summary because the details are in a separate flow diagram, also all details, of what is in and out is mentioned. Moreover, the way we function in slicing and trolley and holding some in cooler, trolley on line, forming machine, battering, ice, visual inspection on shaped material, all verification we add to the flow diagram, breading, where we have bread crumbs entered and in which warehouse it is and how it arrives to the line, and soya for example which I identify so I can assure that I have all details…"

E.4. A Balanced Flow Diagram (Neither Short nor Detailed)

A high caliber international consultant/auditor often finds flow diagrams either too general or too detailed (66FC, 237FC). In quite a lot of cases some needed details are missing, like some ingoing things such as water, air, or compressed air, and some of the outgoing things such as waste and energy. They are missing because companies focus on main production steps and do not consider what is going in and out of certain steps. It is recognized that very often companies divide their processes into different parts so that they do not have only one flow diagram starting from reception to dispatch of goods. But, they cut it into different parts, and in this case, gaps are created in between the parts. For example, one department goes from A to D and B to C and misses steps in between. By doing so, some things get left between departments and lost. Subsequently, the missing parts would not show up in the HACCP analysis, and as a result they are not showing in the linking parts.

E.5. Missing Items in Flow Diagrams

A high caliber consultant/auditor from the Middle East was asked about examples of missing steps from flow diagrams (762FC, 742FC, 732FC). He found that more than 90% of the experts compile the raw materials together in the same flow diagram, in the same group of receiving of raw material, inspection of RM, storage, preparation, cutting, cooking and then serving. When he looked inside them, he found that the idea is that out of 90% of those, in more than 70% of the cases, the problem is that they do not know how to draw a flow diagram, so they simply combine all steps together. Some experts saw that companies often miss the description of the step which holds the hazard (649FC, 619FC). For example, they would write statements like emptying the bag without specifying the container's type and method of emptying. That would influence the type of hazard which later enters the chain. Companies underestimate the steps of receiving and packaging, and rather focus on cooking. By this, they miss out on analyzing the most important hazards that allow the entering of microorganisms into the product.

Auditors noticed that sometimes companies forget re-work, and they add it later after audit (965FC, 804FC). Sometimes, they forget and skip the pre-preparation step, and they jump to a new step and forget it although it is a separate step. Also, if something is in the middle of the process, they get confused. Most confusion, though, is in hazard analysis. Some forget to tell about changing filters in flow diagrams and maintenance items especially in factories; however, in catering the challenge is that the chef never follows the same steps but often works inter-changeably (804FC, 586FC). Some forget to put steps which are control measures, like CCP, though at times it is the best practice and not a requirement. Waste in ISO 22000 is a requirement and must be included.

Two consultants faced the problem of not receiving quantities of ingredients, such as additives because companies claimed that they are secret recipes (874FC, 742FC). Missing such information from flow diagrams could result in overuse of additives and lead to a safety breach. Other missing numbers from flow diagrams are pasteurization time and temperature.

E.6. Reason for Missing Items:

E.6.a. Hiding Information/Objectivity

A consultant struggled with companies hiding information from them which leads to missing steps in flow diagrams (874FC). The reason for hiding is due to secrecy of recipe, or to including illegal

additives. Another saw the flow diagrams from a managerial point of view which does not give them an objective vision of the chart (804FC). This causes the plant to oversee certain steps and skip them from the flow diagrams. Such people often need a third party to verify the flow diagrams.

E.6.b. Consultant Teaching

Some of the experts interviewed have observed that flow diagrams mainly fail when they are following a generic template (762FC, 634FC, 146FC). An auditor/consultant believes that 95% of 480 flow diagrams he audited have wrong flow diagrams. The reason he believes they are wrong, is that they are based on experience and not on theory, and they are made to make a company's life easier and not to identify the hazard correctly. Moreover, they are made limited only to the knowledge that people in this company know, and they don't include information from further research. 'Companies generally don't know how to draw a flow diagram, and they don't have guidance written anywhere' he says. So, they usually hire a consultant and this consultant often has a template that he fills for every company he consults. Such consultants usually make it very easy and simple for the client to understand and apply a flow diagram. Yet, this leads sometimes to miss some steps.

E.6.c. Not all Standards Specify Steps to be Mentioned

Another problem is missing steps like re-work because of standards who don't mention it like the 'codex standard' says another consultant (762FC). He further comments:

> "In ISO 22000, however, there's a full page about flow diagrams in 2 clauses 7.3.5 and divided the flow diagram, said it's supposed to be simple but accurate and detailed enough to a level that allows me to do hazard analysis without missing something, so simple and detailed and allows me to do all, and ISO 22000 saw that there are many points people don't see like re-work recycle and products and bi-products. And from re-work we had a huge outbreak because people don't analyze these steps because they don't include them in the flow diagram in the first place."

E.6.d. Timing of Onsite Flow Diagram Verification

A fourth problem concerns the timing of flow diagram verification (762FC). Industry confirms that a consultant usually fills flow diagrams concerned with the day shift and not the night shifts. They report that the night shift does not follow the same flow in the diagram because there are no managers to supervise.

E.6.e. Working as One Person Rather Than as a Team

Some experts observe that missing items in flow diagrams come from having one person write the flow diagrams and not working on it as a team (689FC, 449FC, 88FC). Another problem is that if different people do different steps – for example, one team member does flow diagrams and the other does hazard analysis –, then some steps are missing, especially if they do not follow a numbered system between both steps (88FC).

E.6.f. Not Included in Scope of Standard/Audit

An auditor usually does not require the step of transportation to be in the flow diagram because he says that the scope of ISO 22000 certificate does not include things outside the manufacturing area (589FC). Thus, auditors do not ask for such a step because it is not included in the scope of the audit.

F. HACCP – Raw Materials

The next series of questions asked to experts were about hazard analysis and critical control points; how they regarded and conducted them. They were questioned about raw materials, whether they were part of these steps or set as a separate program. Experts were asked whether they considered raw material as part of HACCP or as a separate program. They were also asked why they would consider them part of either:

- Are raw materials part of your HACCP or do you control them separately? How?

> FOR CATERERS: Are you concerned about raw material safety in catering and restaurants? How do you manage this concern?

All experts' opinions were split between seeing raw materials either as part of HACCP or GMP or a combination of both.

F.1. Industries' Different Perspectives on Raw Materials

Companies interviewed in Germany generally agreed that raw materials were part of HACCP as well as part of a supplier program; but overall that they were part of the HACCP system because they get into direct contact with the food and because it is all about handling very critical products (65RM, 138 RM, 169RM, 213RM, 957HA). Some classified them as OPRP within HACCP, but those experts did not know why that choice was made inside of their company (957RM).

Other industries had different opinions (445RM, 284RM, 1141HA, 270RM). Some considered raw materials more under GMP and PRPs including visits to the critical suppliers and supplier evaluation program. The choice to visit suppliers more often was based on the risk level and auditing purposes of the supplier's ISO system. This helped them consider raw materials not as a CCP in receiving because the supplier chose it as a CCP in his own premises. Inside one's own plant, raw materials receiving of chicken, for example, are not a CCP. However, trimming temperature is. Therefore, such companies consider receiving not to be part of HACCP; they consider it as a separate system where they can decide to reject materials or not.

A big food company in Lebanon had another opinion about raw materials (284RM, 1141HA). It believed that raw materials are a cross-section between GMP and HACCP. In a sense, they should have hazard analysis as part of HACCP, but their controls need to be similar to GMPs. Additionally, the company also feels that they are a CCP sometimes. For example, in storage conditions, humidity is a GMP, and there is a checklist for it to see if it is a CCP. The reasoning was: 'you see where it is... so here they justify it as something having it in corrective action something filled, if it happens then you can solve it.' So CCP is something which can be removed or added depending on whether monitoring was done well or not. Another big industry regarded raw material part of a storage program which is a PRP. However, upon analyzing the hazards, then this step becomes part of HACCP (270RM).

F.2. Raw Material's Place in HACCP – Auditors' Different Perspectives

Auditors had completely contradictory opinions on whether a raw material step is a CCP or not (HA2381, 541NH, 2034HA, 346RM). Some auditors saw that the receiving and testing raw material step is considered as a CCP if frequent testing of every batch is happening. The challenge with this step for them was to find laboratories that tested chemical hazards in Lebanon like pesticides. However, other auditors said that this step can never be a CCP, unless the plant is using this point for initial safety in order to reject or accept a raw material; however, a CCP in ISO 22000 needs to have online monitoring (541NH).

Other auditors said that it depends on the type of raw material (2034HA). For example, if the raw material is fresh milk and the finished product is milk, then the chemical hazard is antibiotic residue and this receiving step would be a CCP, but if the aim is to produce yogurt then the step is an OPRP. That is because milk is homogeneous in mixing, and one sample is representative. However, if the step is an OPRP, it does not have to be measured continuously. Another auditor

recommended doing hazard analysis for the purchasing step (346RM). He preferred receiving to be part of hazard analysis, hazard assessment, and the HACCP system. This is for receiving being as an act; however, as a structure, they considered it a GMP not a CCP.

F.3. Consultants' Opinion on Raw Material

Several consultants were asked about raw material and whether it is part of HACCP or a separate program (84RM, 148RM, 186RM). The opinions varied widely. Some believed that raw material is part of the receiving program (Wareneingangskontrolle) and that it is not a CCP but a CP. Examples illustrating this opinion were steps such as sterilization of a can and cooling it after cooking to prevent bacteria. CPs are steps such as pest control. Receiving of goods can be a CP as well. They justified it as such and related it to small kitchens which have little ability to control raw materials as CCPs. They prefer to use certificates and certified suppliers.

Another consultant had a different mentality (48RM). He considered raw materials as part of the HACCP because purchasing goods is often a decision taken by a department and there lies a possibility to let in any type of raw materials if there was no strong control. He found this as the department with the most problems related to wrong decisions about the specification of raw materials. Another reason given as to why raw material is part of HACCP is that in the Codex is written that hazard analysis has to take into account the whole food chain. For example, a dairy company has to think about where did the milk come from, what is the quality of the milk, what is the milk like, what is the influence of feeding on the milk, and so on. Some of the companies are surprised daily by raw material characteristics. Therefore, they should take care about what is showing up ahead of time by making the right decision regarding suppliers.

A consultant saw that receiving is an OPRP simply because when it is under the umbrella of HACCP one can highlight its importance (421RM). Although he thinks HACCP implementers consider it a PRP, but it is more highlighted by adding it under HACCP as OPRP. A high caliber consultant (318 RM) defines the receiving step of rice from his client as an OPRP and certainly not a CCP. This is because what is monitored is limited, and the certificate the processor sends is evidence only. So, receiving is not a CCP according to this consultant, because nothing one does could be monitored in real time. Usually, there is a procedure in place as part of PRP for receiving. In ISO 22000 and BRC, PRP is about receiving. Even if one can test instantly – for example, the mycotoxin – upon receiving, it cannot be managed, and nothing can be done to limit its risk. Taking a simple measurement cannot be considered a CCP, because there is no process.

It may be accepted as a CP, but never as a CCP; for it be can accepted or rejected, but it cannot be continuously monitored. Unless 100% of the materials are inspected, they cannot be considered a CCP upon receiving.

A consultant defined the raw material step as either CCP or OPRP depending on whether the supplier is a new one or an old one (128MS). If the supplier is approved, the step is a PRP and there is regular testing for it, but if the supplier is new it is a CCP unless the client shows its safety history. Then, it is a CP or CCP if HACCP is used, and it is an OPRP or CCP if ISO 22000 is used. Hazard analysis can be done according to ISO 22000. If HACCP is used, then hazard analysis is done using Codex tree. Another consultant said that the importance of raw materials lies in the credibility of the suppliers (433RM). Critical examples of raw materials are rice eggs, fish, and oysters – since in England people died from oysters–.

F.4. Governmental Opinion on Raw Materials Classification

Lebanese government inspectors believed that raw material is a CCP because this is where it can be rejected if it has a hazard such as high pesticides levels (3RM, 28RM, 36RM, 117RM, 248RM). Other governmental inspectors from Germany believed that raw materials are part of HACCP because they need to be analyzed. There would be a receiving program, however, the receiving step afterwards would be part of hazard analysis. A governmental expert from Germany did not care so much about the classification given to raw materials as long as they were controlled. She saw that raw materials can be part of both HACCP and GMP. This would depend on whether it was a big or a small company and if they had a laboratory for testing. On new hazards, inspectors in Lebanon identified a problem with detecting the hazards (498NH). The problem is that there are not much scientific researches done, and companies often depended on what they know rather than on doing their own research. Another problem was that there is not much link between universities and industry. Lebanese officials claimed that they agreed with other governments to exchange research results, but that was yet to be realized.

F.5. Credibility of Raw Material

Some auditors from the Middle East related the safety of raw material to the country they come from regardless of whether they are ISO certified or not (HA2381, HA2218, HA2119, HA2034). They expressed that it is related to suppliers who are local Lebanese suppliers or from the Middle East or China, because depending on the country's level, developing or not, their certificates can be trusted to be valid or not. Similarly, an expert expressed facing problems with raw material

receiving due to being in Lebanon (502RM). They believed this step to be an OPRP because it has many hazardous factors affecting the receiving of raw materials, e.g. they can be received not well chilled or expired at times. They believed that abroad such problems are not seen as frequently. This step is not a CCP for this catering company because they follow further steps to control the hazard in raw materials.

G. HACCP Industry

G.1. Hazard Analysis Industries' Application According to Standards

Different food industries and caterers from Lebanon and Germany were asked about how they conduct hazard analysis:

- Can you please describe to me how you conduct hazard analysis? Risk Assessment (FMEA, 2D matrix, random?

  a. And the decision on whether it's a CCP or GMP?

  b. Where do you find information on how to do this? in standard or regulation

  c. Where do you get your information on hazards from: official controls, consultants, regulations, guidance documents, university research, other?

  d. Do you think there is a difference between hazard analysis and risk analysis? Hazard assessment and risk assessment? What is it?

The answers were different but shared some similar aspects. Some companies in Lebanon would study the finished product at first and research about the hazards it may have, and then observe the raw materials and research about hazards in them as well (HA2292). They also observe the flow diagram of the process and assess where money is needed for changes in the process. Afterwards, they do a step by step analysis based on the flow diagram in order to see what potential hazards exist. At each step, they attempt to define physical, chemical or biological hazards. Some of them follow the flow as such: they do the likelihood and severity for each hazard along with its justification, all to find the significant hazard. Then, they pass it through the decision tree, define the acceptable level with references and limits, and finally set specific control

measures for each step. In Germany, some companies applying ISO 22000 in accordance to the standard do the following (978HA):

'Hazard analysis we have it like a template where we first describe the process steps, and then we describe the hazard, the first column is about type biological, chemical, physical, and then we describe the hazard itself, so like contamination in campylobacter or something, so it has to be a specific hazard, and then we describe what is the reason and where does it come from, origin of hazard, and then we evaluate the severity from 1 there is no impact to 4 and it's really a serious impact and we evaluate the probability so 1, never happened, 2 we work with it regularly and then we have like a matrix and the hazard steps are under probability of 1 and severity of 3, and 4 and the of course probability of 2 and severity of 2 or 3 I am not quite sure now, they are all significant, and then we go through the decision tree and the decision tree is based on the Codex Alimentarius. Other numbers are managed by the PRP system and then we have to be sure that our PRP and which kind of control we have and is it really effective. CCP is sieve, hair net is CP and OPRP is cleaning. That's how we classify them'.

G.2. Hazard Analysis Challenges

Some experts expressed that they face challenges to understand, implement or explain the step of hazard analysis. The reasons behind these challenges are explained below by industries at first, and combining the different points of view of consultants, auditors, and inspectors.

G.2.a. Lack of Hazard Naming

The first and most common problem in hazard analysis was the lack of specifying names in hazard analysis (263HA, 536HA, 348HA, 1839HA, 2218HA, 536HA). For example, a HACCP system in a hospital was done by an external consultancy company. When it was checked during the interview, hazards were not named specifically on the HACCP sheet and it looked more of a GMP sheet. The expert responsible for HACCP in hospital did not understand terminology differences in HACCP and had adapted them to a hospital context and focused more on hygiene. Another big catering company does hazard analysis according to 'HACCP principles and 852 EC Food Hygiene Law because they get inspected a lot,' said the company's expert (536HA). The names of the hazards are not written, but they are combined all together for all categories. The monitoring happens for both CPs and CCPs. Similarly, another consultant believed that it is okay to write 'microbiological hazard' and to give an example like salmonella or E. coli or bacillus cereus

randomly (348HA). He believed it is important that companies know in general which microbiological hazards they are dealing with but not necessarily for each step.

Another example in a catering company shows that hazards are named generally and not specifically (1839HA). When asked about how to identify hazards, one of the big consultant companies, showed a company template used for all companies where there was no specific naming for hazards but rather general labels such as microbiological, chemical or physical foreign bodies (2218HA, 536HA). Some experts have related the problem in hazard analysis to people missing steps in the hazard analysis process (2381HA). Examples of this is missing and disregarding allergens as hazards. Another challenge is missing potential hazards in certain steps by not mentioning them and disregarding them in hazard analysis.

G.2.b. Use of Generic HACCP Plans

Another problem with hazard analysis is that companies often use generic HACCP plans found in books or online and just copy the hazards from there (2381 HA, 1838HA). An auditor said that using generic HACCP plans or templates causes the HACCP plan to be one of the weakest documents (2380HA).

G.2.c. Generic Names due to Consultants

When an expert who is also an experienced trainer and consultant from the Middle East was asked about identification of hazards, he said that most hazards he had encountered were replicates from the same consultants (2034HA). They usually bring outside references and apply them to where they locally are and this is another problem with hazard analysis, where all companies are given the same information despite having different products and processes.

G.2.d. Lack of Good Consultants due to Cost

One observation noted by an expert was that very few companies hire a good experienced consultant because they usually are very expensive (2034HA). ‘They would then go for cheaper consultants who are usually inexperienced, or not experts in specific fields’ he added.

G.2.5. Lack of Hazard Identification due to Lack of Legal Requirements:

An observation collected from an auditor was that many companies are not aware that they have to look for legal requirements in Lebanon in order to identify all hazards (HA2119). This auditor has seen a lot of companies who are fully operational for the last 50 years, and yet have no

requirements from the government. The expert said that this lack will lead to a non-conformity during the audit.

G.2.e. Wrong HA due to Wrong Understanding of HA

One expert said that she sees the sterilization of pistachio as a new critical point, however, she does not know which hazard she is controlling; so she just writes a step about sterilizing pistachios in hazard analysis (589NH).

G.2.f. Choosing Every Hazard

An auditor said that a common mistake in hazard analysis is that people do not understand that it is a risk-based study (2118HA). This means that they mention all hazards that may happen and have heard of in their life and forget to do filtration based on hazard assessment as if all hazards were significant. This auditor sees this problem as the main issue. This made her change her audit method by looking directly at the hazard assessment and checking if it is a risk-based research and then go into the details of the hazards.

G.2.g. Laboratory Challenges

Some of the consultants explained that the short-comings of hazard analysis are due to the inabilities of laboratories to test all hazards in Lebanon (HA2292). One expert explained that

> 'In reference to testing non-food items, companies test according to Libnor standards and there could be some pathogens which can't be tested because they are not in the standards. Also testing in Lebanon is very expensive, so companies barely test what is required in the Libnor standard. Examples of this, is testing air quality with IRI or AUB laboratories, and there are also specific tests for air quality inside air ducts. As for hand swabbing, there is a Libnor recommendation in the standards to check if there is bacteria or pathogens on the hands."

G.2.h. Food Emerging Hazards

When auditors were asked about some of the new hazards being discovered in food safety, some of the examples given for Lebanon were pseudomonas in water or acrylamide or solanine in potatoes and nuts (536NH, 1068HA). Furthermore, a company which is ISO 22000 certified has always tested positive for pseudomonas (605NH). Other certified companies as well still test positive for salmonella (511NH, 589NH). Other auditors/consultants talked about specific strains

of bacteria as emerging hazards such as Kentucky salmonella found in an industry (511NH). Allergens were also hazards that were mentioned as often missed by some consultants and auditors and an example of a hospital was given in that regard which didn't mention allergens as hazards for patients (516NH). Some auditors commented that 'Natamycin in dairies for example. When I was in a chicken industry we got to know bird flu. Such things, always you should take it into consideration' (346NH, 270RM). Inspectors in Germany spoke about norovirus, however, they said that it is not a new virus but is new in food, and about the EHEC that came with the sprouts (3NH, 70NH).

G.2.i. Non-food Emerging Hazards

When experts were asked about non-food hazards, examples from the catering field were mostly given (516NH). One example was about an environmental assessment done for a restaurant as part of HACCP where they had natural plants for decoration. They said that this analysis had helped them see that plants attract pests which may be passed over to the food and the customers would complain. Conducting a hazard analysis for this situation helped them make the decision of replacing the natural plants with artificial plants. Other new hazards were flower pots in the hospitals, although the consultant who made this comment revealed that in the kitchen they were using rosemary plants which have hazards as well (181NH).

From the industry, examples of non-food hazards were given such as iron pieces from a sieve, some utilities and equipment, old machinery causing metal to fall into the product, and paint from the ceiling (468NH, 294NH, 312 NH, 274NH). A new hazard from an industry which is not common, was E. coli coming with a plastic bag supplier (360NH). They used the plastic bag to pack the lettuce. Although at first, they thought the bacteria was from food, as is usually the case, they later realized that it is actually from the plastic bag industry. Thus, the bags were contaminating the food. Other examples of emerging hazards given were non-food hazards such as packing material, migration of ink on the material, and the board used to cut this material on as a new non-food hazard (484NH, 230NH).

G.2.j. Challenges of Detecting New Hazards

The experts admitted to some challenges in discovering the new hazards from the two countries. The challenges were mainly country influenced rather than expert influenced.

i. Lebanese Laboratories:

This challenge is related to Lebanon, and the fact that it is not fully equipped for testing and research (605NH, 541NH). 'The challenge with new hazards like with the acrylamide is the lack of testing methods recognized internationally in order to test it and detect its presence' said one of the company experts. For this reason, an ISO certified company had the hazard listed but had not been able to identify its controls. Another challenge for detecting new hazards in Lebanon is the lack of research and development centers (408NH). 'Moreover, Codex isn't updating the food standards,' some experts complained. They complained about their inability to find new information through Codex and had to rely only on their experience. 'Some industries discover new things in their laboratories and send to the national laboratory to investigate more about it however that laboratory says that they have never seen such bacteria before and know nothing about it,' explained another expert.

ii. Catering Challenges in Lebanon:

On emerging hazards, a catering expert answered that they do not have them in catering because they do not have the time to look for them and analyze them as the turnover of food is two days (468NH). Another auditor, when asked about catering and emerging hazards, said that he does not recommend doing HACCP for catering because the hosting environment cannot always be controlled (360NH, 468NH). 'New hazards are found when things go wrong,' commented another consultant. The following are examples of new and undiscovered emerging hazards as expressed by one of the very experienced catering consultants (422NH).

> "Pests, rat feces in tea bags, when making sushi the rice has to be cold rice, particularly we have to keep it warm for so long and mole down with your hand, so something in the rice that people can stomach, the saucepans, wrapping material, chemicals of course, edible flowers, in Joumayra there was loads of flowers experimental kitchen, and many people use flowers, they use them over here, edible flower, they tend now to use fungi, those are poisonous."

iii. Inspectors' Cooperation with Health Department in Germany

Governmental inspectors in Germany, when asked, have expressed limited to no experience in new hazards except for the ones they hear about in outbreaks such as norovirus in strawberries (401NH). The inspectors had some new hazards coming from seeds sometimes, or dioxin hazards (3NH). They said they did not expect norovirus because the health department did not inform them about it as a hazard ahead of time. Inspectors always think about zoonotic hazards

coming from animals such as E. coli or salmonella, but for viruses, they said that the health department is the source of information.

iv. Lack of Tracking Outbreaks in Lebanon

'A main problem in Lebanon is that hospitals or the ministry of health are not tracking food borne outbreaks from patients and relating them to food" said one of the consultants when he was asked about new hazards (389NH). He said that not many new hazards are emerging, because products are not really sensitive to such hazards.

> "Basically, Listeria is not new to us in Lebanon but in Lebanon people do not take care about it and now it's coming more and more, because people are going more into the fresh products, campylobacter is another one, E. coli some types we don't have them here but actually if you go to the other countries you take them as important. In Lebanon nobody got killed form them or nobody knows if anybody got killed from them or sick from them we don't take them into consideration but you know they exist."

Other consultants see that allergens are a new type of hazard in Lebanon although experts do not give them much of importance (349NH).

v. Lack of Auditing in Germany

Other companies follow the regulations and laws very accurately in Germany (NH70). When asked about new hazards, they mentioned hazards like the H1N1 crisis that happened as an example of an emerging hazard. They believed that the salad company did not have HACCP and was not audited and that is why the outbreak happened. They were glad that the law was changed to 'Verordnung 2073' saying that hazards must become updated. They wished that other laws can be changed to avoid other outbreaks such the law for egg products. Hence, the step is also a CCP, as now it is only a CP because it cannot be controlled online. Other companies spoke about having updated their controls recently because DIN came up with a new norm for lowering temperature and time of cooling pasta or rice and this was the emerging hazard discovered by DIN for them (116NH).

G.3. Hazard Assessment – Industry Application According to Standard

After hazard analysis, experts were asked about what they do next. Eleven of the experts followed the Codex method and described the process as such: 'they assess hazards first by measuring

the likelihood and severity of the hazards to see if they are significant or not. If they are significant then they use the decision tree to know if they are CCPs or not' (2118HA, 468HA, 957HA, 1068HA, 1285HA, 1708HA, 1194HA, 1838HA, 59HA, 20133HA). Those experts or companies are mostly ISO 22000 implementers.

Experts, who mainly follow ISO 22000, gave examples of how at first they check the likelihood of occurrence and the severity of a hazard by building a scale of 1 to 3 and multiplying it in a 2D matrix (1839 HA). 'Whatever yields a high number such as 9 is then passed to the decision tree,' explained a company expert. The reason scales of 1 to 3 are chosen is because experts believe that the scale of 1 to 5 scales is for ISO 14000 and this one is for HACCP. This expert chose chilled storage as a CCP. This lack of a written standard for using the matrix was a source of confusion expressed by some other companies using different scales (1068HA). 'The hazard assessment depends on hazard assessment matrix. The problem is there isn't a standard method that specifies which numbers to use, or a matrix you must use. You can use whatever you want,' said one of the company experts. This food company implements ISO 22000, uses Codex standards, and researches a bit to simplify the case of 3 levels by 3 levels.

Another example in a catering company showed that hazards are not named specifically (1839HA). This company does the hazard assessment according to the likelihood and severity matrix. If the frequency is high, it follows the decision tree and vice versa. That is why it has only 2 CCPs: cooking and cooling. Also, the company has defined OPRPs which are receiving. The disinfection step for them is another CCP. It believes that having many CCPs means that the system is wrong. The rest of the experts, however, do not have the same understanding about hazard assessment and carry it out in a different order as per the next 3 sections.

G.3.a. Hazard Assessment – Using Decision Tree Only

Codex-HACCP users, around six of them, were mostly directly using the decision tree after hazard identification (348HA, 1979HA, 2117HA, 809HA, 1005HA, 1579HA). They would skip the hazard assessment step, and directly insert the hazards found into the tree and come out and say if they were CCPs or CPs. Those experts were from the government side, or auditors/consultants of Codex (2003). Moreover, one consultant commented that after identifying hazards, one must use the decision tree directly because he sees that the matrix is quite subjective.

G.3.b. Hazard Assessment Only – No Use of Decision Tree

Five experts chose CCPs or OPRPs based on hazard assessment only, two of which were

consultants training many other companies for ISO 22000 and HACCP (1904HA). Moreover, it was told by a consultancy company that depending on the matrix numbers, one can know if the hazard step will be a PRP, OPRP, or CCP. 'They don't need to use the tree at all to understand what type of step it is,' he commented. Examples of using the scale and matrix vary on the understanding of each expert. Below is an example for implementing ISO 22000 in Lebanon. The company assesses all raw materials, utensils, environment, collecting all hazards, then does hazard assessment for all hazards using 1 to 5 scale. Based on this, the company decides which control step to use: CCP, OPRP, CP, or GMP. Their understanding of those steps is as quoted below:

> "OPRP is related to the basics available in the company like the making of Knefe - a Lebanese sweet. Nylon in food is an OPRP because we control it by training. GMP is more with employee directly like if he should wear gloves or how he should work. OPRP is not just maintenance, it is also other things like water station. CCP is like visual inspection, unless there is a step afterwards. If there's no step afterwards, it can be CCP, but if there's a step after it like grinding and sieving, then visual inspection is not a huge CCP because there is a step after it. Metal detector, is a CCP at its supplier. Hazards that are CCPs, are such as physical hazards inside the nuts like the stapler piece in nuts for example."

A raw material company conducts HACCP using the FMEA to understand the likelihood and severity, and based on this system they have found no CCPs (661HA). They have only control points. Examples are such as closing doors so insects do not enter. They make decisions using team meetings. They also use a 3-dimensional hazard assessment where they control the risk and then re-calculate to see if it still causes risk. They do not use the decision tree as a way of finding CCPs, but rather depend on calculation of numbers in hazard assessment. Another company uses a higher scale for assessment (1579HA). Based on the multiplication they did, they decided that if the number is above 10, this is a significantly high risk, and if it is below 10 then it is not, and its likelihood and severity would be very low. They use the 1 to 10 scale, and when they remove a hazard below 10, they control it using GMPs. When it is above 10, it is automatically considered a CCP. So they have only two options for hazards, either CCPs or PRPs and both options belong to HACCP. They do not have options such as CPs or PRPs or OPRPs.

Another company expert who implements HACCP, believed that CCP is derived depending on whether received material comply with the standards or not (1141HA). However, the decision of whether it is a CCP or not is given by using the 2D matrix. The expert comments that while other

people prefer the decision tree, he feels that the matrix is more precise.

G.3.c. Hazard assessment – Using Decision Tree First Then Matrix

A big company in Germany does hazard analysis according to HACCP principles and 852 food hygiene because they get inspected a lot (536 HA). They started by using the decision tree, and then the hazard assessment with numbers and matrix. Results can either be a CCP, CP or GMP. Receiving is divided into categories and it is all CPs. All heating and cooling are CCPs. The names of the hazards are not written, but they are combined all together for all categories. The monitoring happens both for CP and CCPs.

G.4. Determining Critical Control Points and Control Points:

G.4.a. Application at the Industry

After hazard assessment, control of hazards should take place. Some examples given by some experts were matching the ISO or the HACCP standards (2034HA). In a dairy plant, a CP can be the supplier, selection, and identification for all raw materials. OPRP checks for chemical hazards upon receiving, such as dioxin, or for testing initial count known by measuring the acidity percentage in milk. For milk, UHT, pasteurization, or sterilization are all CCPs.

Some examples were given about chips such as having 4 CCPs in total and 1 OPRP. An example of a CCP as stated by the expert (1068HA):

> "is Solanine which is a chemical hazard that maybe present in potatoes tubers that I remove during pealing complemented by trimming and cutting green section from the tubers, 2 CCPs here, which has HACCP plan. Hazard is Solanine, CCP is pealing, and CCP2 is cutting and trimming green umbers. Monitoring by peel time, peel percentage. It is visual inspection and still CCP. I have acrylamide hazard, and control is blanching of potatoes, it's an OPRP because for acrylamide we have no decided data about acrylamide and it doesn't have a maximum value and also, it's not a hazard that is present and you are eliminating it and reducing it. We are eliminating the likelihood of it formation so this is OPRP and we work on the temperature of water and the speed of the blancher and the time and temperature and we verify it by the acrylamide test and we are the only people in Lebanon who have it."

A corporate company in Germany said they had clear understanding of HACCP terminology and where it needs to be used. They described it saying:

> "So usually you have CCPs or CPs, or nothing but what we did we came up with OPRP or with a PRP or with a CCP and it was difficult for some auditors to understand because it's not a usual system but it doesn't matter. At the end we recognize that it's more precise and more helpful than if you only have CPs or only have CCPs. So, example of PRP we have the CIP cleaning so you can't measure exactly so it's not OPRP but you have to have it that's clear because otherwise you have problems. Typical CCP you have is pasteurization… OPRP is foreign body control."

G.4.b. Confusion by the Industry

Other industries, however, expressed huge confusion concerning what a CCP could mean or signify (HA 2292, HA2119, 1904HA). One sample of the implied misunderstanding about CCPs is such as what one of the company's experts and implementers of ISO 22000 said:

> "Critical is something I can't control or I can't in case it happened I can't fix the mistake there is, I found a way to fix the mistake so I don't think it's critical. Critical is something I don't have a next step to do corrective action."

Another source of confusion in naming the control as a CCP, OPRP or PRP is linked to the change from HACCP codex to ISO 22000 or IFS (HA2119). The experts said that in more than 50% of the cases, the companies have named OPRP as PRP or CP during the time of HACCP and then transitioned it to OPRP when they shifted their systems from HACCP to ISO 22000. Another company expert shared a similar thought about confusion due to switching systems (1904HA). He was quoted saying:

> "They didn't understand the difference between the two systems because it's not clearly defined how to choose a control step. They had many wrong examples of CCPs when they had their HACCP systems for example all temperature measures were CCPs regardless of what they measure. This resulted in a HACCP system that had first contained 100 CCP's and no justification of why it was done that way."

This system was done by a prior quality control manager to the one interviewed (1904HA). The current expert said that when she changed to ISO 22000, she had much less CCPs and fewer OPRPs and justification was added prior to choosing both. She also observed that auditors do

not like using decision trees because it gives many CCPs especially that an auditor was encouraging her not to use it.

G.4.c. Choosing a CCP Based on Equipment Availability

When choosing between a CCP and a CP, a common observation seen by a consultant is that companies tend to decide which step is critical depending on availability of the tools and equipment to measure the control (2034HA). Examples were offered by consultants saying:

> "Measuring water activity is an example. They justify such a step by saying it is a continuous measurement since all the batches can be tested so the sample can normally be representative. Validation, as well, proves this. So once there is the ability to test something, it is immediately a CCP, if it can't be tested then it's not a CCP."

G.4.d. CCPs and CPs Found in Generic Models

When asked about CCPs in the catering sector, some experts said that the choice of CCPs and OPRPs is based on experience (1659HA, 887HA, 1838HA) for example:

> "I have in depth knowledge and you get a feel for things as well and it's not particularly scientific. It is seen that for cooks, food safety is easy because you have to 'cook' the food to get it served and it can't be overcooked because it will burn. A control point might be for quality or customer taking something out of the shop and a CCP within the context of food safety anything critical that might cause a problem for the customer by any means of contamination." (1659HA)

A catering company in Germany started hazard analysis by raw material receiving, such as vegetables, looking for pests and other hazards coming from it (887HA). They controlled vegetables by cooking them well or keeping the inventory very low. Other raw materials were already processed like burger meats. Therefore, they ended up with two CCPs, which were storage of raw material and cooking steps. When it is not a CCP, then it is a GMP; and an example of that is like color coded boards. Other catering experts see that catering has defined CCPs no matter what type of food they have such as raw material, hot area and cold area (1838HA).

G.4.e. OPRP Confuses the Industry

Some company experts and consultants were confused about how to classify OPRP because they have received a pre-set HACCP system and no further training (HA 2292). This example is

of someone who continued following an ISO 22000 system without getting any further training. This yielded confusion about whether cleaning between diet and non-diet products is an OPRP or not. She expressed that in her previous job she received help from the consultant, but this was not the case on this new assignment.

Another big company whose expert implements ISO 22000 according to the standard, see OPRP as the only thing that is not clear in the standard (1068HA). They understood it as a minor CCP. They explained at length saying that:

> "a critical control point like its name, it's a point that needs a critical control to eliminate a hazard that you know that it is existing or to reduce it to an acceptable level. Frying is seen as a CCP for microorganisms so you watch the temperature and time and moisture of the fried product. Also, the allergens, now you know they consider them chemical hazard. But we only have labeling the bag, saying it contains or it may contain, that's it."

H. HACCP – Auditors

H.1. Application by Auditors

The interviewed auditors were asked about how they viewed the meaning of hazard analysis and how they would recommend to choose critical control points (HA2381, 2118HA, 153HA). Generally, a couple of auditors advised to do hazard analysis in the following way:

"You can do hazard analysis based on the existing flow chart or based on every task. However, prior to hazard analysis, end product description and raw material description is needed. In the beginning, the specification for each item is needed. Depending on how the system is put, and we come and check based on the standards (legal and local and international standards). Each auditor is accredited for one food sector. One cannot audit all food sectors. Based on those specifications, the hazard analysis mentioning biological, chemical, physical and allergens is audited. The more you audit, the better. First the company needs to do assessment, to see severity and likelihood, and here we enter another date because there are many methodologies, many consultants, many things, but methodology should convince you as an auditor and we go by it. Afterwards you have to do a corrective action or monitoring. Some people do severity and likelihood and choose a specific score based on that they enter the decision tree or not, others choose also severity and likelihood and based on that they choose a score based on that they choose either CCP or OPRP or other. Other people do none of that and choose only to do the

tree. I prefer Severity, likelihood and the tree. 1 to 5 and multiplied and this is the most common, either he chooses to continue to a decision tree or consider it a CCP directly. We are not fine with it, because in audit if it's a CCP and he proves it, you can't say no. As long as the reasoning is correct they are not picky at all. No method for hazard assessment, whatever the client chooses and sounds logical. Some auditors for first year allows them to have all the CCPs they want, unless it's drastically wrong, the years after they encourage to remove them if they see that no outbreaks or problem where happening, then companies are happy because they monitor less. The problem for auditors mainly lies in microbiological acceptance criteria because there isn't one resource to rely on. Also, some auditors are careful not to make consultant look bad by criticizing all the time but focuses to ensure safety."

While some auditors work based on the logic given to them by experts in companies, others prefer to follow their company's school of thinking (1326HA). Examples of this were given in terms of CPs and CCPs. The auditor said that:

> "Examples of CCPs and CPs are fridge storing powders for quality issue is a CP, whereas a fridge in a delivery van is a CCP because food will be ruined. If the fridge is for cooling it's a CCP however if the fridge is fast chilling this is an OPRP because OPRP is a PRP that is operational, which means at work, like cooking sometimes can be OPRP, because it's a pre-requisite but it's operational."

An auditor also expressed that they are happy when they are auditing big companies who have stricter criteria than internal law (1326HA). One of the challenges auditors faced about the ability to influence implemented systems was their lack of time during audit period (HA2381). The problem was that during the audit time, there was not enough time to explain in details what to fix and where to reference it from because the auditing happens over 2 to 3 days only.

H.2. Terminology Seen Differently by Different Auditors

Auditors did not all agree on the same meaning for CCPs or ORPRs and each one gave his companies a different perspective. Some auditors generally did not mind naming OPRP or CCP and left it for client to decide which is which. For example, OPRP is testing of fridge temperature is one auditor's opinion. An example of a CCP from an auditor's view is the final product's temperature in transportation, however, the auditor told them that if with time they can see that the data logger is showing temperature is not problem in transportation, then it does not need to

be a CCP anymore (HA2381). The philosophy this auditor explained about the choice of CCP versus OPRP and PRP is that:

> "You have many CCPs and then you decrease them to become OPRP and some of them PRPs even. You choose these things according to the hazard and the experience of the extent of employee training and many factors, past outbreaks and data if it's a new company that has no history and we haven't figured out what the situation is and how strict it will be."

H.3. Opinion of Consultant about Auditors

A consultant explained that they conduct hazard analysis in some companies by looking at international references such as FSIS (2034HA). This is beneficial to them because it helped them make new production steps in the plant which did not exist before and that were useful for the plant. However, this led to problems with auditors who had no specific idea about the topic. The consultant explained:

> "So during the audit auditors would depend on their own experience, and if they see something they don't expect usually they don't like it and they start making problems about it. Another example of auditors is that in international reference the critical limit is normally a number not a range. In one of the audits an auditor insisted that it is wrong to have a number on and stated that the freezing level should be between 1 and 5 degrees Celsius. Then he insisted on the company to change it and made it a non-conformity. If that company and their consultant would not change from number to range, they would not take the certificate for ISO 22000 and would fail the audit."

Another problem regarded by some consultants was that the point of HACCP is safety and not making beautiful factories (1839 HA). 'The auditor usually is not a technical person as well,' said the consultant who thinks that nowadays auditors are using a checklist. But, sometimes they would insist on very expensive, difficult, and incomprehensible things to do such as buy a new metal detector or change all your equipment to stainless steel. A consultant believed that auditors are under paid and overworked, and that auditors from outside Lebanon have wider experience but with a solid base, and does not feel like working because of the payment conditions. The problem is sticking to one idea and re-applying it everywhere. The consultant quotes this example:

> "If the concept believed in is that cooking is CCP, then it stays everywhere a CCP. For example, there's a cooking step and has a UV step after it. So, in reality the CCP is UV not cooking, but since auditors learnt that cooking is always CCP they won't accept this step as a non-CCP."

H.4. Auditors as a Point of Reference for Hazard Testing

A consultant depends on the recommendation of the auditor to know whether he should increase or decrease the amount of testing (HA2218). A consultant speaking about surface and air testing said that when the auditor comes, he says:

> "It's too much, don't do that much or extend the frequency from monthly to years and here it's up to the auditor and not up to us. And he tells you I don't need to do this frequency it's so close."

I. HACCP – Consultants

I.1. Application

I.1.a. Starting Hazard Analysis with Training

Some consultants started hazard analysis by teaching and training the companies how to do it themselves (153HA, 348HA, 1659HA). A highly experienced international consultant implemented hazard analysis depending on the standard the company will get certified on. The first step to hazard analysis, he explained, is conducting a company tour, checking for the organizational requirements and for the one in charge of it. He described it as follows:

> "When I see there is something missing I implement first the things we have to know when everything is set up like the HACCP team or we start with the training of the team. So, I don't go through with them in all the charts and the hazard analysis because I want them to think by themselves after the training."

Similarly, another expert believed that the decision on CCP or CP starts by educating people to conduct the hazard analysis correctly (348HA). The first step would be documenting different process steps – such as receiving goods, storage, production itself like mixing, thermal processes –, focusing on evaluating every step, and then looking at microbiological, physical, and chemical contamination.

A HACCP expert majored in food safety for catering advised that in order to do a hazard analysis, it is important to start with the design of the kitchen (1659HA). “Then, you can make sure you train effective people” because many hired people who got certificates on paper, could not implement on the ground. Implementing hazards analysis according to this expert’s opinion starts with the conventional method of starting with the design of the kitchen. 'Systems might be a complete waste of time, because the implementation of them is so factious', then he added that:

> "in some way, you can spend every single penny on training people, but make sure it’s effective people not just a bunch of power point slides to go through and keep them in that room, go through their slides and give them a certificate and end them out, and they pact and take the money. Although there’s some really good training companies” he finally added."

I.1.b. Hazard Analysis According to ISO or Codex

Company experts said that they were advised to conduct hazard analysis according to Codex (2003) initially, before applying for certification (86MS, 118MS). But when they acquired ISO 22000, they adjusted the hazard analysis methodology according to that standard since with HACCP, everything done was brief and did not demand the use of specific names for hazards, methods, of hazard assessment. The controls were not clearly defined either when using HACCP. On the other side, a consultant/auditor believed that hazard analysis should always be done according to Codex (2003) and did not see HACCP as brief or unclear (118MS). A third consultant, however, believed that the companies should do hazard analysis according to ISO 22000 because it has the option of OPRP (96MS). The latter helps when there is a serious hazard which cannot be controlled online so that the monitoring could happen as an OPRP, such as the hazard dioxin in milk.

I.1.c. Consultant Tells Clients What to do

A consultant believed that to do hazard analysis, one should to talk to the staff about the potential risks, define them with the possibility of controls, and understand the process where the food goes (736HA). That consultant said the following:

> "The problem is seen to be very much about awareness. To do hazard analysis one must inform the staff about possible risks and ask them to talk about their process until it reaches the patient or customer. To choose the risk there is A B C depending on how high the risk is. A CP is about monitoring but not immediate danger such holding temperature

of food. CCP is the cooking temperature. Other would be GMPs. This HACCP consultant has not heard of OPRP."

I.1.d. Consultants Solving Clients' Problems Only

Another consultant explained that some consultants are hired to actually construct the systems themselves and not teach nor explain how that will be done as is written in their contract (1194HA). A very high caliber consultant described thoroughly how he usually conducts hazard analysis. The consultant uses the classic way and starts with a flow diagram. He is quoted saying:

> "I have to understand, depending on the brief given to me by my supplier, where does it start and where does it finish. So that could be that it is raw material coming to the factory and finished product delivered by my client. That way I can know where the raw materials are produced, through to when the finished product reaches my client's customer. So, the first thing you have to do is work out the flow then work on identifying the hazards, and then goes the probability of the hazards and where management should be put in place. And then if you look in the specific processes, yes, I agree or no I disagree with the company that this is a CCP but generally speaking I deal with more esoteric problems not just standards but what's happening in the factory. "

The consultant used a combination of textbooks, internet and experience to identify hazards (1194HA). Rarely is any use of governmental books helpful for hazards, because they are not usually covered by those parties. An example is quoted below:

> "I was working on rice products and an issue with mycotoxin contamination. So, the question is in mycotoxin contamination and what steps do they have in place to mitigate it, actually they did the dry the rice extremely well. So that's the control measure. You move from quite serious hazard to a low hazard however the drying is not based on a PRP because if you do not do that well, you have the problem of the mycotoxin. So now you identify that we want to see the records for this, you could argue that this is a CCP depending on how you identify the hazards. But FMEA before you control the measure and afterwards helps you focus on every step within your supply chain, and tell your client for example that on every delivery this is where you need to have daily evidence that there's been compliance or every year you need evidence that there has been compliance."

I.2. Hazard Analysis Challenges

I.2.a. Consultants – HA Is About Changing Equipment

One of the main problems in hazard analysis is quoted by a consultant about consultants, is that they add a lot of upper limits or expectations and call it hazard analysis (1388HA). However, their instruction is about infrastructure and changing it, which usually de-motivates companies from doing hazard analysis. Such consultants focus a lot on the structure of the company itself, because there are lots of risks which are really insignificant, like for example, a rusted equipment 50 meters away from the production line. Some consultants complain that it is not stainless, but this has nothing to do with the process and does not add a risk nor affects the product. The consultant explained that HACCP is there to know what is being done and look where the problems that are going to affect safety would come, and stop them now. It is not so that the company waits for 2 years until a budget is gained. Even if a factory does not have good tiles, there are other things to do which have nothing to do with tiles, but which affect food safety.

I.2.b. Consultants Using Checklists or Spontaneous Advice

Another problem complained about by an expert for conducting hazard analysis is that consultants have no fixed systems to follow when they come to a company, but they use their personal technical analogy instead (406HA). This yields many different interpretations of the system. Some consultants teach implementing hazard analysis using a checklist. The numbers in the checklist decide whether the hazard is a CCP or CP. For example, handling a raw material like meat is CCP and a cake is a CP because of the calculations.

I.2.c. Consultants and Company Confidentiality

Another problem expressed by a consultant about experts was that companies hide information from the consultant; information which they know is crucial but they want to keep the secret because they want to take HACCP certificate without getting found out (1388HA). A consultant describes it as such:

> "The down side is that someday it’s going to explode somewhere because you are going somewhere wrong it will show somewhere, and it will show that HACCP will really not stop this problem. Some do this for commercial reasons, they don’t do it stupidly. Others do it with the help of consultants who help them do it, telling okay don’t show it, because if you tell it you will never take your certificate. And others use the help from the auditor. The

> auditor will not see something, and they try not to see it because they want to give you the certificate, because it is mainly human, and it's part of the commercial environment for that and people are not perfect even if they want to try and make perfect things, they are not perfect and HACCP is perfection, and it's assuring food safety, it's 100% in principle so perfection in a non-perfect environment is difficult, there is always commercial reasons that stop you from doing things right, not because you can't but because you don't want to. This problem is mainly related to Lebanon, I am not sure it happens in Germany."

I.2.d. Lack of Scientific Information for Hazard Analysis in Lebanon /Good Consultants are Expensive

A consultant advised using the 2D matrix with a 1 to 3 scale as a hazard assessment method, because he believed it has a 90% chance of making the right decision (1388HA). That is because there is not enough literature done in Lebanon and the access to needed information on the internet is paid for; and thus, academic information is not for free and is not accessible. Another option for good hazard assessment using a good resource of information in Lebanon is a good consultant, but they are expensive and few people can afford the good ones.

I.2.e. Lack of Specialization of Consultants

A HACCP expert majored in food safety for catering found it strange that young consultants can be specialized in several standards such as 17 types of ISO standards and other standards (1659HA). Hazard analysis needs a lot of expertise and one needs to be specialized in HACCP field such as kitchen, or another sector to carry it out. A veterinary cannot do hazard analysis for a hotel kitchen and vice versa.

I.2.f. Effects of Inexperienced Consultants

A young consultant was asked to identify hazards and establish controls (1285 HA). The brief description given was as such:

> "HACCP is done by naming general hazards, biological chemical physical and then choosing CCPs. CCP example is such as filling or final sieve. End product testing is done for microbiological hazards, or chemical hazards, chosen randomly when thinking of spices or herbs."

One consultant defined a hazard as the survival of pathogens (HA2218). He used this teaching with the companies he consulted. He had his own understanding of hazards and risks.

I.2.g. Terminology Confusion

'One reason for the terminology confusion is due to the emergence of ISO 22000 standard', stated one of the consultants (2118HA). She continued saying that:

> "The standard created disagreement on meanings of terms such as CCP and OPRP and if they need to be specified for all hazards or only for significant hazards. This confusion also happens because some consultants teaches such common mistakes like choosing OPRP's before identifying if this hazard is significant or not, whereas the ISO 22000 standard indicates that OPRP or CCP need to be specified after a hazard is significant or not." She explained how she understands terminologies by saying: "The standard says that OPRP needs to be chosen only for significant hazards and it doesn't need to be monitored online however the CCP needs to be monitored online such as changing a filter every two hour is an example of an OPRP but when pasteurization happens as a last step, this is a CCP."

I.3. Consultants – Hazard Assessment and Choosing Controls: CCPs, OPRPs, CPs

Some consultants recommended using FMEA for assessing hazards, whereas others preferred other methods (HA1194, HA2218, 153HA, 336RM). A very high caliber consultant for different food safety systems described thoroughly how he conducted hazard identification. The next step is that the severity and likelihood are found by using FMEA before and after the control measures are identified. This can help determine if hazards are significant. And, if it is controlled, is it still significant, or does more work need to be done on it? Could this be considered a CCP, or could it be handled via an OPRP? This consultant uses Pareto analysis on top of that to know which are the significant ones using the 80/20 rule.

After identification of hazard, a consultant conducts the hazard assessment by himself and an opinion is given to the client about what was done (HA2218). However, a certain consultant did not think companies actually understand the concept of risk. Moreover, he stated that he went through the CCP decision tree and deduced that on the basis of that logic and what have been done, it should be or not, but it is not his decision to give the final format. He insisted that:

> "I may advise. I could say yes, the HACCP system is well designed, or no it is not. And if I don't I would have to justify it. Then after that I use the tree to decide if steps are CCP or

> not. And you go through it actually subjective rather than documenting it. If it is obvious that this is not a CCP, you don't need to document why. If not a CCP, it's a CP, or OPRP, or PRP. For example: every batch of a material delivered to the site has to be inspected upon delivery that is a Control Point. Not a CCP, a CP unless you are inspecting 100% of it you cannot say it's a CCP. Example: Metal detector on condition that little parts of it can be a hazard and will survive to the packs. You are not managing the shipment."

One of the consultants described the method of doing hazard assessment by doing it themselves first for the company, and asking the client questions about the frequency of occurrence to define its severity (HA2218). Once that information is presented, they decide the choice of CCP, CP or OPRP based on those numbers calculated. So, low risk items are defended as CPs and the higher they are, the more they are OPRPs. The highest ones are then CCPs in case the system needed was ISO 22000. In case it was HACCP, then the consultant uses the codex tree.

Another highly esteemed consultant did not advise using the FMEA and said it was a wrong method to use for hazard assessment (153HA). One of the reasons given was that one cannot find CCPs through this method. He believes that FMEA is misleading and does not help people figure out what is going on, but rather they calculate and deduce answers. He does not believe it is required by the Codex, but that only a tree suffices there, and this hazard assessment step is a requirement by ISO, IFS, and BRC. For example, to analyze a pasteurizer by FMEA in the correct way, one would never end up with a CCP. But everyone else is of the opinion that there should be a CCP or a final heating process with the FMEA to help figuring out that the heating process is not correct. Therefore, the FMEA is good but not good to identify the CCP. The method this consultant uses instead is quoted below:

> "Usually what I am doing when I am doing a HACCP training, before I go into details and tell the guys whether decision trees or method for choosing, I do a blue print of the steps and I ask the guys where are the most critical points and I ask them just from their gut feeling and I ask them where do you have to be very precise and careful and then I write it down and forget about it and when I am through the whole process with hazard analysis and all when we talk about risk analysis method, then I ask them to compare, with FMEA and other methods you get these CCPs but the other day you told me these are most important point and usually the gut feeling is not bad it is better than applying another method but it's not implemented correctly."

Another problem expressed by this consultant about FMEA is that it is based on numbers, and can thus lead to too many or too little CCPs; and then some of them – such as metal detectors or antibiotics in milk – are in the grey zones (153HA). They get an average number on FMEA and this yields to more confusion than help.

On hazard assessment, another consultant also follows the company's style which says that if Codex is done, the decision tree should be used directly; but if it is ISO 22000 then the matrix can be used (336RM). OPRP is an important step, but is not so important to be considered as a CCP. Receiving of raw material, however, is a PRP.

I.3.a. CCP Identification or Lack of It

Consultants do not all agree on what can be a CCP and what cannot be (318RM, 360RM, 1326HA, 1326HA). The receiving step of rice, says a consultant, is an OPRP and certainly not a CCP. Raw materials can be a CCP if, for example, there are hazards that cannot be killed in pasteurization so it can be turned into a CCP to make sure it does not enter the process (360RM). Thus, in tahini for example, the sampling of raw material can be increased to test for the presence of salmonella. However, the risk of salmonella existing seems to be not so high in the finished product tahini, because otherwise people would be falling ill from ingesting it.

Another consultant reduced as much as possible the critical control points stating that 'PRP is not critical and critical needs to be monitored otherwise they will be a problem and it could be serious'. An example is given about monitoring a filling process of milk with maintaining a temperature of 4 degrees, but if it jumps to 5 or 6, then it is not really critical because refrigerating it later would balance it out. A critical point is something that would jeopardize the safety of the product and it is something which can be controlled and tested. In milk, the quality is important in the pasteurization step, and that is why this consultant considers both raw material and pasteurization as CCP. This consultant considers OPRP as a step which cannot be monitored or all the time even if it is critical such as refrigerator temperature. The reason for such controversies as stated by the consultant is: 'these things, go back to the perfection of the system HACCP is a perfect system in an imperfect environment, so how can you be perfect? In what you apply not what you say, how you apply the HACCP system?'

Two consultants did not mind the CCP label as long as the steps are controlled (1326HA, 2119HA). Cooking or chilling could be a CCP, and other companies could consider the same points as OPRPs. However, they expressed not liking to see so many CCPs, because this shows

over-controlling of the system such as 8 CCPs in 1 flow diagram. Yet, companies do not really care about it as long as the system is under control.

One expert observed a type of company which came out with no CCP based in the history of the implementation and the validation of the control measures (2119HA). Those companies are that confident in what they do, and they make their system work without any CCP. They receive an intensive and intricate audit to make sure they are controlling safety well.

J. HACCP – Inspectors

Experts were asked the following questions:

- How often does the food safety authority check on your process?
- Is there an information center you look at to see other company outbreaks investigations and learn from them? (EFSA, BFR)

J.1. Inspection time

Most companies say that they are visited by inspectors on a yearly basis, once a year on an unexpected visit (95CIA, 311CIA).

J.2. Lebanese Inspectors

Lebanese government officials from a ministry described conducting HACCP by previously studying the lines before they go to a company (1980HA). They usually write the process down, look for control measures, and use the decision tree. If the company asks them, they usually make a HACCP plan for them. This specific government body feels that they know the HACCP very well and have the controls memorized. They know their material well in order to detect if the company they are visiting is missing out on any control steps, and give them feedback. These governmental experts see that CCPs depend on the process criteria (1980 HA). If it is a manual process of filling a product, then, it is a CCP; and if it is a machine, then it is not a CCP. However, the inspectors commented that HACCP experts do not yet agree about what a CCP is. For the inspectors, the more CCPs, the better because it means more control, but then it is more expensive for the plant. However, HACCP experts do not seem to agree with those inspectors on this observation.

A Lebanese inspector or a governmental side described conducting HACCP by first identifying hazards, doing a study on them to see if those hazards are considered as CCPs or are OPRPs

(418RM). There were examples given on pest control as being quite important, but it is unclear whether it is a CCP because it is not a tangible or measurable thing to test as to whether results were effective or not. The temperature, the PH, the acidity, or even cleaning are measurable and can be a CCP. Inspectors see cleaning and pest control as OPRPs. Sometimes, packaging is a CCP if it causes an allergen. Therefore, it is a case per case scenario. Sometimes what is a CCP here, is not a CCP there where there are further precautions after a step. They think that raw materials should be included in HACCP (1550HA).

J.3. German Inspectors

When asked about hazard analysis, governmental inspectors in Germany had different points of views. Some were brief and some elaborated more. One inspector was a veterinarian and she acknowledged not to know precisely how companies who use HACCP conduct their hazard analysis (1HA). She used her personal experience and background as a veterinarian, she engaged in dialogues, and looked for gaps when inspecting premises. Other inspectors check HACCP per company without having a specific model in mind because they believe HACCP can be done using different models (432HA). They gave examples about their understanding of hazard analysis such as cooling temperature being a CP and heating or cooking a CCP because one can control this step. Metal detector is a CCP, raw material is also a CCP because it can help prevent a hazard into a process. Like the others, they do not know about OPRPs, but have heard of them in the context of metal detectors in big plants since they cannot detect all metals.

Another governmental inspector had a broader view of HACCP and described it thoroughly when asked about it (59HA). Unlike others, he believed that it is their responsibility to know how to implement it in different places. Governmental inspector describes HACCP steps in details as such:

> "First we draw the flow diagram, and then at each point of the production specify hazards such as, chemical, biological, microbiological, physical, allergens. Then, I ask likelihood of occurrence and severity using numbers, often as a number is greater than eight or nine, then this is a CCP because it is very dangerous, but not easy to detect. And then I ask how can I control the risk, for example by heating or by a detector and the next step is then, how do I ensure it is documented and what shall I do in case of deviations and what corrective actions are performed. Hazard analysis or assessment is best done with numbers because it's easy for industry especially that not all are highly qualified."

However, he elaborated more on the problems they face with companies especially in the hazard and CCP naming quoted below:

> "Bigger problem for me is lack of documentation that often they don't document CCPs or explain how they came to have them. The biological hazards we can name but physical not always. The HACCP doesn't have naming usually. To decide on CCP or CP, they use decision tree. Examples are sausages that is cooked at 60 to get the quality needed but the CCP step is going to 72 to kill the salmonella. A CP is cooking a cake which needs to go to 150 to be cooked and in that temperature any bacteria died at 70 anyways so this is a CP. There PRP which is cleaning and sanitization of the operation."

Another governmental expert finds HACCP rare at companies and is happy when they inspect one (1005HA). In small butcheries, they claim not to have CCPs because there is no heating step. So, inspectors there only look for hygiene and are happy to audit it by themselves. Bigger companies are asked how they made the CCP decision. Heating and metal detectors are considered as CPs. Some have expressed confusion towards CCPs. This is because inspectors understand that CCPs need to be a measure which can be corrected. The confusion expressed is that sometimes things are CPs and in the regulations, they are considered as CCPs, without understanding why. For example, cold temperatures are CPs because they cannot be corrected but heating is a CCP because it can be re-applied. These inspectors have never heard of OPRP.

J.4. Inspection Focus

Several companies and consultants observed that inspectors focus on the hygienic side of companies rather than on the HACCP system and documents (65CIA, 278CIA, 572CIA, 607CIA). Some said this was due to the information the inspectors lack about HACCP, or to the lack of number of inspectors available to cover a big amount of food companies. This can be confirmed via the answers of some inspectors regarding certain steps of HACCP and their knowledge about how to conduct a HACCP study (120CIA). Inspectors as well do not feel that consulting about HACCP is part of their job, rather they are there to audit and inspect. Companies claim to sometimes help inspectors and explain to them some of the latest developments and the food safety parameters to help them understand and perform (171CIA). They relate this to the fact that most inspectors are veterinaries. While veterinaries are responsible and skilled in animal knowledge company experts do not perceive that they have specific food knowledge.

'Inspectors coming from ministry of economy look at the work companies do,' said one of the QA managers (795CIA), and adds that:

> "They drop by randomly and when they come they look mostly at expiree dates, and the system on the floor. In case there was something wrong, they give information about it, and they warn and they give a period of grace."

A Ministry in Lebanon has informed through the interview that they offered trainings for inspectors in all the other ministries in Lebanon on EU food hygiene packages and packaging regulations, HACCP, pre-requisites for HACCP, to train trainers for HACCP and PRP, traceability and foreign export (499CIA). One of the problems a huge company in Germany was facing is that inspectors audited their premises in different states and they observed that each authority worked differently (178CIA). This is why a certain company sticks to DIN standards so that it could apply the same system in all of its 180 locations. The other challenge faced with inspectors was that they do not have clear targets for whatever they object about.

K. Information Sources

Experts were then asked where they search for information about hazards, controls and outbreaks. Industries, consultants, auditors and inspectors searched in different places and the answers were classified below.

K.1. Industries using HACCP

Industries in general used different information sources. What seemed mostly common is the dependency on a consultant during hazard analysis (551IS, 418IS, 192IS) or upon a problem occurring (313IS). Companies that were HACCP certified used the following standards: Codex, FDA, Libnor, DIN, EC and EU guidelines, HACCP, and hygiene seminars hotel and restaurant association and media. Industries that were ISO 20000 or IFS certified used the following sources of information: consultants, Google research, Wikipedia, recalls, alerts, expert's educational experience in food technology, chemistry, microbiology, pathology, agriculture, laboratories results, private standards, suppliers, customers, training, auditors, ministry of agriculture in Lebanon, official EU food safety sites, internal company standards, trainings and media (63IS, 73IS, 162IS, 612IS, 551IS, 461IS, 418IS, 292IS, 278IS, 192IS).

K.2. Consultants

Experienced consultants with 10 years of experience and more, used resources such textbooks, internet, experience, knowledge, expertise, EFSA, FSA, JECFA, UNDC (EU data basis on food additives contact material) (313IS). EU has substantial data basis to be used, in UK health and safety data basis, and FDA, conference literature, private guidelines, Karitas, official websites, and library books (454IS, 211IS). Consultants who were relatively new in the field used sources such as Codex, FDA, Lebanese standards, FDA recalls, Codex Libnor, Google research, website publications, ministry of agriculture, RKI, Newspapers, media (565IS, 399IS, 388IS, 101IS, 454IS).

K.3. Auditors and Inspectors

Auditors and governmental inspectors gather their information sources for food safety in general. Since they do not have to apply hazard analysis, but only audit it, they care about collecting general information about hazards. Sources were coming from: Libnor, experience, UNIDO trainings, micro-books, RASFF, FDA, education background, training, interns, seminars, trainings, practical training on the field – since guidelines do not have new information to offer –, seminars consultants, Codex (2003), Zulassungsbehörde, Homepage, Fachzeitschriften, Europäisches Schnellwarnsystem, Codex (503IS, 631IS, 268IS, 125IS, 111IS, 36IS, 367IS, 3IS).

L. Validation and Verification

The experts were asked the following question:

> 10- Tell me about your validation and verification plans, and how do you implement them? Are they mandatory to have according to your used regulation?

L.1. Standards Used

16 interviewed experts used Codex Alimentarius as their main guideline for HACCP and got certified based on its knowledge. 16 experts used ISO 22000 and/or IFS. The majority of experts from Lebanon used ISO 22000 and the majority of experts from Germany used Codex for the application of HACCP.

L.2. Validation Application in Accordance with ISO 22000 and CAC/GL 69–2008

L.2.a. Prior to Validation

Three of the experts interviewed in Lebanon, had said that validation occurs prior to the production using the HACCP system. This is in line with what the ISO 22000 (2005) standard says. Validation needs to happen as well after changes in product or process (ISO 22000, 2005). When asked about the frequency, a Lebanese food industry expert said that validation happens only once at the beginning of a new product or process and involves different samples and temperature configurations in the oven which are later validated by lab tests (601V, 616V). Another Lebanese auditor agreed to this same opinion explaining that validation needs to be done prior to the production in order to make sure that the CCPs and the OPRPs are correct and even tested by external labs (777V, 780V). One expert insisted that there can be no HACCP without validation especially for legal matters, because then the food business would have no proof of how they are controlling their process and ensuring the elimination of hazards.

L.2.b. Application of Validation

Some experts have given methods of validation in synchrony with ISO 22000 and CAC/GL 69-2008 including validation application and revalidation activities. For example, five food industry experts from Lebanon said that they validate by research, by precedent, process history, in internal or external labs, after corrective action on maintenance problems like a lost screw incident (428V, 433V, 457V, 552V, 789V). One of them said that validation is mainly done through legal references for specified CCPs and critical limits, and when there is a lack of references, then statistical internal laboratory testing is performed in house for the existing process (702V, 705V). A Lebanese consultant had said the same, however, when asked if process variation is part of this activity, he said that it was not relevant for the food safety system but rather for ISO 9001 only (725V, 727V).

When asked if experts saw validation implemented in food safety systems, a German consultant and auditor said that they have seen it done because those companies are applying IFS, BRC, FSSC 22000, or ISO 22000; and since they have to be audited, they are forced to apply it (63V, 66V). Some examples were shared about what a good validation looks like through a German consultant and auditor who said that (60V, 69V):

> "I just saw a very good validation it was from a large kitchen of a large hospital and they had airport over 2 pages they did a literature research a study what happened in last year in hospital kitchen and then they figured out all things they checked then they did an evaluation if could this happen so they really understood what validation is about, it's not just counting some mistakes but looking what the level of mistakes there was, are we close to the next incident or are we far away from next incident by this doing a historical study as part of the validation study."

Other experts linked validation to others parts of an ISO 22000 system (167V, 174V). For example, a German company linked validation to cross checking the complaints received, cross checking if the system is robust, considers all possible risk parameters, and is up to date. A different observation was that German big companies have a validation manager in addition to a HACCP team leader (348V, 379V). They coordinate to implement HACCP, however, the primary has a department on its own. The validation manager does a lot of tests especially upon new operations. A good example of what this department does is "eye camera" checks for products were done by putting bad products and realizing they have 0.2% accuracy for detecting problems.

L.2.c. Revalidation

Examples of revalidation were given by some companies that validate in cases of change in systems such as change of labels for nutrition facts (592V, 595V). One German government inspector understood the difference between both terms as exactly explained by ISO 22000 and he said that the companies he inspects know and apply both, and even offer the inspector to send their files ahead to double check with them before he comes and inspects a new system they have (25V, 37V).

L.3. Validation Definitions not meeting ISO 22000 and CAC/GL 69-2008

An industry expert said that validation is completed by looking at references only (510V). A Lebanese auditor specified that he/she understands validation as microbiological testing for each batch. When asked for specific examples, the following were given (522V, 529V, 563V):

> "Microbiological testing for all raw materials every 3 months, they do external quality of products with swabbing every day, validating their CCPs and testing the sanitizing materials because they are also considered CCPs every 3 months, validating of start and

> end of production, and they do validation for CIP once a week they swab, and they do the chemical residue test. Such are examples of validation."

Other ways this auditor looks for validation proof is validation through records (522V, 529V, 563V). A Lebanese consultant prefers validation to be outsourced, and when asked how it can be implemented, he used the following words (578V):

> "You need to verify, you need to make sure they are verifying, are they sending their equipment for calibration, are they sending samples of products to accredited labs to compare their results with the others results, then you are validating the system, you validate the SOPs to make sure that the SOPs are really comprehensive and they are being well implemented."

When asked about validating a CCP, he/she said that (589-594V):

> "I verify first by sending a sample of the finished product to the lab to make sure that the CFU microbial count is below the critical limit that I have put based on Libnor and codex etc. Now, when I come as a consultant or from 'XXXXX company' I look at their laboratory results to make sure that first the labs they are dealing with are accredited and second the levels given in those reports are good enough if not good enough what is the corrective action, in a way to make sure that the system is from beginning to end is covering all the hazards and is minimizing their likelihood."

Another Lebanese governmental consultant said that validation and verification are intermingled. According to his opinion, validation happens once a year by testing in a laboratory to make sure preventive measures are sufficient. Verification is said to happen on top of the validation. A Lebanese quality assurance manager in a catering company saw that verification and validation steps are the same except for a difference in time (634V). Verification happens a few months later than validation. Examples of validation steps are tasting, micro-testing, and packaging testing. Some Lebanese government inspectors said that they depend on monitoring machines and personnel records to make sure validation has occurred such as health records, line records, sample keeping, and traceability records (655V).

L.4. Experts Opinions on Challenges of Validation

L.4.a. Terminology Results

MEA consultant/auditor explained the challenge in applying validation as originating from a huge confusion between monitoring, verification and validation (670V). Some people validate all control points. He says that in 25% of cases he saw it is being applied correctly based on ISO 22000 method. Some know it in theory, but cannot apply it practically, and this has nothing to do with the company size. The problem, he explained, is that ISO 22000 and ISO 22004 do not give examples so people do not know how or how often to do it, and thus the lack of proper training and teaching is identified to be one of the basic problems (684V).

Some blamed the confusion between validation and verification terms on the lack of Lebanese norms that do not explain well what is needed from them (429V). Not only industries said so, but even some Lebanese governmental consultants said that verification and validation are confusing and that maybe verification is done through tests in labs but they are not sure (565V, 750V). Some German inspectors exclaimed that there is confusion between both terms (12V). He/she tried to explain how some companies do it on their own while others use external consultants to do it, and results depend on the route taken.

A German HACCP auditor admitted that he does not know the difference between validation and verification and that they are two unclear terms (100V). He also believed that big companies had more knowledge about these terms than small ones, and that the government needs to do more training on the terms so that the companies could apply them. A German packaging supplier of big food industries, believed that both terms are the same and are done by external auditors once a year (228V). Several companies in Germany, which apply HACCP only and not IFS or ISO 22000, implemented verification weekly and monthly but not any validation steps in their HACCP (84V). They said it was not part of the HACCP document.

A group from the German authorities who was interviewed together described verification as monitoring, checking by laboratory testing, making sure critical limits are met, and described validation as verification or auditing, as in checking the entire system regularly and periodically to ensure control measures are met (134V). They explained that applying both terms depended on how big the companies are and how much they understood their food systems, but mostly people apply the verification step (144V). It also depends on the type of activity. Thus, a slaughter house

would not have CCPs to even ask about validation and verification. They said that the calibration of thermometers and testing equipment are some examples of validation.

A German consultant described validation and verification in one process which is after fixing the control points, training and recording the outcomes from them (115V). This was another example of how consultants can be the actual challenge and difficulty in implementing validation. Other German caterers who are HACCP certified mixed up terms and believed both terms, validation and verification, were about when government comes and checks their place or when they do their internal audits (322V). In other words, they believed these two terms to mean auditing. Those internal checks included quality stamps of raw material to make sure that everything they received matches the required quality and safety.

L.4.b. Lack of Re-validation

Another Lebanese auditor/consultant said that this is a topic that has a lot of non-conformity (693V). The main problem in validation is lack of validation upon changes. Product development mainly develops new products and launches them in the market as ISO 2200 certified products, without the validation step being done.

L.4.c. Use of Opinion over Science

Another consultant/auditor from the Middle East shared some bad examples he saw in different Arab world food companies (675V). For example, one company he saw chose control parameters and validated them based on instinct and called it experience without any scientific testing. For instance, they changed the frying oil after every 7 frying times just because McDonalds changes it weekly, which means that they changed it more often. But that was based on no scientific test or reference to validate it.

L.4.d. Influence of Consultant or Auditor on Validation

MEA auditor consultant said that he used to be confused with verification but not anymore (712V). And that the reason things are improving depends on the consultant, for if he understands and explains it right, then companies do it right. He said that the problem is that the relationship between consultant and company lacks interaction, and thus the consultant tells the company what to do and the company applies it without a debate or discussion. Another German consultant/auditor agrees that confusion in terms comes from auditor or consultant who ignores the difference (64V).

A German consultant said that one of the challenges is that companies ask the consultant to help with verification and validation only when authorities find something wrong or a problem happens (245V). He/she never sees any company that knows how to do validation unless they are told and guided by consultants on how to do it; only big companies or mass caterers know how to do it on their own without guidance.

A German consultant who understands validation in accordance to ISO 22000, found challenges with documentation for companies because with HACCP in place, people often document all details not just HACCP or validations and this creates confusion for companies if they need to write only CCPs (286V).

L.4.e. Influence of Guideline on Validation

A German consultant auditor gave an example of how a guideline was written by some experts which mixed up the two meanings in the guidelines (490V). This auditor discovered this as he was auditing this company who ended up implementing it wrongly because of the guideline.

L.4.f. Inspector Perception of Validation

A German Inspector believed that the two terms are internal company management related (308V). He did not know if the company knows the difference between them, and as inspectors they do not need them because they have them in their head. Another German inspector said that small companies do not apply these terms, and big companies do maybe upon certification in time because the laws do not specify how often (387V). He found the challenge to be that companies use the same technique and maybe new hazards come but they do not try to apply a new validation system. He understood the difference well and believed that only big companies know it.

L.4.g. Process Variation in Validation

According to the knowledge of these experts, a further question was posed about process variation and if they consider it as a parameter or variable when doing validation (446V). Only two experts have said that they consider process variation in validation. The first is a food company expert in Lebanon who said that variation happens in their machinery and they count it in their validation by looking at machine ranges. The other expert was a German consultant/auditor who saw a good validation system at a large kitchen of a big hospital that considers process variation and uses statistics (74V, 446V).

However, many have found this question challenging. The same German expert who saw the hospital example explained that in order to consider process variation in the validation step of HACCP, some quality control personnel are needed who are fond of statistics, although they are not often found in companies (74V). He further said:

> "This is because statistics is defined only as statistics so they don't really like it or like to work with it. I think some of the companies would like to have some data that they use this data in terms of process analysis but it's not common."

For others, it was a matter of regulation and since it is not mentioned in ISO 22000 that it should be done, some auditors said it is not needed (555V, 707V). For example, a Lebanese auditor when asked about it said: 'no, it's only for ISO 9001 and not needed for food safety systems.' Another auditor and consultant from the Middle East had a clear opinion that process variation is not being done in food safety as well (707V). He shared the same opinion as the latter auditor saying that:

> "Process variation or process validation actually is only included when ISO 9000 is existing because then they are forced to do that due to the clause in ISO 9000 called: 'validation of process' and that's how somehow its included but it's never really that included in food safety unless they have a lab and one of the activities is the process."

For other experts, the terminology of process variation was understood differently (737V, 781V). A Lebanese consultant related process variation as a part of preventive maintenance which should be done monthly or weekly only. Another Lebanese auditor said this question belonged to another section which is verification for flow diagrams (781V). He/she added that validation, however, are checks for CCP or OPRP steps.

A big German industry with ISO and HACCP certifications said that process variation is not linked to food safety but rather to quality, because the limits are already very inclusive for food safety (176V). For example, pasteurization levels are higher than needed and filters are stricter than needed.

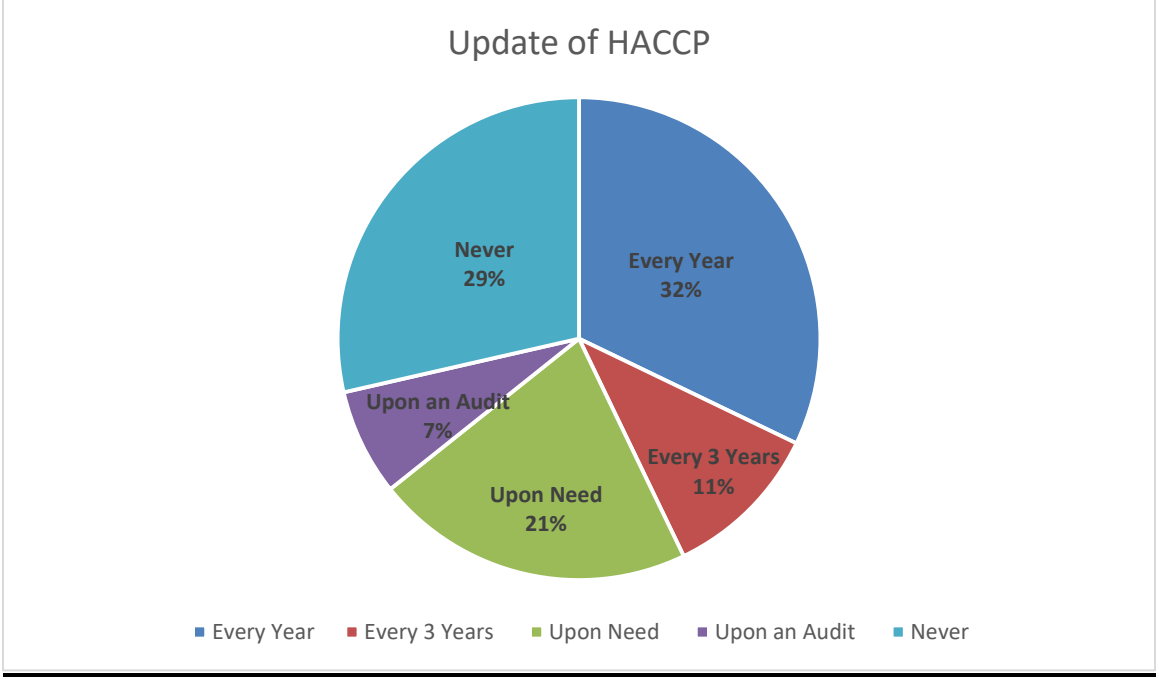
M. Update of Hazard Analysis

Experts were asked how often they update their hazard analysis steps and plans:

- How often do you update hazard analysis system (both raw material hazards and others?)

a. Do you have an example of a new hazard bacteria you recently discovered that you didn't know existed before in your product?

The answers were divided into 5 types as the figure below shows: updating every year, every 3 years, upon need, upon audit need, or never.



N= 33 experts & their respective frequency of updating HACCP

Never (10)
Every yr (10)
Upon Audit (4)
Every 3 yrs (3)
Upon need (6)

Figure 6: Frequency of Updating HACCP

M.1. Every Year

Although they use ISO 22000 (2005), these companies update their HACCP system once a year (332US, 291US, 289US, 197US, 173US, 119US, 3US). Some justify this because every year, there is a need to review the manual in case there was an addition of new production lines, ingredients, flow diagrams, outbreaks, and complaints revised through a traceability system. Some updated them each year only if something changed in the kitchen, a new product was developed, or a new machine was installed (291US, 289US, 197US, 173US, 119US, 3US). The comment is that this process, however, usually takes a lot of time. Some inspectors saw the update often happening because of private auditing companies that visit these enterprises and make sure that their system is updated such as IFS, ALDI, LIDL, or BFC (19US). A consultant observed that only 50% of the companies he visited revised their systems once per year because

this is what ISO 22000 (2005) mandated (321US). However, they revise new lines and products but they do not revise existing hazard analysis nor look for new emerging hazards.

M.2. Every 3 Years

Another company also using ISO 22000 (2005) update every 3 years (306US). They do so because they have huge process steps and cannot revise them as often as every year. Others update every 3 years they said because the new hires they often hire, take time to understand the original system (about 3 years). ISO 22000 auditors expect to see a system updated every 3 years (224US). However, they do see some who update the whole system every year and others do not like to do it at all.

M.3. Upon Audit

Some renew their systems every 2 years and then yearly when the HACCP audit happens (69US, 19US).

M.4. Upon Need

Some consultants and companies decide on this step based on the level of risk of the product (246US, 107US, 91US, 34US). If the product is lemon juice, then the frequency is low. If it is poultry, then they would revise it every 6 months until the process proves stable then they would revise it every year. They would also do it upon need if a new allergen is discovered or a new raw material is used. Consultants find this a very important point and think it is a matter of training and competence looking at trainings and knowing what to focus on or the timing to review the HACCP analysis to see if it is still correct (34US). Some types of companies do not even recognize if there are changes in the systems although they should look out for incidents outside and consider this in their HACCP update. Other consultants observe that companies update when they face problems, otherwise they take this step for granted (235US, 216US).

M.5. Never

Some high caliber consultants never see the hazard analysis updated (209US, 90US, 31US, 90US). Unless a new process in a new location is built, then maybe a team would sit and re-look at the whole process again and again (131US). The expectation from a HACCP consultant is that they update it as least once a year (90US).

An inspector in Germany saw that small companies never update their systems, however, the big ones have the chance to do it sometimes (192US). Another inspector said that 'only until some inspectors go to companies and start comparing the HACCP system on paper to what they have on the floor, do the companies feel the need to look at their one written system' (144US).

A university cafeteria almost never updates the hazard analysis system because they said that the products are the same and they were done well from the beginning, however, they always watch out for new legal requirements and if those come, they would update (159US).

The first part of HACCP was described as such (468HA):

> "We have one key person who takes care of the HACCP system itself and she gets the information and if she recognizes okay we have a new kind of allergens then she is looking up the current flow charts and the current risk analysis and inviting for the next time all the participants of the HACCP team and do the discussion with the team members if the process steps are already covered by the steps we have in place or if we have to consider a new step or if you have to expand the list of allergens inside then decision comes from team and training of the needed people."

N. Terminology Confusion for Hazard and Risk

None of the interviewed people were able to tell the difference between risk analysis, hazard analysis, risk assessment, and hazard assessment (1-361TC). Most people can understand the difference between hazard and risk, however, not between the rest of the terms**.** An expert said that:

> "There is a total confusion because in the same document people would imply different meanings for the same word. In terms of risk management and the risk concept, it might be an idea to go to ISO 31000 which is risk management, that’s because it’s a generic risk management standard and there is no reason food can be any different. It has been used everywhere in engineering, financing, it is been used in many industries, and it is generic, and if we have started with that as a standard, simple terminologies and simple techniques, and then work forwards, life would be a lot easier. At the moment we got WHO view, Codex view (which is slightly different to WHO) then WHO applies it to human disease, Codex to food and so it goes on. Whereas ISO 31000 the structure for food businesses it provides a much more workable matrix."

O. GMP vs HACCP

Experts were asked whether the difference between GMP and HACCP is clear to them and if it was, what examples can be given about each of them:

- Is it clear for you in the “standard” you use what the difference is between GMP and HACCP, what are some examples of it?

O.1. Difference is Clear

Very few consultants and companies are clear that GMPs are pre-requisites that need to be in place before starting a HACCP study (373GVH, 297GVH, 260GVH, 114GVH). 'Clarification comes from the training,' is what one of the auditors said (509GVH). She believed that all the companies she audits are clear on the difference because she forces them to have a number of trainings per year about that.

O.2. Difference is not Clear

Several company experts feel that knowing the difference between these terms and adding to it to PRPs and others are a mess (497GVH, 403GVH, 422GVH, 305GVH). They do not really understand why they have to have so many names when they are all topics relating to each other and to safety. The reason some experts get confused is that in university they were also not so clear about them when they studied them; and then in the standard itself, they do not see practical examples which can help them learn the difference between them (422GVH, 305GVH).

A consultant expresses that sending the Codex document for customers without her help or guidance makes it really hard for them to understand and to know the difference between these 2 terms (448GVH). Only companies that do a lot of research in order to understand the difference or the ones who have a good consultant can differentiate between the 2. But the general view is that people do not understand the difference. One consultant, however, finds FDA documents to be easier to read and understand for people who are not in the field of documentation (485GVH, 348GVH). Some consultants themselves have a vague image of the difference between the 2 terms (323GVH). They know well that GMP comes first, however, the importance of each on food safety is unclear. Even some very high caliber consultants insisted that this confusion is because of the structure of the document, because HACCP is just an appendix to the codex document (314GVH).

Auditors similarly find that people continue to be confused about these two terms (474GVH, 355GVH). They see that it has added a problem even more to people when ISO 22000 started and added the term OPRP. It is not clear in all circumstances for the people. Another auditor saw that this terminology difference causes a bigger problem (355GVH). He said:

> "I will tell you one thing, let's be clearer, identification of CCPs and OPRPs or CPs or whatever else you want to call it, is still a conflict until now between two different auditors. This is the biggest weakness inside the standard and regulation that's why strong consultants are winning inside over auditing because he can easily tell you this is not a non-conformity because he says there's no evidence what is a CCP, or other. Also, FSSC didn't solve this problem, it only solved identification of PRPs because before it was not clear. Now we don't have this problem anymore with FSSC where it specifies what type of wall we should build."

People usually think HACCP includes both GMP and HACCP so an auditor for example allows the company to pass if the elements of GMP and HACCP are both in the study even if the company cannot distinguish the difference between both (59GVH, 35GVH)

Two governmental officials did not know the difference between both terms when asked (437GVH). They saw HACCP as more related to the plant and stricter, but GMP as more pertaining to general hygiene. Others see clearly that GMP comes before HACCP (363GVH). However, they do not understand the need for separating the names and the difference each one brings to food safety.

P. Indications for a Successful HACCP System

Experts were asked about what signifies a successful HACCP system to them and what indications can there be for it:

- What are the indications whether a HACCP system is successful in an enterprise or not?

Answers were divided into 21 types of indicators for successful systems, however, the answers that were most common were that about amount of corrective actions done by the company per year and if the staff is well trained from the lowest level of staff to the highest managers. Results were as below:

1) Number of corrective actions per year and how many cases of non-conforming products or unsafe products that were in a certain period of time and amount of recalls, outbreaks and if they are getting reduced yearly is another indication especially recalls in crisis time (609SS, 562SS, 427SS, 224SS, 166SS, 17SS, 1SS, 183SS, 536SS, 441SS).

2) Well trained staff especially the knowledge of the smallest employees is another frequently mentioned indicator (551SS, 454SS, 346SS, 284SS, 224SS, 576SS, 79SS, 17SS).

3) Management commitment. When there is clear commitment from the upper management and the upper management is very serious about HACCP, about the attitude and culture of HACCP, experts can be sure that HACCP is well implemented (609SS, 576SS, 503SS).

4) Qualified leaders or experts in food safety exist: food safety manager or the team leader or someone who is really qualified is important to consider, because otherwise companies may write anything (609SS).

5) Employee turnover: the turnover of employees is another indicator. Companies with high turnover often have 'systems that are breaking,' said some experts (609SS, 536SS, 536SS).

6) Availability of on-floor staff: the supervision on the ground, how many real supervisors are on the floor, for example every 20-30 employees have one supervisor; how much supervision is being done on the floor for personal hygiene, for CCP or any activities is one major indication (609SS). Another is if there is a crew who was just hired for HACCP, this can also show this company is serious about HACCP.

7) Companies which follow standards precisely: companies that are honest enough and follow standards can show if they are serious or not and if HACCP can be successful there (576SS).

8) Updated HACCP: companies that update their system give a positive indication (551SS, 475SS).

9) Laboratory Testing: regular testing or companies that have internal laboratories show signs of successful HACCP (536SS, 475SS, 337SS, 224SS, 114SS).

10) Too many CCPs: the system is not successful in the presence of too many CCPs (637SS, 475SS). Also, demonstrating the right evidence as to why a certain point is a CCP in another important indicator (346SS, 261SS, 114SS, 79SS, 17SS).

11) Detail Oriented Hazard Analysis: good initial hazard analysis shows that the system is intellectually robust (475SS). Experts say that it needs to be checked by reading through and looking at the logic and the document itself, have they thought of things and whether they identified the right things (346SS, 388SS, 261SS, 17SS).

12) Lack of customer complaints is another sign that the system is successful, said some experts (475SS, 441SS, 325SS, 300SS).

13) Continuous Auditing: companies that have designed audits to pick problems up, such as internal and external audit with scores improving are showing signs of successful systems (337SS, 388SS, 183SS).

14) In Depth Audit: successful systems use new methods of checking on the existing systems such as in depth observation like narratology, or in depth audit (under the iceberg) which one cannot do in five minutes, however, one has to spend a few hours, and get to know the chefs well (454SS).

15) Few Line Stops: when the line does not stop often and the machines are in control, then the system of the plant indicates success, said some of the experts (412SS, 536SS, 314SS, 224SS, 114SS, 57SS).

16) Good Flow Diagrams: which shows that the company understands its process well and a good description of the process is one way a system can show success (346SS, 17SS).

17) Validation: when looking for statistical process control, this is a sign of preventive control (346SS). This means that people are not just waiting for something to happen or are monitoring the process so it does not happen, but they are actively anticipating the events. This is a sign of a successful system.

18) Culture of the Staff: people and how they behave can indicate whether a system is successful or not (346SS, 364SS, 300SS). It is crucial to check who talks about HACCP in the plant and who does not make a huge difference: if a factory manager does not talk

about HACCP, then there is a big problem, says one of the experts. “If marketing talks about HACCP, it is a big surprise.”

19) Certification: one expert believed that certified plants is a good sign for success (221SS).

20) Documentation: presence of documentation for inspectors is another positive sign of the success of HACCP (114SS, 100SS, 79SS).

21) An expert said he does not know any indication for a successful HACCP system (593SS).

Q. Outbreak Analysis Germany

Inspectors, in particular, were asked about what can be improved in the outbreak analysis method in Lebanon and in Germany (36OA, 108OA). The majority of German and Lebanese inspectors have agreed on similar suggestions. They would like to have a better system of sharing information with other states about outbreaks that have been occurring. They pushed for sharing information not only with other states, but also among different functions such as veterinarians, health specialists, agricultural engineers and food specialists. They believe that to improve the outbreaks analysis situation, it needs to start from the highest levels of government involved and going downward. It is important for them to do a thorough analysis before the story leaks outside to the media by taking the right samples together in agreement with specialists of different functions. The challenges they continually face are the availability of resources to do this work, sampling, and testing especially with professional people in their respective field.

One also suggests to have more trainings about the current food safety hazards occurring in the world (5OA). Others suggested using journals and online resources such as Nationale Gesetzgebung, LFGB, TLMHV, and LMHV. There is a need for specialists who can help with the problem before it happens (148OA). Moreover, it is important to have a centralized data base system where all the outbreaks are collected and displayed so that all parties from the different government sides, companies, consultants, inspectors and auditors can see the outbreak analysis results (160OA). Other suggestions were about creating an online application for the consumers so they can immediately report any food poisoning related to a food they ate, so that the officials can track and further analyze this problem (166OA).

Some suggested improvements of the information given about the GMPs that must happen in food premises (62OA, 108OA). This information is concerning hygiene regulations about kitchen tables and sinks, as well as refrigerators. They wanted this information to focus especially on

catering and the hygiene of the staff working inside the catering facilities. Norovirus, for example, was used to illustrate the fact that hand hygiene, if monitored closely, can eliminate the emergence of many dangerous hazard. They suggested continual training for that, focusing on understanding the technical requirements in kitchens, and monitoring of staff. Another suggestion for outbreak analysis improvement is to have the authorities practice it more and improve the methods each time (93OA).

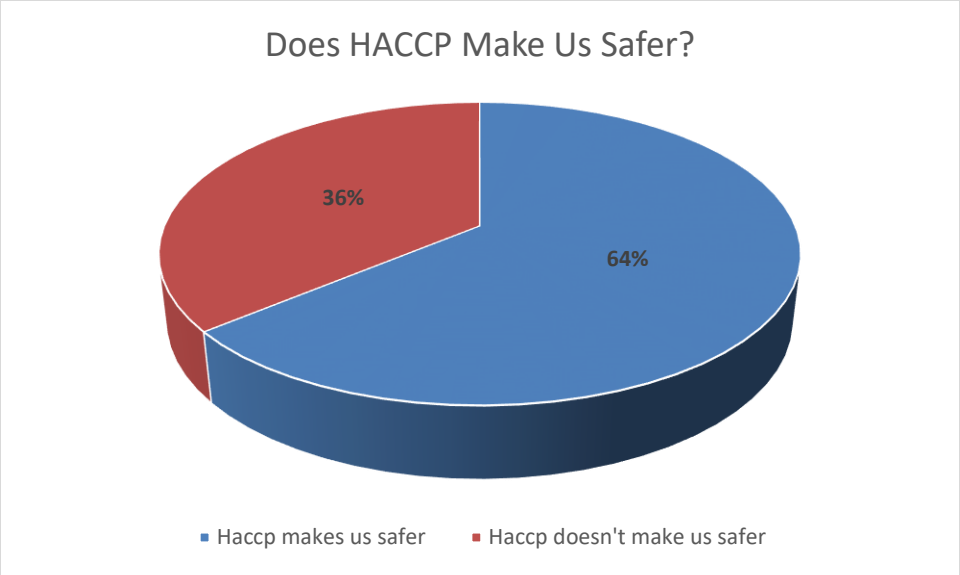
R. HACCP Perception – Makes us Safer

All experts interviewed were asked a last question, whether they believe that HACCP makes them safer or not:

> - Just between me and you, as a personal opinion, do you think HACCP has made our food safer: Do you think HACCP in general makes the food safer? And why? (Or why not?)

The experts were split in opinion, where more than half of them believed it did and rest believe it did not (650HS, 628HS, 607HS, 36HS, 493HS, 451HS, 428HS, 529HS, 517HS, 149HS, 354HS, 71HS, 462HS, 370HS, 16HS, 1HS). The part that believed that it did make people safer were a good mix of auditors, consultants, company experts and governmental inspector. They all agreed that HACCP definitely makes the world safer if some conditions were fulfilled, such as having qualified personnel, having a commitment from that personnel to apply the HACCP steps, and applying the system in the correct way in the company.

The other half that said that they do not believe HACCP makes anyone safer because they see that it makes people more aware, but it cannot stop or inhibit the incidents from happening (621HS, 437HS, 107HS, 471HS, 639HS, 417HS, 402HS, 600HS, 247HS). Another part of those people felt that it does not make the world safer because HACCP has been commercialized and used for export of products rather than for its real meaning of safety. This aspect inhibits them from seeing HACCP making anyone necessarily safer rather than giving an image of safety. The statistical results can be seen in the diagram below.



N= Number of experts interviewed (33) & the percentage reflecting their respective opinions, 21 Experts feed its makes them safer and 12 feel it doesn't.

Figure 7: Question Asked to all Experts Whether HACCP Makes Us Safer

IX. Discussion

A. System and Scope

A.1. Reasons for Using HACCP

This research aims to understand factors behind the success and failure of HACCP and HACCP based systems. Companies in Lebanon were mainly focused on HACCP based systems that can give them certification acknowledgment, and can help them export their products such as ISO 22000. Companies in Germany however, were keen on abiding to the national laws of Germany which mandated the implementation of HACCP since 1998 (Bönnhoff and Hemker, 2007) (p. 1). They were also keen on fulfilling the needs of the retailers by implementing IFS Food or even ISO 22000 which would enable trade inside and outside Europe (Henson, 2008). Big German companies that mainly export their products were mainly ISO 22000 (2005) certified. Only one case had IFS Food certification. Caterers in Lebanon also followed the application of ISO 22000 because they mainly see it as a trend. Caterers and small shops in Germany would abide to HACCP from Codex, HACCP based systems, EU laws, or national German laws such as: Gütenachweis für Kleinbetriebe HACCP, Verordnung 852, DIN Normen and EU-Leitlinien / Leitfaden für die Umsetzung von HACCP SANCO/1955/2005. It is positive that companies in both countries apply HACCP even if, for different reasons, it being a trend or abiding to laws or exporting. A study on barriers to implement HACCP showed that companies tend to have the perception that they are too small to implement HACCP or that the current food safety controls that they have are sufficient (Herath and Henson, 2005; Gilling et al, 2001). It was quite noticeable that none of the experts said that they implement these systems for food safety reasons. Although when asked about HACCP and if it leads to food safety, the majority of experts agreed that it did.

A.2. Country Difference – Developing Verses Developed

One of the variables in this thesis is the country difference, and whether it made a difference if the experts came from a developed country such as Germany or developing such as Lebanon. However, the results showed no connection between country level and choice and output of a system. On one hand, having the HACCP from the Codex as international and recognizable as it is, as well as ISO 22000:2005, have made its spread easy among experts, especially with the globalization and rise in trade rates for all countries including Lebanon and Germany (Cato, 1998). Moreover, European and American countries have mandated industries to have ISO 22000 or HACCP if they wanted to allow products to pass through their boarders (Lelieveld et al, 2016).

Moreover, when the European Union created the project QUALEB in Lebanon, they have offered free trainings for company experts, on ISO 22000: 2005 (MOET (2012). This has made companies aware of HACCP through the ISO 22000 system. Not only experts were trained but also governmental agents especially that the project came through the ministry of economy and trade who took the responsibility to train their inspectors and inspectors from other ministries as well (MOET, 2012). Other reasons for why there was no country difference, is that both industries in both countries, send their experts to training seminars in different countries and work on increasing their profiles. This was evident when experts talked about the trainings they attend that helped them gain knowledge on HACCP and ISO 22000 (1-634 IS).

A.3. Consultants and Auditors Qualifications

Consultants and auditors had a wider variety of systems that they were trained and certified on regardless of their age and years of experience. The interviewed consultants and auditors' years of experience ranged from 1 year to 40 years of experience in the whole food field. The standards covered by these experts included ISO 22000, ISO 9000, FSSC 22000, FDA, HACCP, 15593 Norm for packaging, ISO 14001, Codex (2003), BRC, ISO 9001, GMPs, IFS, and Menu-Safe HACCP. Some standards were food safety related, whereas other ones were for environmental safety such as ISO 14000, energy safety such as ISO 50001, and other standards, national and private. The fact that each expert was knowledgeable and consulting a number of standards rather than being specialized in one specific standard, raises the question about the level of expertise available in the field (Figure 7). The other fact is that the experts were consulting in multiple fields of food such as catering or industry or farming without being specialized or experienced with one in particular. Hazards and processes in the food industry differ according to the product and to the type of company and level of technology. Consultants, as well as auditors, need to have a broad spectrum of knowledge and experience in order to help identify problems in the food field (Surak and Wilson, 2014). Taylor (2001) speaks about the importance of having a food chemistry or food microbiology knowledge alongside HACCP methodology. Sometimes, HACCP training is given by lecturers rather than by people experienced in the field (Arvanitoyannis, 2009). A guideline by IAFP (2014) explains how the search for external help is based on expertise in a specific field of food or process. A study done on (TQM) total quality management creates a tool to identify the best consultant for the specific task because of the belief that a successful TQM system depends on choosing the right consultants (Saremi et al, 2009). In food safety, such a tool or method is not established yet; there are only

recommendations from books and studies on the qualification of consultants in general. (Surak and Wilson, 2014)

The other variable affecting the quality of consultants and auditors was the years of experience (Figure 9). This study shows that some consultants and auditors are getting hired directly after university without having acquired sufficient experience in one or several food sectors before they start consulting or auditing. In the European Union or Lebanon, official requirements for consultants and auditors are not found. However, private companies lay their own rules for that. The Canadian government, for instance, issued specifications indicating the qualifications a consultant should have, and a list of accepted consultants by the Manitoba government (FSP, 2010). Such specifications could give the food companies guidance and assurance on the selection of high quality consultants and auditors.

Examples of experts' varying qualifications were seen throughout the interviews. One company in Germany in particular, who claimed to follow a HACCP system, has shown documents that covered GMP instead and an FMEA study and called it HACCP. They received the help of a student and hired a consultant to do this work. This is one of the misconceptions about the HACCP system where experts perceive they are applying HACCP but instead they are applying another system. Similarly, an auditor in Germany who said he trained and audited a HACCP-based system, was not familiar with certain aspects of HACCP such as hazard analysis, verification and validation.

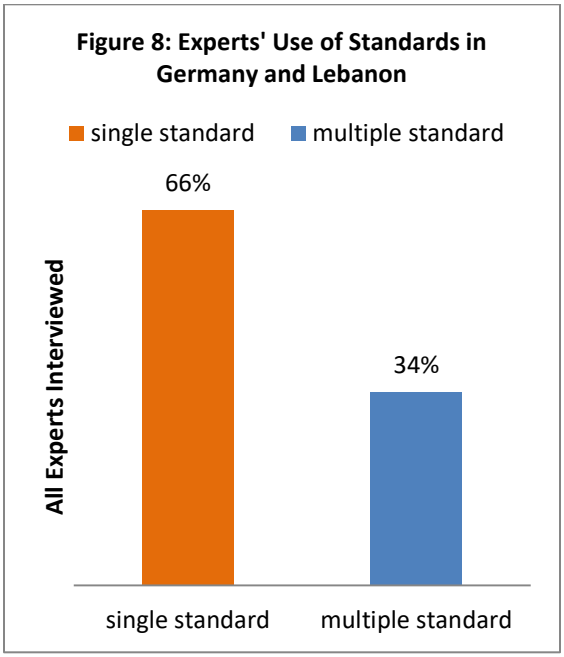
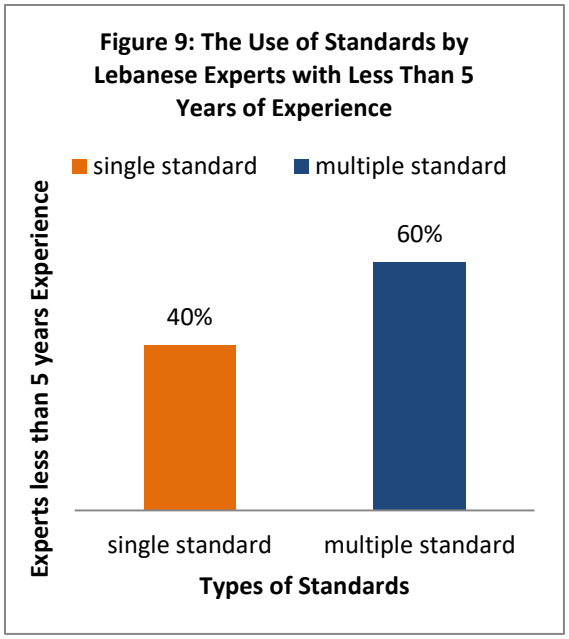


Figure 8: Experts' Use of Standards in Germany and Lebanon

N= 33 Experts of which the respective percentage reflecting their preference to use a Single Standard (22) versus Multiple Standards (10)

Figure 8: The Division of Standards' Use from Experts



N= 10 Experts with less than 5 years of experience, of which 4 use single standards and 6 use multiple standard

Figure 9: The Use of Standards by Lebanese Experts with Less Than 5 Years of Experience

A.4. Limiting the Scope of HACCP – Risks and Disadvantages

When asked about the scope, experts perceived the scope of HACCP and ISO 22000 differently. ISO 22000 was perceived as showing more flexibility to choose any scope, even if a limited one, such as choosing one processing line in the plant, or limited steps of the flow diagram. However, the perception of HACCP was that it covers everything from farm to fork. In reality, the HACCP document offers even more freedom by stating that the scope of the HACCP plan should be identified and even the general classes of hazards are to be addressed, with the freedom of choosing which ones are to be included in the scope (Codex, 2003). The perception of the ISO 22000 was correct since it provides freedom about the product category, process, and production site.

This study showed that this freedom of choosing the scope appears to have caused gaps in the food safety chain, allowing hazards to occur and therefore eventually outbreaks to happen. Interviewees from industries and catering companies admitted to selectively choosing scopes inside their plants or kitchens such as a new production line only as opposed to leaving out older

lines, or certain product types, or a central kitchen that feeds many branches and small kitchens but excluding those branches and kitchens. Experts confessed that leaving out the other scopes, was due to the system's flexibility and because it gives them a bigger chance at getting certified faster and with less effort. This certificate is often linked to their brand name, and allows the customers to think that all of the company's products and branches are ISO or HACCP certified, and subsequently these companies' market shares and reputation can grow. Some outbreaks or recalls have occurred due to these limitations and were related to certified companies (Soon et al, 2016). Some of these outbreaks or recalls were traced back to areas that were not covered by the scope of HACCP. For example, an ISO 22000 certified Poultry Company had above the allowed limits of salmonella during an official inspection at one of its retail shops that are outside the scope ISO (MOPH, 2015)

The second area of freedom that seems to be associated with outbreaks or recalls is transportation. Neither ISO nor HACCP nor IFS Food mention it in the section of hazard analysis as part of HACCP. There are separate standards covering it such as IFS Transport, or PRPs. But the interviewees did not feel that transportation is mandatory and should be part of the scope. HACCP studied in poultry, eggs, and fish products have also identified hazards and their multiplication during transport (Arvanitoyannis, 2009; Soon et al, 2016).

Traceability was yet another section that was only linked with ISO 22000 users. HACCP users, especially governmental officials and inspectors, did not speak about it as part of the scope since it is not part of HACCP in the Codex Alimentarius. The Codex (2003) document does not include traceability neither in the HACCP part, nor in the PRP part (Codex, 2003). The lack of traceability in companies leads to failure in recalling products during an outbreak or an alert especially if the raw material comes from another country (Soon et al, 2016). The presence of an active and effective system of traceability is essential in food safety systems in the crisis management part. Few resources in the literature are found to establish the link between HACCP success or failure and the availability of an active traceability system in the company. A study in Ontario, however, identified traceability and GMPs as the most important practices for achieving food safety (Herath and Henson, 2005). Unfortunately, in the EU, the official controls do not make the documentation of prerequisite procedures mandatory to companies and that includes traceability as well (EC, 2015).

Consultants and auditors play a huge role in the choice of the scope. An example was offered by a company in Lebanon which did not include transportation in the scope, although its products

were temperature sensitive. Since the auditor, however, did not ask about this point or ask them to include it, neither them nor the consultant have added it. Their reasoning was that they will have less to do this way. Here again the role of the auditor entails both responsibility and opportunity to save the company and consumers from a critical risk specifically for food companies in Lebanon who are mainly owning the transportation trucks and are responsible for the safety during transportation.

A.5. Suppliers Effect on the Supply Chain

Another observation concerning the scope of HACCP is that companies can often have good HACCP plans, but that does not automatically imply that their suppliers also have the same level of HACCP knowledge or implementation in spite of having a HACCP certificate. This was observed during this study when packaging or raw material suppliers were interviewed. Some suppliers apply a system that is HACCP-based but does not have all the steps of HACCP. The danger is that food industries depend on the certificate shown by the supplier as being HACCP certified without an on-site check or visit to see if critical points are really controlled (Mortimore and Wallace, 2013). The solution to this is to conduct regular audits at the supplier premises which can enable checking whether there is complete HACCP system in place, and to check whether it is working effectively and whether it is updated on a regular basis.

B. HACCP Team

B.1. Team Importance

The second part of the discussion will cover the first step of HACCP which is ‘assembling the HACCP team’. The interviewer asked about the first thing experts think of doing when starting a HACCP study. It was asked with the intention of seeing the level of importance the HACCP team occupies for the individual experts. Only German governmental inspectors, who rely on HACCP from Codex (2003), have answered that the HACCP team is the first thing that comes to their mind. Since the inspectors were the only experts in the interviews using Codex and not a multiple of other standards, this answer shows clearly that they follow the order of the HACCP steps as is written in Codex (2003).

Several ISO 22000 auditors have agreed that the first step of HACCP is management commitment. This is because management commitment has a whole chapter dedicated to it in

ISO 22000 document's clause 5.1 which comes ahead of the HACCP chapter. In the Codex (2003) document, management commitment is mentioned only in the introductory statement of the beginning of the HACCP chapter, but it does not have a chapter or clause for itself. This draws a comparison between the steps put in standards and their level of importance as perceived by experts. Codex users regarded the HACCP team as the first step according to the Codex standard, whereas ISO 22000 users regarded management commitment to be the first step because ISO 22000 have placed it ahead of the HACCP team.

Hutter (2011) sees that HACCP can function effectively only if both management and the work force are committed to implementing HACCP along with adequate training. Other studies have also found management commitment to be the key to HACCP success (Wallace et al, 2010; Arvanitoyannis, 2009). However, during the interviews when experts were asked about indication showing success of HACCP, only three experts spoke about management commitment. Consultants, on the other hand, were influenced by their role and said that training was the first thing that they think of about HACCP. Training is found in almost every research about HACCP and is listed to be as one of the barriers and limitations (Mortimore, 2001c; Wallace et al, 2010; Wallace et al, 2014). That is due to the limited knowledge of industry workers or due to the price of training. However, the type of training offered or the type of understanding is very varied and not based on an official understanding, and that is one of the main problems found in HACCP through this research.

Companies' answers varied based on their size. The bigger companies showed clear concern about hazard analysis and named it as the first thing they think or worry about. They did not mention the HACCP team because big companies usually have enough expertise. Smaller companies however, answered that they were worried about finding qualified people, and about paying money to improve premises. The latter shows that small companies have a faltered perception about what HACCP is and confuse it with GMP. This will be further discussed in this thesis (see section 6 in terminologies).

B.2. Team Gaps

Almost all interviewed experts, when asked who they think should be part of the HACCP team, agreed to the necessity of having the main functions such as quality control, chefs, warehouse, and maintenance to be part of the HACCP team. However, major functions were missing when experts were asked about the HACCP team such as sous-chefs in catering, cleaning, hygiene,

marketing, sales, R&D, engineers, delivery, drivers, and legal department personnel. Some functions are missing purposely; for example, a few quality control managers said they do not like production to be part of the team because production only cares about producing large quantities in the fastest way. On the other hand, not having people like sous-chefs and lay personnel does not allow the food safety team leader to know specific details about what happens on the ground especially during rush hours. It was also a surprise that functions like cleaning and hygiene are not part of the HACCP team although they are key players in certain aspects of the flow diagram. Excluding R&D and production could result in a failure in HACCP (Mortimore and Wallace, 2013). Unless the HACCP team receives immediate information about changes in formulas or processes, it cannot update the HACCP plan in a timely manner in order to find and control new hazards (Mortimore and Wallace, 2013). Another challenge is that it was often noticed that teams are made of managers or supervisors only, rather than a good mix of all personnel levels. The correction of that problem is that a HACCP team should have someone who has sound theoretical knowledge about HACCP and science, and who should be the facilitator of the team along with experienced participants in the field of risks of the operational hazards (Wallace et al, 2010). Furthermore, it is important to understand the strengths and competences of the team members before diving into their roles in the HACCP team.

Yet, this leads to another problem which was seen throughout the interviews: the level of qualification and positioning among the HACCP team is usually about having a team where only the qualified personnel end up writing and executing the HACCP plan on their own. This happens usually in SMEs where the quality control manager is the only one with a university degree and the ability to do research. This limits HACCP because the QA manager struggles alone to get the commitment and support of the personnel, and very often designs HACCP on his or her own. A change in culture of the whole team is needed in order for HACCP to be successful (Taylor E., 2008). Here, the role of training and empowering the other workers is significant for HACCP to work. It is important to train the workers on the mentality of preventive hazard analysis steps, and inform them about their important role in detecting and limiting those hazards, even though they do not have the degree, language, or writing ability (Taylor E., 2001).

B.3. Role of Auditors, Consultants and Inspectors

Another misconception perceived by some auditors and consultants is that HACCP teams and ISO 22000 teams need to be made of different groups of people. This is probably because HACCP's description of a team was general: 'optimally, this may be accomplished by assembling

a multidisciplinary team' (Codex, 2003) (p. 25), whereas the ISO's description is a little bit more specific: 'the food safety team shall have a combination of multi-disciplinary knowledge and experience….This includes, but need not be limited to, the organization's products, processes, equipment and food safety hazards' (ISO 22000, 2005) (p. 11).

In SMEs, consultants tend to lead or be part of the HACCP team. This shows that the influence of a consultant's knowledge is huge especially when the majority of food enterprises in Lebanon or Germany are SMEs (Baumann-Popczyk and Sadkowska-Todys, 2010; RKI, 2011; Jones et al, 2008). Mortimore and Wallace (2013) have made it a point to food companies that HACCP requires technical expertise and judgment and reminded food experts that they need to recognize the HACCP team limitations and continually seek expert help where necessary (Mortimore and Wallace, 2013).

Consultants throughout the interviews have shown to be of 2 types: they can either offer to do the HACCP plan for the team themselves, without explaining how it was done, or they can play the role of the teacher and trainer and walk them through how it should be done. The reason consultants do not teach the companies how to plan HACCP is either because their contract defines this condition or because they personally want to come back for personal gain the next time a problem happens or when HACCP needs to be updated.

Consultants can either have a positive or negative influence on a company. If the consultants are experienced in the specific food field and in HACCP, they can pass this knowledge and teaching to the food safety team leader and to the team. However, if the consultants do not have a lot of information and experience, the influence they can have on the company is harmful. That is because they would be teaching the company their own point of view and interpretation of HACCP and usually they would use some generic plans to guide them through HACCP. A study about understanding the barriers of a successful HACCP showed that sometimes food operators receive inappropriate information from official control or guidelines and do not doubt the source (Gilling et al, 2001). This information would make them unknowingly apply HACCP in a way that would cause it to fail due to these negative external factors.

Inspectors in Germany, in particular, have said that they focus on the quality of the HACCP team when they do their inspections. This was a positive point to hear although when companies were asked about inspectors in both Germany and Lebanon, they perceived them as focused only on hygiene and cleanliness during their inspections, rather than on the HACCP system and on the

CCPs. This was a similar outcome to a study done by the European Commission where it was reported that inspectors in the EU failed to find problems in the HACCP system, identify deviations in CCPs and notice shortcomings in verification and validation (EC, 2015). This was because when inspectors visit companies with ISO or IFS standards, they tend to focus on general hygiene or general controls rather than on getting lost in all the different terminologies of ISO and IFS. Some of them claimed to use online alert systems like RASFF. Inspectors, although they have the role of enforcing the food safety law and ensuring it is a risk-based system, have shown to be short on this task due to several reasons (Mortimore and Wallace, 2013). Some shortages expressed during interviews were in relationship to lack of a big number of inspectors versus the big amount of food enterprises, the introduction of systems such ISO 22000 that they were not trained on, and the lagging behind on new scientific advancements (EC, 2015; Taylor, 2001).

The quality of the HACCP team members and their respective training were some of the most common answers given by interviewed experts when asked about the indications for a successful HACCP system. This shows that food experts do indeed value a multidisciplinary HACCP team as the regulation and standard ask for, yet, still face some limitations. These include the lack of good training for staff, what HACCP really means, and how to learn specific skills to make it work on the ground; moreover, such limitations can cause serious threats to food safety (Arvanitoyannis, 2009). Staff at food companies generally lack food safety education and not training. The difference is that education helps them understand the why of what they are doing, and engages them into a culture of food safety rather than simply applying rules. Education would involve information about bacteria and spores and temperatures (Yiannas, 2009). The type of training offered can make a difference in the output of the HACCP system. None of the interviewees have said they offered or received such a food safety educational training.

C. Flow diagrams

Experts implementing HACCP were asked to show or tell about their flow diagrams during the interviews. These flow diagrams were generally of two types: extremely brief or very detailed. The reason given behind the choice of either type of flow diagrams was that the consultant had advised them to do it this way, either orally, or via a generic sample that was offered to them.

When asked, experts said that they tend to prefer brief flow diagrams due to time restrictions at work. This makes HACCP easier to write and to understand. Other experts – especially some consultants – support the idea of brief flow diagrams as well because through experience, they

concluded that with a bigger flow diagram there would be a bigger amount of CCPs. Companies that showed brief flow diagrams were generally catering or supplier companies. They were also generally using a generic flow diagram including main steps such as receiving, producing, cooling, and storage. The risk of brief flow diagrams is that the steps and their descriptions, and the specific type of ingredients may miss hazards when specific steps are absent from a flow diagram (Mayes and Mortimore, 2001; Wallace et al, 2010). German guidelines tend to show generic brief flow diagrams as examples (DEHOGA, 2012; IHK, 2012). This is another reason why small companies in Germany in particular would have brief flow diagrams. Catering guidelines, in particular, have flow diagrams defining generally fixed production steps (DEHOGA, 2012; LAVES, 2010; FDA, 2011b). Another point of view seen during interviews is having brief flow diagrams and accompanying them with detailed SOPs. This is based on Codex (2003) pre-requisite programs which ask to write a detailed description for each process step.

Experts were asked about the most common missed steps in flow diagrams in their plants or that they have seen over their years of experience, and they were: in-going things like water or air or compressed air, and some of the out-going things like waste, energy and re-work, air entry, gas entry, pre-preparation, or changing filters, etc. All of those items are related to maintenance or cleaning departments. This observation is linked to the missing functions on the HACCP team. If the persons operating such places were not involved in HACCP preparation, the food safety team and leaders may as well not be involved in the technical details. Additionally, such misses can often lead to hazards being missed and therefore discovered eventually through a recall or an outbreak (Soon et al, 2016).

Hiding information from flow diagrams was one of the observations experienced by consultants and which had led to outbreaks, recalls, or alerts namely in Lebanon. Several Lebanese companies having ISO 22000 certifications had their products rejected through alerts due to the presence of illegal additives which can be seen as FDA alerts that are continuously updated (FDA, 2016). Another example is from a recent scandal that happened in Lebanon about the presence of high quantities of an additive in a Lebanese dairy product at a company which is also HACCP certified (MOPH, 2015). It was revealed by the media and the consultant declared that he did not know about these additives (El-Jardali, et al 2014).

Verifying flow diagrams on the ground was another step that almost none of the food industry experts spoke about. One consultant, however, spoke at length about how the lack of this step, especially verification during night shifts or in the times of rush hour, causes the flow diagrams to

have important steps missing. Having a schematic design and verifying flow diagrams at different time are very important as preliminary steps to hazard analysis (Taylor J., 2012) (p.15).

D. Raw Materials

Raw materials are another topic that all experts had a split opinion about. Some believe it is part of good manufacturing practices, and others believe it is part of HACCP. Namely, German inspectors believed it belongs to a separate program, and Lebanese inspectors believe it should be a CCP. This confusion is clearly coming from the classification of raw materials in standards. HACCP, for example, has a section about raw materials in clause 5.3 called 'incoming material requirement' which is part of the PRPs prior to HACCP (Codex, 2003). ISO 22000 speaks about raw materials in 2 sections: the first one is called the PRP section in 7.2 and speaks about creating a program for raw materials among other items, and the second one is in section 7.3, which says that hazard analysis must be done for raw materials (ISO 22000, 2005). It is the same in IFS Food (IFS, 2012). A correlation can be made between the standard's positioning of raw materials and the experts' confusion. That is this difference first between ISO and HACCP in the position of raw materials, and then between the 2 sections of ISO, have led to the confusion of experts on whether it is a PRP or part of HACCP itself. Clearly, in ISO, its position shows it to be part of both since they request a program for it, and they request analysis of each raw material during the HACCP study (ISO 22000, 2005).

This leads to the next question which is whether raw materials can be a critical control point or it has to remain as part of the pre-requisite programs. Several consultants and auditors from either countries insisted that it is a critical control point. They have done that with the aim of preventing its entry to the plant in case it did not meet the critical limits set for it. However, a few very experienced consultants from Lebanon and from Germany objected to the idea because of the clauses 7.6.4 in ISO 22000 (2005) about monitoring CCPs which implies that monitoring needs to happen online to a CCP through indicating monitoring times and frequencies. The clause 7.6.5 specifies planning a corrective action when critical limits are exceeded, meaning that CCPs need to be correctable which cannot work in the case of raw materials (ISO 22000, 2005). This is similarly described and proven in HACCP Codex (2003) through the HACCP description in page 24. Moreover, an international food safety book explains that veterinary inspection has proven to be very ineffective because there is no reliable way to detect the presence of that many bacteria and virus in normal animals (Heijden, 1999). They say that there is no statistical plan or testing to ensure the absence of pathogens from all samples because it is both physically and financially

impossible. Testing samples cannot ensure food safety even with a strict sampling plan (Mortimore and Wallace, 2013). So, it is not possible to have raw materials as a CCP. However, if the hazard assessment identified a material as critical, then, this could mean that its CCPs can be checked and monitored at the supplier's place.

The risk with considering raw material a CCP is that the company will end up with a lot of CCPs and thereby with lots of HACCP plans (Mortimore and Wallace, 2013). This will especially be the case in Caterers using a lot of ingredients or in industries with a lot of lines and products. Having too many CCPs is another limitation for HACCP which will be later discussed at length. (See part 5.5.3.2)

Some consultants were teaching that raw materials are OPRPs because they are risky, but not too risky. They seem to overlook the context of ORPR in ISO 22000 which says that it needs to be monitored as well when identified (ISO 22000, 2005). Moreover, those consultants justified their position by saying that since OPRP is monitored as well in clause 7.5 (c), this can help the companies make sure that they do not receive bad raw materials. Hence using the same justification as was given to name it a CCP.

E. Hazard Analysis Critical Control Points

E.1. Hazard Identification

Hazard analysis had three major areas of study: identifying, assessing, and controlling of hazards. The results were divided based on the experts' roles and different points of views. There was a lot of correlations between the understanding of the industry and the advising experts. This section will explain how the understanding of consultants, auditors and inspectors influences how hazard analysis and critical control points are chosen inside the food sector and how this has led to failures in HACCP.

Hazard identification was the first challenging area facing industries and caterers. Their challenges to identify hazards were due to the lack of naming the hazards, emerging hazards, missing steps from flow diagrams leading to missing steps in hazard analysis, using generic hazard analysis samples, choosing every hazard possible, inability to afford experienced consultants, lack of some critical limits in regulations and laws, naming hazards wrongly, and the inability of laboratories to test the depicted hazards.

E.1.a. General Hazards

Writing general hazards is one of the most common challenges seen in this study in hazard identification. Industries or caterers would choose to write the hazard names generically as 'biological hazard' or 'bacteria' without going into specifics about whether it is a spore forming clostridium, or an infectious salmonella or a norovirus or any other name that can help describe how to control or eliminate this hazard. This is in line with the study done in Germany and Poland where less than 10% of 152 companies have written specified hazard names whereas the rest used general naming (Trafiałek et al, 2015). Other experts would group hazards as well although studies show that grouping the hazards as such causes a problem because there are major differences in where they arise from and how they are controlled (Taylor J., 2012; Wallace et al, 2010). A book called “HACCP Level 3” shows an example from the catering companies about a biological hazard that was controlled using chilling at 5 degrees (Taylor J., 2012) (p. 13). The problem here is that certain hazards cannot be controlled at this temperature and may need a lower one.

Company experts were also asked about information sources they use to collect hazards. As a result, the following correlation can be drawn: company experts who reported to use general Google sources and Wikipedia were more associated with hazard analysis systems that had general hazard names. Company experts who used resources such as outbreaks or alert websites, food safety related standards such as Codex, FDA, and Libnor standards, laboratory results, recalls and alerts were experts associated with specific descriptions of hazards in hazard analysis.

E.1.b. Consultants’ Qualification

The use of general names was primarily linked to consultants finding generic plans for hazard analysis on the internet or inside guidelines, and applying them to their own premises. Moreover, some consultants hand out the same HACCP plans to several companies. This has caused such a phenomenon to spread widely. Mortimore (2001c) has also observed this in her research and linked it to a lack of expertise in company experts, management and consultants. She sees this problem as resolved if the HACCP team leader is of a sound scientific background and is well trained for HACCP use by recognized sides. Consultants, on the other hand, should be evaluated according to a standard and not just hired to fill a position.

Furthermore, both consultants and auditors with very little experience in the field were associated with naming general hazards. They were also sending out a lot of raw materials and finished products to test on different hazards in the laboratory, and thus costing their companies a lot of money. Consultants with limited experience are being hired in consultancy companies. This enables the widespread of their methods especially if the company is international and covers several countries like some of the interviewed companies. This is one way how HACCP plans will have general hazards, and therefore will be unable to design specific controls to eliminate that hazard.

However, experienced consultants who have been long in the field seemed to have more information sources. They have realized that standards and regulations are not enough to implement HACCP, and that a reliable source based on science and research such as EFSA, FSA, UNDC, and FDA are needed to correctly name an updated hazard as some experienced consultants expressed in the interviews. These consultants can coach and teach companies to follow the same strategy (Mortimore and Wallace, 2013). In this case, companies can independently learn the importance of reliable information sources and can update their systems in time. This can lead them to construct a robust HACCP system ready to detect and prevent any new hazard before penetrating their system. Companies need to recognize their need for further technical knowledge and thereby seek the help of specialized sides.

E.1.c. Generic Plans

Using generic plans was mainly linked to SMEs as observed in this research and in previous studies (Mortimore, 2001b; Schmidt and Newslow, 2007). Some of the high caliber consultants interviewed stated that one problem SMEs face in particular is that they do not have the money to hire a well experienced consultant. This was seen throughout the interviews where one caterer for example, would hire a student to write down the HACCP study for the company. Other SMEs in this research who did not hire a consultant would refer to the internet as the source for hazard analysis plans. The salary of an experienced consultant was spelled out to be one of the barriers to a sound hazard analysis (Taylor, 2001) (p. 7).

E.1.d. Wrong Naming

Naming hazards wrongly is mostly associated with the fact that industries complained about their limited ability to access academic studies that can apply to products in Lebanon. Not only in Lebanon, but in Germany too, experts have to pay for publications or books related to HACCP

and food safety. This was similarly expressed in studies about HACCP barriers (Taylor, 2001) (p. 5). The limitations of laboratories to detect and test all types of hazards in Lebanon was one of the recurring answers that company experts, consultants, auditors, and even governmental inspectors have complained about in specific to Lebanon. Laboratories as described by experts were not able to test certain strains of bacteria or chemical residues such as pesticide residues that were sent to them. Another problem expressed especially by governmental inspectors is not discovering new hazards due to a lack in local scientific research coming from universities and partnerships with other countries and research centers. The inspectors related the difficulty in identifying hazards due to the lack of information sharing across the Arab world. Literature concerning laboratories in Lebanon was not found and recommendations to further investigate this point are needed. This is one clear difference between the two countries. German inspectors on the other hand complained about the lack of collaboration and continuous research between them and universities.

Naming the hazard incorrectly was common to both Germany and Lebanon. Names such as 'heating step' or 'the chicken' would be mentioned in some hazard analysis plans (Trafiałek et al, 2015). One expert in particular said that they carry certain control measures because the system was put this way, and she did not know exactly which hazards were being eliminated. This is related to the fact that this expert had very little experience in her field, almost no HACCP training, and did not have a consultant helping her understand the system when it was previously put. This expert is the HACCP team leader in that company and has even passed two ISO 22000 (2005) audits with such limited information and knowledge.

E.1.e. Inspector’s Qualification

Lack of documentation and legal standards are observed particularly in Lebanon as described by some Lebanese auditors. Industries or caterers did not necessarily have Libnor standards or other international standards that can be their legal guide to choose the hazards in their local products. Moreover, checking for these regulations and documents is not the primary focus of Lebanese and German inspectors when they do their yearly visits. They rather ask about hygiene measures and make observations. SMEs, though, tend to depend on official control due to their limited resources (Taylor, 2007). Unfortunately, inspectors, governmental officials from the health department, or veterinaries do not have the most updated knowledge on the right uses of HACCP, or detecting CCP deviations since they have the HACCP version from 2003, and have no awareness about private standards such as IFS Food or ISO 22000 (EC, 2015; Hutter, 2011).

The majority of inspectors did not mention a word about risk, or risk-based HACCP when asked about hazard analysis. They affirmed using a checklist to conduct inspections, focusing on either hygiene or documentation. Both German and Lebanese inspectors interviewed did not study food science or food safety. In Germany, the inspectors interviewed mostly had a veterinary degree where as in Lebanon they had an agricultural degree. The lack of education in the specific field of food sciences, didn't help the inspectors especially with problems inside the food industries or the catering businesses.

E.1.f. Auditors Qualification

This leads to question the role of the auditors during audits and the type of investigations they perform upon certifying a HACCP system. Clearly in the example above, the auditor did not investigate the knowledge of the people, and rather only looked at documentation. Auditors need to study the HACCP team, qualifications and training plans, as basic part of the audit, say Mortimore and Wallace (2013) and Surak and Wilson (2014). The effect of auditors was seen indirectly during another study measuring companies' effectiveness of HACCP where auditors were viewed to stick to the HACCP document and steps rather than conduct a wider examination which can uncover dynamically without using a checklist (Wallace et al, 2014).

E.1.g. Choosing Every Hazard

Another common observation made by consultants or auditors, in particular, is that companies choose every hazard possible for each step of the hazard analysis. The reason maybe comes from the wording HACCP used when it described the step of hazard analysis as: 'should list all of the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption' (Codex, 2003) (p. 25). This statement was misunderstood and led companies to collect every single hazard possible whether significant or not. This was similarly observed in a study in the UK about butchers where researchers found that it occurred due to a misinterpretation of methodology (Taylor, 2001; Wallace et al 2010). Taylor (2012) identified this as a problem when companies tend to 'pick every pathogen in the textbook' (p. 23). She adds that it is important that the HACCP team stays focused and chooses hazards that cause a significant health risk. When hazards are general, they cause the hazard analysis study to be difficult and the plan to be weak (Wallace et al, 2014). Choosing every hazard instead of the significantly high-risk hazards leads to loss of time and lack of focus (Taylor J., 2012).

E.1.h. Emerging Hazards

A very common challenge for hazard analysis is emerging hazards. Experts, when asked about emerging hazards, gave examples that did not necessarily match its definition. EFSA (2007) defines an emerging hazard it as 'a risk resulting from a newly identified hazard to which a significant exposure may occur or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard' (p. 1). Some experts spoke about packaging material and its migration to the food. Others, however, spoke about norovirus and how although it is not new, it was new in terms of the occurring food outbreaks. The definition of emerging did not seem clear to all experts which is the reason they gave wrong examples about it. When experts are not aware that bacteria can adapt to new conditions and emerge, there is the risk of failure in HACCP. Dubois-Brissonnet (2012) spoke about how 'the resistance of Salmonella to antimicrobials can evolve as a function of its living conditions. If bacteria are subjected to stressful conditions, they can increase their survivability under conditions that would normally be lethal' (p. 2). A good example of this would the survival of salmonella in a very fatty environment such as peanut butter or sesame paste (FDA, 2012). Allergens on the other hand, were not very familiar to the Lebanese enterprises. This is why many Lebanese experts named it as an emerging hazard, although, it is not new per say. It simply became familiar because of import rejections from USA on the Lebanese products (FDA, 2016). The lack of knowledge and expertise on emerging hazards from the company's sides is one of the most important reasons as to why HACCP is failing.

The reasons behind the lack of knowledge about emerging hazards are related to developmental differences in countries. In Lebanon, for example, experts found limitations with laboratory testing and with academic information allocation. Experts also said that the lack of outbreak tracking in the Lebanese health system is another limitation to knowing about emerging diseases. In the other hand, German inspectors in particular, complained about the lack of information sharing between the health department, universities and themselves and names it as a reason they are not updated on emerging diseases.

Another reason for this lack of knowledge can be related to how often experts update the hazard analysis. When experts were asked about the update of hazard analysis, the majority had admitted to never updating it unless a problem occurs, information from the media comes out, or the yearly audit is due. However, updating does not necessarily mean that hazard analysis is newly researched and updated, but rather that the documentation is adjusted with new dates or

maybe a new process was added in order to show the auditor that the document has been reviewed.

Caterers in general did not have a wide variety of emerging hazards to offer during the interview. One of them said that this is due to the lack of time for testing, because they often cook and sell the products during a short period of time. Hutter (2011) states that the catering business suffers the most in terms of HACCP due to the high amounts of foods they produce and to the high complexity and high turnover of employees that they experience continually.

Experts seemed to be familiar with non-food hazards. A few examples were given about pests from plants as decoration in weddings or caterers or hospitals. This is especially important if they are using plants for cooking and decorating, which they confirmed they do, and which comes in direct contact with the food. An outbreak in Germany discussed earlier was related to flowers in weddings (Wissmann et al, 2010). Similarly, a study on the perception of HACCP in the EU and USA expressed the same concerns towards applying HACCP in a place where environmental factors cannot be controlled such as the weather (Hyde et al, 2014) (p. 23). Non-food hazard examples were given about different GMP related equipment and machinery, however, one example given by an interviewee was truly emerging; the discovery of E. coli coming from plastic bags. E. coli is likely to come from animal or plant origin (Jay et al, 2008). Finding E. coli related to plastic bags creates the question about finding advanced methods to predict the emergence of hazards.

Emerging diseases is not a simple formula that the companies can learn and apply. It involves biological and chemical understanding of the evolvement of particles, accumulating data on population subgroups and vulnerability differences, and finally information about novel methods of biotechnology (Heijden, 1999). Companies, consultants, auditors and even experts do not usually have the qualification or the time to come across this information. Hence, this should be the continuous work of a professional organization consecrated for this job.

In Germany, BfR is responsible for hazard assessment. Along with RKI which conducts epidemiological case control studies, they both attempt to resolve the current outbreak events (RKI, 2011). They do this as well in coordination with local authorities. The complaint coming from inspectors in Germany is mainly with the aim of having early communication of emerging diseases in order to warn companies ahead of time. Although BfR on its website declares that it does communicate with certain vulnerable groups such as nursing homes, clearly a faster and more

efficient cooperation and communication is needed between the official controls in the different states and the BfR center (BfR, 2016). This is different to what is found in Lebanon.

In Lebanon, there are no official research centers for food safety (El-Jardali, et al 2014). In the government, the political challenge and the conflict between the different ministries does not help with creating a system for communication. Around 6 ministries claim ownership for food safety and none of them have studies on emerging diseases or even a database for that. Epidemiological data is also not existing. The recommendation would be to form a new food safety organization that would conduct continuous studies on emerging diseases and hazards and that can be the common link between several parties collecting and sending out timely information. The different parties involved should be: the different ministries of industry and agriculture, the local municipalities, the hospitals that do private initiatives on new diseases, and the laboratories that receive new hazards from foods.

E.2. Hazard Assessment

Hazard assessment is the second step of hazard analysis. The results showed that less than half of the experts were following the order of HACCP or ISO 22000 in identifying hazards, then assessing them and then choosing controls. Some of the experts choose to either skip this step of hazard assessment and go directly to choosing controls using the decision tree, or choose to use this step as a final step and as a method to choose critical control points instead of using the decision tree. Only one industry expert, however, decided to do hazard assessment after the decision tree and this person was from Germany. The rest of the experts however choose to follow another order for assessing the hazards and these are shown in the paragraphs below.

E.2.a. Lack of Hazard Assessment

About 6 experts choose to move all the hazards identified to the decision tree without doing hazard assessment. All of those experts were users of Codex (2003) rather than ISO 22000 or IFS Food. One reason could be that the Codex describes the steps of hazard assessment with the words 'wherever possible' – so it is perceived as if the whole step is optional although is it not – and does not call the step hazard assessment but rather places it as a part of the paragraph about conducting hazard analysis. Another possibility is described by two experts who find the hazard assessment quite subjective and prefer relying on other factors such as the decision tree. Several studies agreed to this theory and talked about the difficulties in quantifying risk. One study in particular saw that quantifying hazard analysis was found ineffective by most food industries and

tried to create a predictive quantitative model by using Microsoft Excel sheets in Korea (Ryu et al, 2013). However, the model has a question that is also based on the opinions of experienced workers which makes the formula subjective again. It has been affirmed that experts still use their experience and expertise to assess hazards due to the perceived complexity of using matrixes and numbers. Most trained experts were not able to carry out hazard assessment in spite of being trained in a multinational company (Wallace et al, 2014).

Consultants and auditors did not express complete support of the matrix method or even FMEA because they consider it very subjective and not designed for food. Although Wallace et al (2014) relate the lack or shortage of using hazard assessment to the understanding and quality of the training of experts, they also highlight that the trainers and consultants themselves are also shying away from applying the assessment and directly using the decision for the same reasons. Highly experienced consultants blame this on the lack of guidelines or methodology offered by HACCP or ISO.

Consultants, who used HACCP, often did not use the hazard assessment matrix and depended only on the decision tree alone to identify whether the step was a CCP or not. This is because they found it quite objective this way, and preferred to depend on their gut feeling to figure out the real CCPs. Moreover, they knew that FMEA was not created for food safety purposes so they do not find it applicable to food, especially since Codex does not mention it. The danger in using only the tree, without a hazard assessment is that companies will end up with many CCPs. This point will be discussed later in the chapter about CCPs (see below part E.3.b).

E.2.b. Hazard Assessment using Matrix to Find CCPs

Another group of experts were using the hazard assessment matrix without the CCP decision tree to choose CCPs and OPRPs. All of the companies doing this in the study have received this method from consultants, or are consultants themselves and designed it that way. The structure of ISO 22000 may have led to this implementation. ISO 22000 places, both OPRPs and CCPs in sections 7.5 and 7.6 after hazard assessment which is in section 7.4, therefore implying that hazard assessment should be done for both CCP and OPRP. Afterwards, ISO 22000 (2005) clearly says that whatever is the method to be used for decision making shall be documented. This causes a sort of grey area for the interpretation of this section. Whether the decision tree must be used before or after hazard assessment is not clear in ISO 22000.

Almost all auditors, when asked about which method of hazard assessment they look for, during audits, said that they did not care much for the method as long as the needed controls are mentioned. Many auditors said they look for the logic behind any method and accept it as long as it is logical. This neutral opinion shows the companies that the method they are using is right and accepted. However, few companies and consultants complained that although they sometimes conduct a certain method, if the auditor is not convinced by it, he or she will not let the company pass the audit. An example given to support this point is if the auditor believes that the cooking of bread is a CCP although there is no significant hazard detected by the company, then the auditor would not allow the company to pass the audit. Thus, the company usually changes the method on paper to please the auditor in order to pass the audit and get the certification. Again, examples like that were associated with inexperienced auditors who are not specialized in the field they are auditing. These auditors have usually learned defined control steps and tried to apply them in their audits. At times, auditors recommend systems that are not in line with HACCP, and companies do not have the money to ask consultants for help, and so they rely on those suggestions and recommendations of the auditor (Gilling et al, 2001) (p.5). This leads them to unknowingly fail the implementation of HACCP due to this external factor. However, further understanding of the dynamics of how auditors influence HACCP success or failure, were not explicitly found in literature.

A consultancy company in Lebanon that chose such a method of assessment that is in contrast to what ISO and HACCP dictate, was chosen in 2015 to train governmental inspectors on food safety (Executive Bulletin, 2015). While this company would train inspectors to its own methods, namely general naming of hazard, and using matrix to choose CCP and OPRP without a decision tree; this illustrates the widespread of food safety methods based on private company methods. This causes more confusion to the industry when the inspectors ask for this methodology, and a consultant and auditor will ask for another. Such controversies in influences tend to be the cause of HACCP confusion among the industries. Little to no research has yet been done in this area.

E.2.c. Hazard Assessment using FMEA

The experts interviewed used a different set of numbers for the hazard assessment matrix and their choice was influenced by several sources. Some experts were following ISO 14000 which is for the environment and uses a scale of 1 to 5. The experts would therefore adapt it and use it for food safety. Others in Germany mainly use FMEA which is originally designed to find process problems in any industry. Many using FMEA will often come out with no CCPs as seen in some

German companies (Schaeffers and Murphy, 2014). The interviews showed that this is because they calculate the possibility of detection with severity and likelihood before and after applying the control measure. The interviewees that used FMEA, understand the two FMEA calculations as steps responsible to find a critical control point, rather than the first step is to find a CCP and the second steps is to test whether the control measure is effective. However, they fail to understand that the first calculation should yield into a CCP and the second should confirm that the control measure defined is effective. Their failure to understand the difference between the two calculations causes them to have no CCP. Another example of FMEA was done at the University of Bonn in Germany where they used FMEA in the context of farming as part of a HACCP study (Gödderz et al, 2007). FMEA has also not yielded any CCP, nor was there a column to identify the type of control (CCP or PRP or OPRP). The calculation was done twice to ensure that the control is adequate. This is another example of the inability of understanding FMEA and therefore yielding no CCP. Although this study was said to be a HACCP study, FMEA principles were followed. Whereas FMEA is a great tool to help with process parameters and is excellent for GMP failure detection, it needs to be adapted to food safety systems for high-risk hazards allocation and critical control finding (Arvanitoyannis, 2009). However, based on the above finding, FMEA, when it is used incorrectly in its original design, it is clearly causing HACCP more harm than help.

E.3. Control Points

When asked about control points, each expert answered according to what he understands this step to be or according to the training or the guideline that was used. Generally, HACCP and IFS Food users were familiar with CCP, CPs and GMPs. ISO 22000 (2005) users were familiar with CCP, OPRP and PRPs. Catering on the other hand had defined only CCPs and the rest were called hygiene steps or programs. The justification comes as well from standard's naming and structure primarily. When companies who have HACCP switch to ISO 22000 or IFS Food, they tend to keep the same hazard assessment and allocation of critical control points according to HACCP, unless a consultant or an auditor says it is not the right way, then they would update it to ISO 22000 where some GMPs or CPs will be named PRPs and OPRPs and the CCPs remain the same. This is the general observation deduced about the choice of controls at different companies.

Interviewees using Codex (2003) had no confusion about choosing CCPs. They inserted the hazards into a decision tree and this enabled them to tell where it is a CCP. The grey area for them was whether the remaining steps are CPs or GMPs. The answers varied between CPs,

which to them were process steps where hazard will be eliminated in the next steps not in those steps, and GMPs being either hygiene programs, maintenance. Some even choose quality measurement as a GMP or a CP. This confusion usually came from personal interpretation of the standard or guidelines that used terminologies interchangeably (Dehoga, 2012; Laves, 2010; BVL, 2013; Trafiałek et al., 2015).

E.3.a. OPRP Definition Confusion

For the ISO 22000 users, the hazard assessment shows several methods to reach an answer. Some interviewed companies created customized decision trees that resulted in CCPs, OPRPs and PRPs. ISO 22004 (2014) which is a guideline to ISO 22000 implementation offered a decision tree with the end options being either CCP or OPRP. Moreover, when looking in literature for further guidelines about this topic, information found supported this interpretation of ISO 22004 (Afoakwa et al, 2013). IFSQN (2011) designed an ISO 22000 guideline which included a HACCP plan template. This template had columns for hazard analysis, hazard assessment and the decision tree to figure out whether the control step is a CCP, OPRP, or PRP and called it 'the HACCP calculator' (IFSQN, 2011). Coca-Cola in synchrony with Michigan State University were one of those who has transformed the HACCP decision tree into a CCP/OPRP decision tree (FSKN, 2009). This was also assured by another ISO issued PowerPoint explaining ISO 22000 and showing the differences in the table below:

Table 3: Checklist taken from ISO International Organization for Standardization, ISO Regional Workshop on Conformity Assessment, 9 and 10 May 2007

Purpose of the control measure	PRP	OPRP
Maintenance of the basic hygienic conditions and activities	Yes	No
Controlling hazards identified by hazard analysis and need to be controlled	No	Yes
Validation is required	No	Yes

According to the table, and the definition provided for OPRP in the ISO 22000 standard. An OPRP is very similar to a CCP in terms of how to control and monitor it (ISO 22000, 2005). When asked about OPRP, auditors did not express a clear understanding of it during the interviews. Consultants have expressed confusion as well and were complaining that ISO 22000 has added yet another terminology confusion to the already existing ones. Inspectors in Lebanon and Germany never heard of the term OPRP and this is mainly coming from the fact that they follow HACCP from Codex (2003) only which does not include this term.

E.3.b. CCP

One of the barriers to an effective HACCP was related to the high number of CCPs chosen by some companies during the interviews (Taylor, 2001). This phenomenon is due to generic samples in guidelines or commonly understood examples of CCPs (Heijden, 1999; Pierson et al, 1992). An interviewed consultant gave the example of pasteurization in a sterilized milk product. The company would name it CCP just because some generic samples always have any heating step as a CCP, although there is a sterilization step after it. Other experts gave examples such as naming all metal detectors CCPs, and not just the last one. These examples clearly show that experts do not understand that a critical control point is the last step in place with the aim of controlling and eliminating a dangerous hazard. This leads to a point in the system where, due to having many CCPs, deviations may start to be negotiated (Wallace et al, 2010). To resolve this, Mortimore and Wallace (2013) advise using the decision tree for the significant hazards only, which means using a hazard assessment method before the tree. Another study showed that having too many CCPs could result from the lack of compliance to GMPs or PRPs in the system (Roberto et al, 2006). This is why understanding the importance of PRPs and applying them is key to start up HACCP. Reducing the CCPs could result in an effective HACCP system. A study in Ghana about producing cocoa beans attempted to reduce CCPs by introducing ISO 22000 and replace CCPs with PRPs where needed (Afoakwa et al, 2013). This was done through a matrix with questions. They were able to reduce 6 CCPs to only 2 CCPs, replacing the rest with PRPs. This yielded a very effective and risk-based HACCP.

Companies with many CCPs justified it as extra control. The reason behind this mentality is not just from generic plans and guidelines, but is also related to auditors. Some of the auditors interviewed did not have a problem with having too many CCPs at a company. Their justification was that too many CCPs signify more control, so they allow the companies to have as many of

them as they want. However, they see the process as a progressive process where CCPs can decline from year to year when the company has a better grasp of HACCP. Auditors' agreeing to this phenomenon or even teaching it to their companies, explains why certain companies insist on that many CCPs without seeing the danger of losing focus on significant hazards.

F. Terminologies

All experts were asked about different terminologies that have shown to cause confusion. None of the experts were able to distinguish the difference between hazard analysis and hazard assessment, or risk analysis and risk assessment. The companies that were using more than one standard had differing opinions according to which standard hazard analysis should be done. They were mostly consultants who answered this question and each one of them chose the hazard analysis description according to what they think was the better way. They did not base their decision on any resource or regulation. Inspectors, when asked this question, would always to be seeking methods from Codex Alimentarius because this is what they know and use daily. Industries and caterers, however, would choose the method that the auditor or consultant or even inspectors have asked for. The influence of auditors and consultants in specific was highlighted concerning what the industry understands and implements. This was clearly different at as well in the literature review part in section 2 where the term “risk assessment” (based on C No 178/2002) was often used by different publications in the meaning of “hazard analysis” (based on ISO 22000). In this thesis, the results, discussion and conclusions used the term hazard analysis, rather than risk assessment. However, this clearly shows how terminologies are causing confusion not only to experts but also to academics who have many publications.

Most companies were not able to clearly distinguish between HACCP and GMP. Very few consultants were clear that GMPs are pre-requisite programs that need to be in place before starting a HACCP study. Most governmental official did not associate with the terms when asked. However, the latter knew that GMP comes before HACCP and that HACCP has more to do with the plant and the process where a GMP has to do with hygiene. This was confirmed in the recent study done in EU where official control did not really take GHP/GMP into account during their food safety audits (EC, 2015) (p. 23).

Several reasons are attributed to this confusion. One of them is the structure of the Codex document having HACCP as an annex at the end which gives the impression that everything done for food safety is called HACCP. The second reason is coming from consultants, auditors, and

sometimes even inspectors who are giving the perception to companies that HACCP is about buying very expensive equipment such as expensive stainless steel or new metal detectors. The perception given about HACCP is one reason small companies do not want to implement HACCP (Taylor, 2001). Although changing equipment is linked with GMP improvement, which is also a preparation for HACCP, this misconception deviates the experts from the main goal which is that HACCP is about finding hazards and controlling them. Consultants, auditors, and inspectors have the responsibility to transfer the right information to food companies. However, the interviews did show that most of those consultants and auditors, also do not understand the difference between HACCP and GMP.

The third reason derived about confusion in terminologies is that experts who study food safety courses in university were not given practical examples that help them remember and distinguish the difference between both. Similarly, in companies, several experts have expressed that they have asked for recognized examples from the Codex Commission or the International Standard Organization explaining the difference between the different terminologies. They have also requested an elimination of the multiple terminologies given to controls. Such initiatives are recommended to be elevated to an official level in order for a change to happen.

G. Validation

G.1. Validation Definition

Validation as a word was familiar to all experts, German or Lebanese, who applied ISO 22000 or IFS Food but not necessarily to experts who applied HACCP. Almost 8 of the experts from the 33 interviewed were able to give a definition in synchrony with ISO 22000 standard and supply validation methods meeting the descriptions in Codex Validation standard (Codex, 2008). However, none of those have mentioned this document when asked about which guidelines they use to implement validation. Examples of these validations were done via one or more of the following methods: research, precedent, analysis of process history, using internal or external certified labs, legal references, and statistical lab analysis. Some even discussed that re-validation is also performed after corrective action on maintenance problems. All these answers came from experts who apply or consult on ISO 22000 (2005) and IFS Food, but not on HACCP. Such result was not country specific, or company size specific, because the results equally varied between both countries, which helped see that the influence of the understanding of validation comes from other factors such as: impact of the choice of standard or guideline used, confusion

of terminology, influence of consultant, auditor and inspector on validation and lack of process variation in validation. A good hazard analysis and an update of the hazards in time are key factors for preparation of a good validation. Their importance is discussed earlier in the chapters (see part E.1.g).

G.2. Validation According to Codex (2008)

The implementation of validation as a section of HACCP regardless of whether it matched the correct definition of ISO 22000 (2005) or not, was related to companies who exported their product to other countries. Every company interviewed stated that exported products have validation documentation as part of the HACCP principles. An auditor confirmed this link between export and specific standards by saying that most companies he consults and audits for whether in EU or in other parts of the world, have to supply validation documentation as part of HACCP in order to get the ISO 22000 or IFS Food certification which allows them to export products. In Lebanon, the Ministry of Economy, started the QUALEB program with the aim of helping Lebanon ascend to the WTO. This happened via offering free consultations for one year for food companies in order to implement and get certified in ISO 22000 to enhance the export of Lebanese food industries (TDN, 2010). This is why most companies interviewed in Lebanon had ISO 22000 certificates, and most consultants and auditors and even governmental inspectors were more knowledgeable in ISO rather than in HACCP Codex, and hence have heard of the term validation. Not all of them, however, understood it in accordance to Codex (2008) or even the definition of ISO 22000.

G.3. Challenges of Validation

Although all interviewed companies in Lebanon were ISO certified, only few understood the actual meaning of validation; it concludes that other certified companies apply validation only on paper work. The question arises about whether auditors auditing those companies catch this lack of understanding, or are they themselves confused about the real meaning of validation? But, prior to that comes the question about what influences a correct application of validation and what influences a wrong one?

Concerning the first question, this research showed that not all companies with certification applied validation in accordance with Codex (2008) or even in line with ISO 22000 explanation. This seemed to be depending on several factors. All companies interviewed for this study were certified; however, only 8 of them had validation done in accordance with Codex validation

document and ISO 22000. The remaining companies have received their certification without having implemented or understood validation. Factors influencing the correct implementation of validation were always related to the understanding and the training of the consultant(s) when the company was medium sized, and was related to the use of international standards and guidelines for HACCP such as FDA or private company standard when the company was big. The second question is related to the quality of the auditors, their experience and their ability to distinguish the application of validation in the system. This was clearly not the case in the examples seen during the interviews. This leads to recommend stricter or standardized requirements for certifying auditors since private company standards are clearly inadequate. (See G.3.e for more about auditors and validation)

G.3.a. Validation Terminology

Validation misconceptions have been one of the results of this study as well. Some experts, whether from the industry or consultants or auditors or even governmental inspectors confuse validation for verification, monitoring, auditing, or inspection.

The most common mistake committed by experts was applying verification and validation as one clause just as it is written in HACCP. A book on HACCP in the meat industry discussed how the functions of the two terms were not clearly separated (Brown, 2000). Experts who related to this interpretation were experts using HACCP Codex 2003 as a guideline to apply HACCP in their premises. Validation in HACCP was not seen as an independent step needed to ensure that hazards are correctly chosen in accordance to the process in place and to the final results needed by each country or state. Rather, it is seen as a checking measure, or additional checks over monitoring done with verification. This is not a surprise since codex itself expresses validation where it is possible to be carried out, freeing the industry from any obligation to implement it. Hence, food industry experts were not making use of validation as a step to ensure that HACCP preparation and design are adequate to control the hazards as described in ISO 22000. Validation was even turned to an extra burden, yet causing more challenges to HACCP when some company experts interviewed explained it as “testing and checking every process step or every batch no matter if it is a CCP or a GMP”.

Others applied validation as monitoring, by recording control data, or auditing it as a validation step by calibrating machinery using accredited laboratories. There was no clear justification as to why experts who used validation as a monitoring step did this. Mainly governmental officers and very small industries using Codex (2003) were the ones who understood validation as being what

the inspector does when he comes and visits them every once in a while. A microbiology guideline addresses this confusion and clarifies the differences between the three terms as such: 'validation focuses on the collection and evaluation of scientific, technical and observational information and is different from verification and monitoring' (ICMSF, 2011) (p. 3). Since the scope of applying validation was not clear in standards, experts confused its definition with monitoring. For example, IFS Food and FDA both advise implementation of validation also for pre-requisite programs. This can lead the experts to regard validation as an auditing step. Such variation in standards can create misconceptions for experts and cause further confusion between validation and auditing.

This terminology confusion stems from several other reasons as well. The Codex (2003), IFS Food, and ISO 22000 guidelines or standards do not provide examples showing how to practically apply validation (Surak, 2009). Thus, personnel end up applying validation according to what they understand from the brief standard definition or according to what they have been told by the consultant. Providing correct examples on several food processes with standards can make a huge influence on the understanding and implementation of validation. The other confusion comes from the terminology inside the standard ISO 9001 (2015) which is called process validation. Some auditors namely, and consultants generally, when asked about validation of the process including studying variation have said that this question is confused by ISO 9001, and that this step belongs to quality manuals rather than to food safety.

What was also obvious from the interviews is that industry experts do not look beyond the HACCP document or other published regulations such as EC regulations in order to understand specifically each HACCP principle. This can justify why experts do not know or understand the specific outlines of validation in IFIS or Codex validation guidelines. None of the industry experts gave these specific references when they were asked about guidelines or standard that helped them implement HACCP. The most common answers were that they look at Codex in general, FDA, EFSA, and Libnor in Lebanon. German experts said to bring resources from guidelines however did not give specific names. Governmental inspectors name some guidelines which however did not mention validation. One German big company had a validation manager, which means a specialized person only doing the tasks of validating all quality and safety plans in the company. This is not country specific, but rather related to the fact that this company was a multinational company with a lot of experience and expertise.

G.3.b. Process Variation

In literature, process variation is an important part of validation because some of the HACCP failures happened when the process was not acting within the normal ranges known as mid-ranges, but when the process was varying due to an instability in the machine, the raw material or even the process settings (ICMSF, 2011). Among the experts, this was not common knowledge and only two experts were able to understand and relate to this question. This is caused due to many reasons such as the lack of such knowledge from the main food safety standards used such as ISO 22000, IFS Food and Codex (2003). 'Process variation is also found to be absent from the food industries interviewed because a good foundation of statistical analysis expertise is needed in order to apply such a step,' according to one of experts. In other words, if the food experts do not have the engineering or mathematical background or training, the mentality of checking process variations is thus non-existing by default. The inability to incorporate process variation into the validation steps is also linked to the lack of engineering departments from the some of the HACCP teams. The two interviewees who understood this step, had learned about it from a personal engineering background, as they were highly experienced consultants as well. Literature did not discuss variation in process validation in relationship to HACCP pass or fail for both HACCP and general food safety. This showed a huge lack in the HACCP implementation among the different experts even the specialized ones, i.e. consultants and auditors. Process variation in validation has no references about its link with the success of HACCP. More studies are recommended in this direction to inquire better about the relationship of process variation and outbreaks occurring.

G.3.c. Influence of the Consultant

A common opinion among the food experts interviewed and auditors was that whatever the consultant teaches the industries, it is applied without further research. In other words, if the consultant has the right definitions and examples of validation, the consulted companies will apply it correctly, and vice versa. In the literature found, the role of a consultant was not highlighted; however, the use of expert help was repeatedly mentioned as clearly needed for HACCP implementation (Mortimore and Wallace, 2013; Wallace et al, 2014; Taylor, 2001). This study showed that more often than never, consultants are the only source of information for the companies. The knowledge of consultants was a major factor influencing validation. The common observation is that consultants belonging to an organization had less knowledge about the different standards than the freelance consultants. This is because they followed the internal company's standard and example which in the case of the interviewees did not provide a clear

understanding of validation and rather portrayed it much like verification. In the case of freelance consultants, all of them knew exactly what validation had meant whether in Lebanon or in Germany and justified it by reading a lot of online guidelines that helped them gather this knowledge. Some of the interviewees mentioned guidelines such as FSIS for validation or general Codex but none have mentioned Codex (2008) which was specifically designed for validation. A highly qualified European freelance consultant highlighted that validation is essential for legal matters; in case a law suit happens, the company can protect itself by using scientific evidence. This can be justified by the difference in the nature of work between freelance consultants, and consultants working with companies.

G.3.d. Influence of the Guideline

Others companies follow guidelines that explain validation differently to ISO 22000 as if it means verification or monitoring, and so these companies or consultants follow such guidelines and therefore apply it wrongly. This was the opinion of one of the experts who had identified mistakes in guidelines in Europe and sent emails for corrections. But, there was no positive response because opinions were different and there was no clear standard document proving otherwise. Guidelines, used by the industry or consultants, can influence their understanding of the elements of HACCP (Taylor, 2001) and namely validation implementation. This was confirmed by another consultant interviewed who specifically found guidelines with switched the meanings of validation and verification. The consultant was able to see the effect of this mistake on the company he was auditing since they applied validation exactly as this guideline was teaching, hence incorrectly. In Germany, several checked guidelines would include verification, but would not mention validation in the 6th principle of HACCP (Azevedo and Joh, 2010; Dehoga, 2012). Some guidelines consider it as verification or self-audit checking and advise making a yearly plan for it (BVL, 2013; MDPH, 2003). A similar example can be seen in different online samples. A guideline done by a state in the USA had the definition of validation written in synchrony to ISO 22000; however, the examples of applying it gave it the meaning of an audit (MDPH, 2003). For instance, the title of the page was 'Guidelines for Validating Whole Shell Eggs' (p. 28). However, on this page there is an application checklist of the HACCP steps and GMP steps, meaning an audit checklist. This local guideline can be used by every food industry expert, consultant, inspector and auditor of the state and hence it can justify one of the reasons validation is not implemented in the right way in the food industry since there are no standardized guidelines coming from one common source.

G.3.e. Influence of the Auditor

This point discusses the inability of auditors to spot the wrong validation documents and examples, and still give certifications to companies. To understand that point further, some auditors who audited companies with wrong validation understanding were interviewed. It was clear that not all auditors understood validation in accordance to how it is explained in both ISO and Codex. The common confusion they showed concerning validation is that it is the same as verification or laboratory testing. Common examples given by auditors from Germany and Lebanon who have 5 years of experience or less, about their perception of validation are the following: 'validation is when the company does external quality with swabbing every day,' 'they validate their CCPs and test the sanitizing materials because they are also CCPs every 3 months,' or 'they do validation for CIP once a week, they swab, and they do the chemical residue test.' Such are examples given from auditors on validation.

G.3.f. Governmental Role

Inspectors feel that validation is not related to HACCP because they simply do not use regulations or standards such as ISO 22000, and IFS Food. These standards emphasize validation. The inspectors were not familiar with validation as a term or even as a definition, especially since they depend on (EC) No 178/2002 and regulation (EC) No 852/2004 which do not mention validation at all (EC,2002; EC, 2004). It was mainly among the inspectors interviewed and some HACCP consultants that a validation definition was not provided. The ones who did provide a definition, have confused it with verification and said their reference was the HACCP from Codex (2003) or local guidance documents. None of the experts using Codex (2003) have mentioned the Codex (2008) validation guideline when they were asked during the interview about guidelines and standards they use to apply HACCP. Some of the interviewed experts blamed their confusion on the lack of governmental training or inspection guidance. They said that the government does not emphasize this principle. Most governmental inspectors had a common opinion that validation is not needed in small companies or cannot apply it such as a meat butcher for example, because they do not have enough resources or expertise to continuously update their hazards and their systems. This is why they did not give this clause much time or importance. The involvement of external experts and regulatory officials in the development of both the master validation plan and the validation protocols is essential to ensure technical adequacy and acceptance by authorities (ICMSF, 2011).

X. Conclusion and Recommendations

When experts were asked about the indications of a successful HACCP system, 21 different indications were offered. This is to say that HACCP's success is not a simple formula where one can add a few recommendations and then accomplish success. There are numerous factors influencing the success or failure of HACCP. This research focused on factors in relationship to industries, caterers, consultants, auditors and inspectors specifically in Lebanon and Germany.

The fact that around more than half of the experts agreed that HACCP increases safety, shows that HACCP is a promising tool to implement for food safety. However, there are several gaps that need to be addressed in order to ensure a successful and effective implementation.

Difference between Germany and Lebanon

This study clearly shows that the influence of the country level, whether developing or developed is proved to be insignificant and is not a major factor that influences the success or failure of HACCP. There were minor differences between the countries that are not directly influencing the application of HACCP. The lack of highly developed governmental agencies and laboratories in Lebanon is one difference from Germany. This lack inhibits both the inspectors and the industries from testing and therefore staying up to date with emerging bacteria. Germany on the other hand, has a handful of laboratories and private and governmental bodies that do sufficient research, however the cross-communication across all sectors, private and governmental faces challenges and can handle a good amount of improvement as German inspectors have complained. Another difference is that in Lebanon, ISO and HACCP are applied because they are trendy and needed for marketing and export. In Germany, they are carried out due to the legal obligation on the enterprises that is coming from the government. The rest of the variables influencing the application of HACCP are caused by other factors than country level as was discussed previously and will be concluded with below.

Scope

The fact that the standard allows the selection of limited scopes in the food chain, or within an organization, appears to be one of the main reasons for the failure of HACCP. This means that certain companies are saying that they implemented HACCP, in a certain line or area of the food place, but not the other for example central kitchen but not branch or pistachio line chocolate bars but not the biscuit line, and still claim to have a HACCP study or certificate in place. Thus,

choosing certain limited scopes with in one company is leading companies to miss significant hazards and thereby leading to outbreaks in the areas that are out of the scope of HACCP. A solution for that enforcing the law for public and private auditing sectors to be mandating scopes to be holistic for a company and not limited.

Management Commitment

Management commitment seems, although enhanced by standards such as ISO 22000, to be understated by the interviewees and is not gaining enough recognition. Management commitment is a major leeway for HACCP to be properly implemented in a company. Six sigma, a disciplined, data-driven approach and methodology for eliminating defects, emphasizes on greater upper management involvement for success in change. Similarly, ISO 9000 and ISO 22000 focus on management commitment, however the results showed that the companies still do not see the value of upper management being directly involved in food safety since it doesn't directly add profit to the company. Cases in the US however reported the cost of losses reaching to $37M to $74M in one case, from a tainted spinach outbreak (TIS, 2012). An article by Harvard business school discussed how the E. coli outbreak in Germany in 2011 was reported to have had a cost $1.3 billion in losses to the global agricultural industry (Gerdeman, 2016). The challenge of engaging management and getting their commitment could be by marketing food safety as a cost saving tool rather than only a legal obligation. One method can be by communicating clear numbers to upper management on costs of recalls and outbreaks.

Terminology

Terminology differences among the standards and legal documents caused confusion among experts. Starting with differences between GMP and HACCP, to hazard analysis versus hazard assessment, and risk assessment versus risk analysis, to validation and verification, to correction and corrective action; all have caused industries to apply the standard in the way they understand it best, rather than the way it was intended to be in the standard. Such wording and definitions exist interchangeably in official regulations and standards. GFSI is one way such a problem can be mitigated. GFSI is the institution having the role of benchmarking and approving standards based on Codex Alimentarius and on GFSI Guidance document (GFSI, 2013). GFSI could be the organization who would help on harmonizing and standardizing the definitions and terminologies. The GFSI Guidance document, enables benchmarking existing food safety standards that are used starting with the farm and progressing through food distribution, manufacturing, wholesale

and retail. It also compares existing standards against the requirements included in the GFSI Guidance Document which would have as a minimum the requirements in the GFSI Guidance Document. This document covers general sections that must exist in a standard like GHP or GMP or HACCP plan, however it doesn't specify technical method or details such as which terminology to use. It uses the general definitions of Codex Alimentarius. However, out of this research, GFSI could be recommended to include a section about the harmonization of terminologies at least between its approved standards.

Validation

Validation, in particular, seems to be overlooked and not understood, although it is one of the major steps that can ensure the HACCP plan fits the designated food and premise available, and is effective. Validation is one of the findings that need to be explored more explicitly in relationship to HACCP success and failure. Further research needs to be done on validation, in order to evaluate its direct relationship to the failure of certain critical control points and how to avoid such failures. HACCP in Codex needs to include Validation as a clause before Verification, with a clear definition of what it is, and the difference between it and verification. GFSI could also include validation as an additional section of importance for obtaining evidence that the HACCP plan is effective and ensures that benchmarked standards takes it into consideration.

Various Interpretations of the System

The application of some HACCP steps was interpreted differently by the experts. The most critical of these interpretations are flow diagrams, identifying hazards, assessing hazards, choosing critical control points, and validation of the HACCP plan. This difference in interpretation leads to missing major hazards, or the inability to control them in the right way. Guidelines are one method we can use to overcome this challenge. Current guidelines, have shown variation in the interpretations of the standard, where some are very detailed and choose detailed hazard for example and others are general. To fix this, guidelines need to be changed and transformed based on several findings. For example, existing guidelines with generic HACCP plans for certain types of food can be enhanced and updated with emerging hazards inserted in them, critical control points shown differently, based on the equipment used, and validation examples offered which include how to assess process variation relative to every industry and machinery.

Roles of the Consultants, Auditors, Official Authority

Consultants and auditors play a major role in spreading the different interpretations whether right or wrong. The problem lies with wrong interpretations that lead to an ineffective HACCP system in industries. Ineffective HACCP systems have proved to be a major cause for outbreaks (Soon et al, 2016).

Consultants seem to be one of the main sources of information for companies (Arvanitoyannis, 2009). The experience and expertise of the individual consultant play a major role in the HACCP plans in different food sectors. More studies are needed on the correlations between what consultants understand and teach, and how HACCP is being influenced. This was one of the main highlights of this study and further studies can prove if working on this factor can improve HACCP application in the industry.

Auditors, who have a huge responsibility in certifying food safety systems, appear to be falling into the same category of confusion as the industry experts. They also rely on their own understanding and interpretation of the system. While some can be right, the wrong assessment is prevalent since certified companies are having breaches in the HACCP system which sometimes may lead to outbreaks.

Inspectors seem to be behind in several areas of the standards such as ISO 22000 as well as news and information in terms of emerging diseases and other preventive controls needed for food safety. EC suggests that its third parties be more cooperative with official controls to minimize the efforts on auditing and inspecting (EC, 2015). Government inspectors need to become up to date in terms of systems and hazard updates because they are often the only source of inexpensive training and information for SMEs (Taylor, 2001). Moreover, the number of enterprises is much greater than the number of inspectors which causes the inspections to be seldom. This problem can be solved by using a new risk-based approach. This approach has been tried in the Arab world by the Taylors' under the company name TSI, where inspectors get trained on assessing the places with the highest risk and marking them down. Afterwards, they identify which places need intensified visits and which places need less time to inspect. This system bases its categories on the population and how susceptible it is such as hospitals or elderly home are considered high risk places, whether the food is ready to eat and using fresh vegetables or raw food, in combination with the history of audit of this place, and whether he has

a robust food safety system, or one with many faults. Inspectors get trained to look beyond the tip of the iceberg, by analyzing, the effectiveness of the HACCP system rather than only the hygienic system of the place. This way, high risk areas can be covered and advised more often, and time is not wasted on places that have been well treated. If the food authorities are trained in that manner, they are able to put pressure and positively influence their surroundings, and be able to transfer the correct information and methods for a more rigorous food safety system.

Standardizing information about Emerging hazards

The other gap that forms a challenge to companies in particular and all other experts in general is staying up-to-date with emerging bacteria and new hazards. While EFSA is carrying a task of being the risk assessment center in Europe, more intense risk communication about the role of EFSA across all SME's, is needed. EFSA's current communication strategy covers risk managers, risk assessors, policy makers, national authorities, stakeholders (scientists and academics) and the media and public at large about scientific aspects of food safety and nutrition and to provide scientific advice in an open and transparent manner (EFSA, 2010). EFSA however, has expressed certain challenges in its communication strategy through issuing the new EFSA strategy 2015-2020 (EFSA 2015b). Areas that need to be focused on are establishing a plan for the transformation of the EFSA into an open science organization over the next 5 years to focus more on being open-minded, paying attention to scientific uncertainties, opening up to scientific advice (Deluyker et al, 2016). Apparently EFSA is successful to communicate well with its key partners such as European Parliament, European Commission and member states (EFSA, 2010). EFSA however, plans to improve its communication strategy with different scientific parties such as specialized academics or different researchers (Deluyker et al, 2016). Another challenge faced by EFSA is the need for faster and more efficient access to data and information. It plans to resolve this through the use of high-throughput screening into health assessments for example. All such improvements will enable the discovery and deliverance of emerging hazard in a timely manner to scientific bodies, policy makers, and national members.

What was not clearly described in the EFSA 2015-2020 strategy report was the exact communication method of EFSA to reach the small food handlers. One reason could be that they are depending on the competent authorities to deliver such data. Nevertheless, small to medium enterprises, be it for food, or even consultancy agents, need to receive such information in order to be able to enable a preventive risk-based HACCP system.

In Lebanon, the challenge lies in the governmental organization and hierarchy of the roles of food safety. While this is a political problem that this thesis does not plan to address, the alternative would be to use the academic sector to standardize trainings for HACCP. This is easily achievable in Lebanon because it is a small sized country with limited universities and few professors. Also, because university professors, in several cases, are the governmental food safety advisers, and the owners of consultancy and auditing companies. Harmonization can happen through the universities such as Lebanese American University and American University of Beirut that are yearly inviting to food safety conventions and can start influencing a change through those conventions. Another option would be to use European-funded projects such as QUALEB spoken about earlier, which gives free trainings to all experts in Lebanon, as a vehicle to deliver standardized food safety aims.

Hypothesis Reformulated

To conclude, the hypothesis given at the beginning of the research that HACCP fails or succeeds due to the first two principles of HACCP was relatively correct however, this being an inductive study showed that this failure or success of these two principles is linked to different factors such as the differences in the level of understanding of the experts and the way they interpret HACCP. This is not only limited to the first two principles but also to principle 6 verification and validation, to step 2 of HACCP which is flow diagrams mainly. Primarily the influence of consultants in both countries on the understanding and application of HACCP is a major factor for failure. His or Her level of education on the topic, years of experience, and ability of understanding HACCP itself before the other interpretations is what makes him or her qualified or not, however food enterprises don't have that knowledge upon hiring them. Furthermore, the power that the auditor executes on clients because he has the influence to give them a certificate, will influence the methods they will use of HACCP in order to solely please him. So, his level of education of HACCP, his integrity, and his expertise in the field he is auditing will also affect the outcome of what a certified company understands and applies as HACCP. Lastly the role of the inspectors, and their lack of update on new versions of HACCP doesn't develop nor help the misunderstandings in HACCP but brings them to a further confusion. Moreover, the variety of the food enterprises and the limited number of inspectors with limited education and experience doesn't give them an advantage in that situation. Furthermore, all steps in HACCP can be subject to multiple interpretation depending who is viewing them especially with the various number of standards and guidelines in the market. Unfortunately, validation is the most affected step since it is not yet a principle of HACCP. The actual definition of validation and the huge difference it can

make in confirming a successful HACCP system, is still a big lack by the food industry, especially in terms of detecting variations and mechanical and chemical errors. Flow charts, are the backbone for a healthy hazard analysis, are also subject to confusion. Some do them as brief charts, eliminating the ability to see steps clearly in order to analyze them, and some see them as detailed pages, leading to confusion of what is important to be analyzed. Hazard Analysis in terms of identification of hazards and assessment of risks is not yet comprehended to such depths among the food enterprises especially the small ones. The confusion is still on the level identifying the hazard using the right wording. Assessment of risk similarly has not even reached the level of quantification based on lab analysis and country demographics and immunity levels, it is rather stuck at the level of which method is used, matrix or other, and which one is the least subjective. If done correctly, hazard analysis step can save a lot of money and time, and risks and this amount of savings, is yet to be tested and quantified. Finally, Critical control point, due to its several interpretations, is sometimes losing its effect, which is eliminating the found hazard once and for all. If the definition and wording of critical control point is further clarified primarily in standards, then in guidelines and trainings, HACCP can further be improved.

Standardization and unification of understanding is an area with a lot of branches that can be further researched if divided by country and by type of expert. Food safety can be addressed better when approached from institutions like GFSI or EFSA who can spread and harmonize communicating of hazards across sectors and countries. Further research from this thesis can be carried with the focus on validation, HACCP standardization of terminologies and understanding, and harmonized education of consultants, auditors and governmental inspectors.

List of References

Ababouch, L. (2000). The role of government agencies in assessing HACCP, Institut Agronomique et Vétérinaire Hassan II, P.O. Box 6202, Rabat, Morocco, Food Control, 11(2), 137-142.

Adams, J., Khan, H. T., Raeside, R., and White, D. I. (2007). Research methods for graduate business and social science students. SAGE Publications New Delhi, India.

Afoakwa, E. O., Mensah-Brown, H., Crentsil, G. K., Frimpong, K., and Asante, F. (2013). Application of ISO 22000 in comparison with HACCP on industrial processing of milk chocolate. University of Ghana, Legon-Accra, Ghana. International Food Research Journal, 20(4).

Almabrouk F. (2007). Risque de salmonellose humaine liée à la consommation de fromage à pâte molle au lait cru: développement d'un modèle pour l'appréciation quantitative du risque, Travail réalisé : ENVA, UEAR, Unité d'epidémiologie et d'analyse des risques F-94700 Maisons-Alfort, le 17/12/2007 p. 4.

Arvanitoyannis, I. S. (2009). HACCP and ISO 22000: Application to foods of animal origin. School of Agricultural Sciences. University of Thessaly, Volos, Greece. John Wiley and Sons.

Arvanitoyannis, I. S., and Varzakas, T. H. (2007). A conjoint study of quantitative and semi-quantitative assessment of failure in a strudel manufacturing plant by means of FMEA and HACCP, Cause and Effect and Pareto diagram. University of Thessaly, Volos, Greece & Technological Educational Institute of Kalamata, Kalamata, Greece. International Journal of Food Science and Technology, 42(10), 1156-1176.

Asefa, D. T., Kure, C. F., Gjerde, R. O., Langsrud, S., Omer, M. K., Nesbakken, T., and Skaar, I. (2011). A HACCP plan for mycotoxigenic hazards associated with dry-cured meat production processes. Oslo, Norway. Food Control, 22(6), 831-837.

Azanza, M. P. V., and Zamora-Luna, M. B. V. (2005). Barriers of HACCP team members to guideline adherence. University of the Philippines, Diliman, Quezon City 1101, Philippines. Food Control, 16(1), 15-22.

Azevedo U.A., and Joh, H. (2010). Hygienemaßnahmen und Qualitätssicherung in Gastronomie und Gemeinschaftsverpflegung, Matthias Verlag GmbH, 7, Hamburg. Auflage 2010 p.13.

Baker, S. E., Edwards, R., and Doidge, M. (2012). How many qualitative interviews is enough?: Expert voices and early career reflections on sampling and cases in qualitative research. National Centre for Research Methods, Southampton, UK.

Ball, B., Wilcock, A., and Aung, M. (2010). Background factors affecting the implementation of food safety management systems. University of Guelph, Guelph, Ontario, Canada. Food Protection Trends, 30(2), 78-86.

Baumann-Popczyk, A., and Sadkowska-Todys, M. (2010). Foodborne infections and intoxications in Poland in 2009. Przeglad epidemiologiczny, 65(2), 227-234.

Bayerisches Staatsministerium für Umwelt und Verbraucherschutz (2014). Handbuch Zulassung

Bazeley, P., and Jackson, K. (Eds.). (2013). Qualitative data analysis with NVivo. Sydney, Australia. Sage Publications Limited.

Behravesh, C. B., Williams, I. T., and Tauxe, R. V. (2012). Emerging foodborne pathogens and problems: expanding prevention efforts before slaughter or harvest. Division of Foodborne, Waterborne and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA. Institute of Medicine (US). Washington (DC): National Academies Press (US); 2012.

Berelson, B. (1952). Content analysis in communication research. University of Illinois, United States of America.

Berg, B. L. (2004). Methods for the social sciences. Pearson Education Inc, United States of America.

Bernard, H., Faber, M., Wilking, H., Haller, S., Höhle, M., Schielke, A., and Hamouda, O. (2014). Large multistate outbreak of norovirus gastroenteritis associated with frozen strawberries, Germany, 2012. Euro Surveill. 2014 ;19(8):pii=20719. Article DOI: http://dx.doi.org/10.2807/1560-7917.ES2014.19.8.20719

BfR (2007). Food involved in disease outbreaks in Germany in 2007 BfR Information No. 010/2009, 31 March 2009, Berlin, Germany.

BfR (2008). Food involved in disease outbreaks in Germany in 2008 BfR Information No. 033/2009, 31 May 2009, Berlin, Germany.

BfR (2009). Food involved in disease outbreaks in Germany in 2009 BfR Information No. 033/2010, 27 July 2009, Berlin, Germany.

BfR (2010). Federal Institute for Risk Assessment, Guidance Document for Health Assessments, 2010, Berlin, Germany.

BfR (2010). Guidance Document for Health Assessments, Federal Institute for Risk Assessment, 2010 edition, Berlin, Germany.

BfR (2011). EHEC: What is the role of BfR in the current EHEC outbreak event, BfR Opinion Nr. 020/2011, 6 June 2011, Berlin, Germany.

BfR (2014). EU Food Safety Almanac, 3rd updated and revised edition of the EU Food Safety Almanac, BfR, Berlin, Germany.

BfR (2016). Foodborne disease outbreaks, Food Safety Microbial Risk, BfR homepage. Accessed on December 17, 2016: http://www.bfr.bund.de/en/foodborne_disease_outbreaks-53818.html

Binder, S., Levitt, A. M., Sacks, J. J., and Hughes, J. M. (1999). Emerging infectious diseases: public health issues for the 21st century. Division of Parasitic Diseases, National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC), F-22, 4770 Buford Highway, NE, Atlanta, GA 30341, USA. Science, 284(5418), 1311-1313.

Blismas, N. G., and Dainty, A. R. (2003). Computer-aided qualitative data analysis: panacea or paradox? Building Research and Information, 31(6), 455-463.

Bonne, R., Wright, N., Camberou, L., and Boccas, F. (2005). Guidelines on HACCP, GMP and GHP for ASEAN Food SMEs. EC-ASEAN Economic Cooperation Program on Standards, Quality and Conformity Assessment.

Bönnhoff, N., and Hemker, M. (2007). Lebensmittelhygiene. Fach Hauswirtschaftswissenschaft-Technische Universität Dortmund, Germany.

Boyatzis, R. E. (1998). Transforming qualitative information: Thematic analysis and code development. Case Western Reserve University, Ohio, USA. Sage.

Brackett, R., Ocasio W., Waters K., Barach J., Wan J. (2013). Validation and Verification: A Practical, Industry-driven Framework Developed to Support the Requirements of the Food Safety Modernization Act (FSMA) of 2011. Institute for Food Safety and Health, Illinois Institute of Technology, 6502 South Archer Road, Bedford Park, IL 60501, USA. The Preventive Controls Summit 2013 - Validation and Verification Principles, 2013.

Bremner, H. A. (Ed.). (2002). Safety and quality issues in fish processing. Danish Institute of Fisheries Research, Denmark. Woodhead Publishing 2002: Published: 25th July 2002. Elsevier.

Brown, B., McGregor, M., and McMillan, D. (2014). 100 days of iPhone use: understanding the details of mobile device use. In Proceedings of the 16th international conference on Human-computer interaction with mobile devices and services (pp. 223-232). ACM.

Brown, M. (2000). HACCP in the meat industry. Woodhead Publishing Limited, Cambridge, England. p.234.

Bryman, A. (2001). Social research methods. Published by: Oxford university press, United Kingdom.

Buchanan, R. L., and Whiting, R. C. (1998). Risk assessment: a means for linking HACCP plans and public health. U.S. Department of Agriculture, Agricultural Research Service, Eastem Regional Research Center, 600 East Mermaid Lane, Wyndmoor, Pennsylvania 19038, USA Journal of Food Protection, 61(11), 1531-1534.

Buchanan, R. L., Potter, M., Ross, T., Farber, J. M., Kasuga, F., Zwietering, M., and Liu, X. (2011). Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance. New York, Springer.

Burson D. (2006). Verification and Validation of HACCP Plans in U.S. Meat Processing Facilities, originally published as a National Pork Board/ American Meat Science Association Fact Sheet. University of Nebraska Lincoln.

BVL (2013). Leitfaden zur Kontrolle der Anwendung des HACCP-Konzeptes Futtermittelhygiene Band 2,3. Auflage, Stand 03.01.2013.

Caswell, J. A., and Hooker, N. H. (1996). HACCP as an international trade standard. University of Massachusetts, USA. American Journal of Agricultural Economics, 78(3), 775-779.

Cato, J. C. (1998). Seafood safety: Economics of hazard analysis and critical control point (HACCP) programmes (No. 381). Food & Agriculture Org. Rome, Italy.

CDC (2012). Center for Disease Control, Multistate Outbreak of Shiga Toxin-producing Escherichia coli O26 Infections Linked to Raw Clover Sprouts at Jimmy John's Restaurants (Final Update April 2012).

Cerf, O., Donnat, E., and Farm HACCP Working Group. (2011). Application of hazard analysis–Critical control point (HACCP) principles to primary production: What is feasible and desirable? Paris, France. Food Control, 22(12), 1839-1843.

Clarke, R. (2010). Private food safety standards: their role in food safety regulation and their impact. 33rd Session of the Codex Alimentarius Commission, Rome, Italy.

Cliver, D. O., Potter, M., and Riemann, H. P. (2011). Foodborne infections and intoxications. School of Veterinary Medicine, University of California, Davis. Academic Press.

Codex (1999). Alimentarius Commission, Principles and guidelines for the conduct of a microbiological risk assessment (CAC/GL-30. 1999).

Codex (2003). Alimentarius Commission: Recommended International Code of Practice, General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 4-2003.

Codex (2007). Alimentarius Commission: Principles and Guidelines for the Conduct of Microbiological Risk Assessment, CAC/GL/30-1999 Rev- 2007.

Codex (2008). Alimentarius Commission: Guidelines for the validation of food safety control measures (CAC/GL 69–2008). Joint FAO/WHO Food Standards Program, FAO, Rome

Codex (2014). Joint FAO/WHO Food Standard Programme, Discussion paper on the need for a revision of the general principles of food hygiene (CAC/RCP 1-1969) and its HACCP Annex, Codex committee on food hygiene, 46th session, Lima, Peru, 17-21 November 2014.

Comer P. (2004). Risk assessment workshop review, DNV consulting, UK, WMHIC, July 2004 p.24.

Creswell, J. W. (2009). Research design: Qualitative and mixed methods approaches. London and Thousand Oaks: Sage Publications.

Creswell, J. W., and Clark, V. L. P. (2007). Designing and conducting mixed methods research. Published by Sage Publications, California, USA.

Cusato, S., Tavolaro, P., and de Oliveira, C. A. F. (2012). Implementation of Hazard Analysis and Critical Control Points System in the Food Industry: Impact on Safety and the Environment. In Novel Technologies in Food Science (pp. 21-37). Springer New York.

DEHOGA (2012). Hygiene-Leitlinie für Gastronomie Deutscher Hotel und Gaststättenverband e.V. (DEHOGA Bundesverband) Am Weidenddamm 1 A 10117 Berlin p.48.

Deluyker H., Rodríguez Peña, A., Scannell, M., Tarazona, J., & Url, B. (2016). What does the future hold for assessment science?. EFSA Journal, 14(S1). © 2016 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

DGQ (2009). Lebensmittel Hygiene, HACCP, GVO, Allergene und Kennzeichnung in der Lebensmittelwirtschaft: Anwendung des IFS 5 für Praktiker - International Food Standard (DGQ-Band)Taschenbuch– 1. Januar 2009 von DGQ, Frankfurt.

Dirschauer C., Liesen E., Revermann M. (2014). HACCP Gesundheitliche Gefahren durch Lebensmittel identifizieren, bewerten und beherrschen, DGE-Praxiswissen, Bonn.
Accessed on June 25, 2016:

www.in-form.de www.schuleplusessen.de

Directive, E. C. (1993). 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs. FAL No. 43, 1994. Official Journal of the European Communities No. L, 175, 19.

Drescher T., and Lamparter A. (2008). HACCP in der Praxis , Der richtige Umgang mit Lebensmitteln. Essen, Germany.

Dubois-Brissonnet, F. (2012). Adaptation of Salmonella to Antimicrobials in Food-Processing Environments. AgroParisTech, UMR MicAliS, Massy INRA, UMR 1319, MicAliS, Jouy-en-Josas, France. INTECH Open Access Publisher.

EC (2002). European Commission EC No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

EC (2004). European Commission EC No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.

EC (2005). European Commission Guidance Document, Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses, Health and Consumer Protection, Directorate General, Brussels, 16 November 2005 p. 12,13.

EC (2009). European commission to the council and the parliament with the aim of sharing the experience gained from the application of the hygiene Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004the hygiene Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004, European communities 2009.

EC (2014). European Commission Volume 4, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Annex 15: Qualification and Validation, Health and Consumer Protection, Directorate General, Medicinal Products – Quality, Safety and Efficacy, Brussels, 6 February 2014, SANCO/TSE.

EC (2015). European Commission Final overview report on the state of implementation of HACCP in the EU and areas for improvement, Food and Veterinary Office European Commission Co. Meath, Ireland.

Edmunds, K. L., Hunter, P. R., Few, R., and Bell, D. J. (2013). Hazard analysis of critical control points assessment as a tool to respond to emerging infectious disease outbreaks. Centre for Ecology, Evolution and Conservation, School of Biological Sciences, University of East Anglia, Norwich, Norfolk, United Kingdom. PloS one, 8(8), e72279.

EFSA (2007). Definition and Description of "emerging risk" within EFSA's mandate, Scientific committee and Advisory forum unit, European Food Safety Authority, Parma.
Accessed June 20th 2016:
http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/escoemriskdefinition.pdf

EFSA (2010). EFSA's Communications Strategy. 2010 – 2013 perspectives.
Accessed on May 8, 2017:
http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/commstrategyperspective2013.pdf

EFSA (2015). Scientific Opinion on the public health risks related to the consumption of raw drinking milk, European Food Safety Authority (EFSA), Parma, Italy 13 January 2015.

EFSA (2015b). EFSA strategy for 2020, Draft for public consultation 2015, European Food Safety Authority, 2015.

El-Jardali F, Hammoud R, Kamleh, and R., Jurdi, M. (2014). K2P Briefing Note: Protecting Consumers in Lebanon: The Need for Effective Food Safety System. Knowledge to Policy (K2P) Center. Beirut, Lebanon; November 2014.

EMA (2014) Guideline on process validation for finished products information and data to be provided in regulatory submissions, European Medicine Agency, 2014.

Europe, I. L. S. I. (1999). Validation and verification of HACCP. In Report series. ILSI Press Washington, DC.

Executive Bulletin (2015). Boecker introduces the Ministry of Tourism's inspectors to the latest practices in food safety, Executive Bulletin, Business, Beirut, Lebanon. February 11, 2015. Retrieved from: http://executive-bulletin.com/business/boecker-introduces-the-ministry-of-tourisms-inspectors-to-the-latest-practices-in-food-safety

FAO/WHO (1995). Application of risk analysis to food standard issues, Report of the Joint FAO/WHO Expert Consultation, Chapter 6. Risk Assessment of Biological Agents in Food Geneva, Switzerland, 13 - 17 March 1995; p. 10,22.

FAO (1997). Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application, Annex to CAC/RCP 1-1969, Rev. 3, 1997.

FAO (1997). Risk management and food safety report of a Joint FAO/WHO Consultation Rome, Italy, 27- 31 January, 1997.

FAO (1998). Food Quality and Safety Systems - A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System: Food and Agriculture Organization of the United Nations, Rome, 1998.

FAO/WHO/BfR (2004). The 5th World Congress Foodborne Infections and Intoxications took place from 7 –11 June 2004 in Berlin: Federal Institute for Risk Assessment (BfR) and FAO/WHO Collaborating Centre for Research and Training in Food Hygiene and Zoonoses, 2004.

FAO (2004). European Food Safety Control Systems: New Perspectives on a Harmonized Legal Bases. Paper prepared by the Ministry of Agriculture, Nature and Food Quality and the Food and Consumer Product Safety Authority of the Netherlands.

FAO/WHO (2014). Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene, 46th Session, Lima, Peru, 17 – 21 November 2014 Discussion Paper on the Need for a Revision of the General Principles of Food Hygiene (CAC/RCP 1-1969) and Its HACCP Annex.

FAO (2016). Food Nutrition and Agriculture, Food Safety through HACCP, The FAO approach. Accessed on June 25, 2016:
http://www.fao.org/docrep/V9723T/V9723T0E.HTM

Fares, A. (2007). Risque de salmonellose humaineliée à la consummation de fromage à pâtemolle au lait cru : développement d'un modèle pour l'appréciation quantitative du risque. Doctorate Diss., Institut des Sciences et Industries du vivant et de l'Environnement, AgroParis Tech, Paris, France.

FDA (2004). Guidance for Industry PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance, U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Veterinary Medicine (CVM) Office of Regulatory Affairs (ORA). Pharmaceutical CGMPs September 2004.

FDA (2011a). Guidance Document Seafood, U.S. Department of Health and Human Services, Food and Drug Administration Center for Food Safety and Applied Nutrition. Accessed on June 20, 2016:
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm - http://www.accessdata.fda.gov/cms_ia/importalert_118.html

FDA (2011b). Guidance for Industry1, Process Validation: General Principles and Practices, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM), Current Good Manufacturing Practices (CGMP), January 201, Revision 1.

FDA (2012). U.S. Food and Drug Administration, Rapid Response Helps Contain Outbreak Linked to Peanut Butter, Consumer Health Information, November 2012.

FDA (2016). Alert on Lebanese products.
Accessed on June 20th 2016:
http://www.fda.gov/Safety/Recalls/

Flick, U. (2006). Coding and categorizing. An introduction to qualitative research, 295-319, Berlin Germany.

Flick, U. (2009). An introduction to qualitative research. Berlin Germany. Sage.

Florence D.B. (2012). Adaptation of Salmonella to Antimicrobials in Food-Processing Environments, Salmonella - Distribution, Adaptation, Control Measures and Molecular Technologies, Dr. Bassam Annous (Ed.), In Tech, DOI: 10.5772/29612. Paris, France.
Accessed on June 20, 2016:
http://www.intechopen.com/books/salmonella-distribution-adaptation-control-measures-and-molecular-technologies/adaptation-of-salmonella-to-antimicrobials-in-food-processing-environments

FP (2014). Food Protection. HACCP Utilization and Food Safety Systems PDG, Discussion on the Drafted White Paper "HACCP Steps: Principles, Content and Industry Gaps", New York, Sunday, August 3, 2014.
Accessed on February 2, 2016:
https://www.foodprotection.org/upl/downloads/get-involved/committee-pdg/minutes/haccp-utilization-and-food-safety-systems-professional-development-group-08-03-2014.pdf

FSAI (2001). Report of the task force on the burdens of food regulations on small businesses. August 2001 Food Standards Agency, London, UK.
Accessed on February 2, 2016:
www.foodstandards.gov.uk/multimedia/pdfs/taskrep.pdf

FSIS (2015). FSIS Compliance Guideline HACCP Systems Validation, April 2015.

FSKN (2009). Coca - Cola Company and Michigan State University Training on: Critical Control Points and Operational Prerequisite Programs.
Accessed on February 2, 2016:
http://www.fskntraining.org

FSP (2010). Food Safety Program Selecting a food safety consultant, Manitoba, Canada.

FSSC 22000 (2014). Food Safety System Certification 2014 Version 3.1.

Gadiel, D., and Abelson, P. (2010). The economic cost of foodborne disease in New Zealand. New Zealand Food Safety Authority, Applied Economics Pty Ltd.

Gallay A, Vaillant V, Bouvet P. (2005). How many foodborne outbreaks of Salmonella infection occurred in France in 1995? Application of the capture-recapture method to three surveillance systems. Paris, France. Am J Epidemiol 2000; 152:171–7.

Georges Cu, M., Constantin, S., Vulpe, G., Neagu, I., Paunescu, I. (2013). Rethinking validation and verification through scientific data freshness in order to meet food safety management requirements – a case study. Bucharest, Romania Agrolife Scientific Journal, 2(2), 60-66.

Gerdeman, D. (2016). Food Safety Economics: The Cost of a Sick Customer, Harvard Business School, 16 May 2016.

GFSI (2013). GFSI Guidance Document, Sixth Edition, Version 6.3, October 2013.

GFSI (2016a). Auditor Qualifications
Accessed on June 25, 2016:
http://www.mygfsi.com/news-resources/news/283-auditor-competence-scheme-committee-progress.html.

GFSI (2016b). Benchmarking [on-line].
Accessed on June 25, 2016:
URL: http://www.mygfsi.com/about-gfsi/gfsi-recognized-schemes.html

Gilling, S. J., Taylor, E. A., Kane, K., and Taylor, J. Z. (2001). Successful hazard analysis critical control point implementation in the United Kingdom: understanding the barriers through the use of a behavioral adherence model. Journal of Food Protection, 64(5), 710-715.

Gödderz, A., Schmitz, T. Mack A., Petersen B. (2007). Failure Mode and Effect Analysis (FMEA) as a decision support tool within a quality information system in pork production chains, University of Bonn, Institute of Physiology, Biochemistry and Hygiene of Animals, Katzenburgweg 7-9, 53115 Bonn, Germany.

Gonzalez-Miret, M. L., Coello, M. T., Alonso, S., and Heredia, F. J. (2001). Validation of parameters in HACCP verification using univariate and multivariate statistics. Application to the final phases of poultry meat production. Sevilla, Spain. Food Control, 12(5), 261-268.

Gubrium, J. F., and Holstein, J. A. (2002). Handbook of interview research: Context and method. Sage. London England.

Guest, G., Bunce, A., and Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and variability. Field methods, Volume: 18 issue: 1, page(s): 59-82, Sage Journals.

Hanna, N. M., Adib, S. M., and Daoud, Z. (2009). Food-borne salmonella outbreak at a bank cafeteria: an investigation in an Arab country in transition. Beirut, Lebanon. Eastern Mediterranean Health Journal, 15(2), 470-474.

Hatab, H. A. (2013). The implementation of a customized food safety system in community kitchens in rural Lebanon (Doctoral dissertation), Beirut, Lebanon.

Heijden, K. A. (1999). International food safety handbook. Marcel Dekker. New York.

Hennessy, T. W., Hedberg, C. W., Slutsker, L., White, K. E., Besser-Wiek, J. M., Moen, M. E., and Osterholm, M. T. (1996). A national outbreak of Salmonella enteritis infections from ice cream. New England. Journal of Medicine, 334(20), 1281-1286.

Henson S. (2008). The role of public and private standards in regulating international food markets, University of Guelph, Canada. Journal of International Agricultural Trade and Development, Volume 4 Issue 1, pp.63-81, 2008 Nova Science Publishers, Inc.

Henson, S., and Humphrey, J. (2011). 5. Codex Alimentarius and private standards. University of Guelph, Canada. Private food law, 4(1), 149.

Herath D., and Henson S. (2005). Identification and quantification of barriers to HACCP implementation: Evidence from Ontario Food Processing sector, Department of Agricultural Economics and Business, University of Guelph, Canada, July 24-27, 2005.

Hsieh, H. F., and Shannon, S. E. (2005). Three approaches to qualitative content analysis. Qualitative health research, Fooyin University, Taiwan and University of Washington, Seattle, 15(9), 1277-1288.

Hutter, B. M. (2011). Managing food safety and hygiene: governance and regulation as risk management. Edward Elgar Publishing.

Hyde, R., Hofland, A. B., and Pautz, M. (2014). One HACCP, two approaches: experiences with and perceptions of the hazard analysis and critical control points food safety management systems in the US and the EU. University of Nebraska at Omaha, 6001 Dodge Street, CPACS 113D, Omaha, NE 68182, USA.

IAFP (2014). HACCP Steps: Principles, Content, and Industry Gaps, A practical guide developed by industry for industry, developed by the IAFP HACCP PDG – Back to Basics working group, Draft 1.0 July 15, 2014.

ICMSF (2011). Microorganisms in Foods 8, Use of Data for Assessing Process Control and Product Acceptance, International Commission on Microbiological Specifications for Foods (ICMSF), 2011 p.13,16.

IFS. (2012). International Featured Standard, Version Food. Berlin.
Accessed on June 25, 2016:
http://www.ifs-certification.com/images/ifs_standards/ifs6/IFS_Food_V6_en.pdf.

IFSQN (2011). ISO 22000 Food Safety Management System, International Food Safety and Quality Network.
Accessed on June 20, 2016:
http://www.ifsqn.com/pdf/IFSQN%20ISO%2022000%20Food%20Safety%20Management%20System%20Product%20Information.pdf

IHK (2012). HACCP in der P–axis - Der richtige Umgang mit Lebensmitteln, Industrie- u. Handelskammer für Essen, 45127 Essen.

ILSI (2001). Report on Validation and Verification of HACCP, ILSI Europe Risk Analysis in Microbiology Task Force, 83 Avenue E. Mounier, Box 6, B-1200 Brussels, Belgium, this report has been written by an expert group of the Risk Analysis in Microbiology Task Force and under the chairmanship of Dr. R. Kirby, Unilever (UK).

ISO 22000 (2005). Food safety management systems – Requirements for any Organization in the Food Chain.

ISO 22003 (2013). Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems.

ISO 22004 (2014). Food safety management systems – Guidance on the application of ISO 22000.

ISO 9001 (2015). International Standard Organization, Quality Management System-Requirements.

Jacob, S. A., and Furgerson, S. P. (2012). Writing interview protocols and conducting interviews: Tips for students new to the field of qualitative research. Slippery Rock University and Texas University, USA. The Qualitative Report, 17(42), 1-10.

Jamal B.K., Pieternel A.L., Jacxsens L., Bendantunguka P.M.T. (2013). Diagnosis of food safety management systems performance in food processing sectors for export and domestic markets. African Journal of Food Science and Technology. 3(10):240-250.

Jatto, E., and Okhamafe, A. O. (2002). An overview of pharmaceutical validation and process controls in drug development. Faculty of Pharmacy, University of Benin, Benin City, Nigeria. Tropical Journal of Pharmaceutical Research, 1(2), 115-122.

Jay, J. M., Loessner, M. J., and Golden, D. A. (2008). Modern food microbiology. Springer Science and Business Media. New York, United States of America.

Jones, M. L. (2007). Using software to analyze qualitative data. University of Wollongong, Australia.

Jones, S. L., Parry, S.'M., O'Brien, S. J., and Palmer, S. R. (2008). Operational practices associated with foodborne disease outbreaks in the catering industry in England and Wales. Journal of Food Protection, 71(8), 1659-1665.

Karesh, W. B., Cook, R. A., Bennett, E. L., and Newcomb, J. (2005). Wildlife trade and global disease emergence. Wildlife Conservation Society, Bronx, New York 10460, USA. Emerg Infect Dis, 11(7), 1000-1002.

Kassaify, Z. G., Najjar, M., Toufeili, I., and Malek, A. (2010). Microbiological and chemical profile of Lebanese qishta (heat-coagulated milk) /Profil microbiologique et chimique de la qishta libanaise (lait coagulé par traitement thermique). Beirut Lebanon. Eastern Mediterranean Health Journal, 16(9), 926.

Keener, L. (2001). Why HACCP systems are prone to failure. Food Safety Magazine. Dec 2000-Jan 2001; 6(1) 17-19;40.

Kussaga, J. B., Luning, P. A., Jacxsens, L., and Tiisekwa, B. P. M. (2013). Diagnosis of food safety management systems performance in food processing sectors for export and domestic markets. Afr. J. Food Sci. Technol, 4, 240-250.

Kvale, S. (1996). InterViews – An introduction to qualitative research writing. SAGE Publications, Mar 14,–1996 - Business & Economics.

Lau, T., and Wolff, S. (1983). Der Einstieg in das Untersuchungsfeld als soziologischer Lernprozess. Kölner Zeitschrift für Soziologie und Sozialpsychologie, 35(3), 417-437.

LAVES (2010). Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit (LAVES) im Geschäftsbereich des Niedersächsischen Ministeriums für Ernährung, Landwirtschaft, Verbraucherschutz und Landesentwicklung, Oldenburg.

Lee, G. C. H. (2006). Private food standards and their impacts on developing countries. Stagiaire: European Commission, DG Trade Unit G, 2, Brussels, Belgium.

Lelieveld, H. L., Holah, J., & Gabric, D. (Eds.). (2016). Handbook of hygiene control in the food industry. Woodhead Publishing. London, UK.

Lofland, J., and Lofland, L. H., (1995). Analyzing social settings: A guide to qualitative observation and analy[si]s (3rd ed.). Belmont, CA: Wadsworth.

Lücke, F. K., and Skowyrska, A. (2015). Hygienic aspects of using wooden and plastic cutting boards, assessed in laboratory and small gastronomy units. Fulda, Germany. Journal für Verbraucherschutz und Lebensmittelsicherheit, 10(4), 317-322.

Lücke, F. K., and Trafiałek, J. (2010). Harmonized food safety. Germany & Poland. Fleischwirtschaft, 90(1), 43-45.

Luning, P. A., Marcelis, W. J., Rovira, J., Van der Spiegel, M., Uyttendaele, M., and Jacxsens, L. (2009). Systematic assessment of core assurance activities in a company specific food safety management system. Trends in Food Science and Technology, 20(6), 300-312.

Marshall, B., Cardon, P., Poddar, A., and Fontenot, R. (2013). Does sample size matter in qualitative research? A review of qualitative interviews in IS research. Journal of Computer Information Systems, 54(1), 11-22.

Martinez, M. G., Fearne, A., Caswell, J. A., and Henson, S. (2007). Co-regulation as a possible model for food safety governance: Opportunities for public–private partnerships. Food Policy, 32(3), 299-314.

Massoud, M. A., Fayad, R., El-Fadel, M., and Kamleh, R. (2010). Drivers, barriers and incentives to implementing environmental management systems in the food industry: A case of Lebanon. Journal of Cleaner Production, 18(3), 200-209.

Mayes, T., and Mortimore, S. (2001). Making the most of HACCP: Learning from other's experience. Woodhead Publishing, London, UK.

McLellan, E., MacQueen, K. M., and Neidig, J. L. (2003). Beyond the qualitative interview: Data preparation and transcription. Field methods, 15(1), 63-84. Sage Journal.

MDPH (2003). Validation and Verification of HACCP Plans, In Retail Food Establishments, A publication of the Massachusetts Department of Public Health, Division of Food and – rugs - Food Protection Program, Massachusetts Department of Public Health, Revised August 2003.

MOET (2012). Ministry of Economy and Trade Lebanon, About QUALEB; Ministry of Economy and Trade; Quality Unit, Beirut, Lebanon.

MOPH, (2011). Ministry of Public Health Lebanon, Statistical Surveillance; Diseases Surveillance Data: 2008-2011 statistics, Beirut.

MOPH (2015). Food Safety - List 65, Ministry of Public Health, Lebanon, 2016.
Accessed on June 20, 2016:
http://www.moph.gov.lb/userfiles/files/FoodSafety/FoodSafety-List65.pdf

MOPH (2016). Food Safety Reports in Lebanon, a list of weekly reports accessed by this website.
Accessed on June 20, 2016:
http://www.moph.gov.lb/PREVENTION/Pages/FoodSafety.aspx.

Mortimore S., Wallace C. (2013). HACCP a practical approach, 3rd Edition, Springer 2013.

Mortimore, S. (2001a). Significant Hazards in relation to Prerequisite Programmes – Problems in the application and implementation of HACCP Plans. (a)
Accessed on 1 June, 2015:
http://www.nutricion.org/publicaciones/pdf/mortimore.pdf

Mortimore, S. (2001b). How to make HACCP really work in practice. Food Control, 12(4), 209-215. (b)

Mortimore, S. (2001c). Problems encountered applying the HACCP approach to food safety: (If HACCP can work so well, then why do so many businesses have problems with it?). Australian Journal of Hospitality Management, 7(2), 41-48. (c)

Motarjemi, Y., Moy, G., Reilly, A., and Kaferstein, F. K. (1998). Food safety. International Occupational and Environmental Medicine, 602-619.

Norton, C. (2003). Validation: HACCP's final step. Food Management. Penton Publishing, 38(4), 70.

Nvivo (2015). Nvivo 10 for Windows Help. QSR International Pty Ltd.

Oevermann, U., Allert, T., Konau, E., and Krambeck, J. (1979). Die Methodologie einer „objektiven Hermeneutik "und ihre allgemeine forschungslogische Bedeutung in den Sozialwissenschaften. Interpretative Verfahren in den Sozial-und Textwissenschaften (pp. 352-434). Metzler, Stuttgart.

OIE (2013). World Organisation for Animal Health Update on Highly Pathogenic Avian Influenza in animals 2013.
Accessed: 20 April 2013:
http://www.oie.int/animal-health-in-the-world/update-on-avian-influenza/2013/

Panisello, P. J., and Quantick, P. C. (2001). Technical barriers to hazard analysis critical control point (HACCP). Food control, 12(3), 165-173.

Pierson, M. D., Corlett, D. A., and Institute of Food Technologists. (1992). HACCP: Principles and applications. New York: Van Nostrand Reinhold.

Pharmaceutical CGMP (2004). Guidance for Industry PAT – A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance. Guidance for Industry, PAT – A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance, DHHS, Rockville, MD September 2004.

Psomas, E. L., and Kafetzopoulos, D. P. (2015). HACCP effectiveness between ISO 22000 certified and non-certified dairy companies. Department of Business Administration of Food and Agricultural Enterprises, University of Patras, 2 George Seferis str., GR-301 00, Agrinio, Greece. Food Control, 53, 134-139

Quality, F. F. (1998). Safety Systems: A Training Manual on Food Hygiene and the Hazard Analysis Critical Control Points (HACCP) System. Food and Agriculture Organization of the United Nations, Rome.

RASFF (2014). RASFF for safer food — The Rapid Alert System for Food and Feed — 2014 annual report.

Rausand, M., and Høyland, A. (2004). System reliability theory: models, statistical methods, and applications (Vol. 396). John Wiley and Sons. Norwegian University of Science & Technology, Norway.

Richards, T. (2002). An intellectual history of NUD*IST and NVivo. International Journal of Social Research Methodology, 5(3), 199-214.

Ritchie, J., Lewis, J., Nicholls, C. M., and Ormston, R. (Eds.). (2013). Qualitative research practice: A guide for social science students and researchers. Sage. London, UK.

RKI (2011). Robert Koch Institute. Report: Final presentation and evaluation of epidemiological findings in the EHEC O104:H4 outbreak, Germany 2011. Berlin 2011.
Accessed on June 25, 2016:
http://www.rki.de/EN/Home/EHEC_final_report.pdf?__blob=publicationFile

Roberto DC., Brandão SCC., and Silva CAB., (2006). Costs and investments of implementing and maintaining HACCP in a pasteurized milk plant, Food Technology Department, Federal University of Viçosa, 36 570-000 Viçosa, MG, Brazil. Food Control, 2006. Elsevier.

Robson, C. (2002). Real world research. 2nd Edition. Blackwell Publishing. Malden. UK.

Rubin H., and Rubin I. (1995). Qualitative Interviewing: The Art of Hearing Data, Thousand Oaks, CA: Sage, 1995.

Ryu, K., Park, K. H., Yang, J. Y., and Bahk, G. J. (2013). Simple approach in HACCP for evaluating the risk level of hazards using probability distributions. Food control, 30(2), 459-462.

Sampers, I., Toyofuku, H., Luning, P. A., Uyttendaele, M., and Jacxsens, L. (2012). Semi-quantitative study to evaluate the performance of a HACCP-based food safety management system in Japanese milk processing plants. Food Control, 23(1), 227-233.

Saremi, M., Mousavi, S. F., and Sanayei, A. (2009). TQM consultant selection in SMEs with TOPSIS under fuzzy environment. Iran. Expert Systems with Applications, 36(2), 2742-2749.

Schaeffers M. Murphy, S. (2014). FMEA and HACCP: A comparison, datalyzer international, 2014.
Accessed on June 1st 2016:
https://datalyzer.com/wp-content/uploads/2017/03/FMEAandHACCP.pdf

Schmidt, R. H., and Newslow, D. L. (2007). Hazard Analysis Critical Control Points (HACCP)? Principle 3: Establish Critical Limits and Principle 4: Monitoring Critical Control Points (CCPs).

Schmidt, R. H., and Newslow, D. L. (2013). Hazard Analysis Critical Control Points (HACCP) Principle 1: Conduct a Hazard Analysis, University of Florida, IFAS Extension, published 2007, revised 2013.

Schutt R. K. (2012). Investigating the Social World, The Process and Practice of Research, University of Massachusetts, Boston, Seventh Edition p.11-13.

Scott, V. N. (2005). How does industry validate elements of HACCP plans? Food Safety Programs, National Food Processors Association, 1350 I St. N.W., Suite 300, Washington, DC 20005, USA. Food Control, 16(6), 497-503.

Soon, J. M., Manning, L., and Wallace, C. A. (Eds.). (2016). Foodborne Diseases: Case Studies of Outbreaks in the Agri-food Industries. CRC Press. UK.

Sperber, W. H. (2005). HACCP does not work from farm to table. Cargill, Incorporated, 2301 Crosby Road, Wayzata, MN 55391, USA. Food control, 16(6), 511-514.

Squires, A. (2009). Methodological challenges in cross-language qualitative research: a research review. Center for Health Outcomes & Policy Research, University of Pennsylvania School of Nursing, 418 Curie Boulevard, Room 338R, Philadelphia, PA 19104, United States. International journal of nursing studies, 46(2), 277-287.

Srikaeo, K., and Hourigan, J. A. (2002). The use of statistical process control (SPC) to enhance the validation of critical control points (CCPs) in shell egg washing. Food Control, 13(4), 263-273.

Stöcker, P., Rosner, B., Werber, D., Kirchner, M., Reinecke, A., Wichmann-Schauer, H., and Frank, C. (2011). Outbreak of Salmonella Montevideo associated with a dietary food supplement flagged in the Rapid Alert System for Food and Feed (RASFF) in Germany, 2010.

Strauss, A., and Corbin, J. (1998). Basics of qualitative research: Techniques and procedures for developing grounded theory. Sage Publications, Inc. San Fransisco, USA.

Sumner, J., Ross, T., and Ababouch, L. (2004). Application of risk assessment in the fish industry (No. 442). Food and Agriculture Org. Rome, Italy.

Surak, J. G. (2009). The Evolution of HACCP – A perspective on today's most effective food safety system. Food Quality Magazine, February/March 2009.

Surak, J. G., and Gombas, K. L. (2009). GFSI's role in harmonizing food safety standards. Food Safety Magazine.
Accessed on June 1st 2016:
https://www.foodsafetymagazine.com/magazine-archive1/junejuly-2009/gfsis-role-in-harmonizing-food-safety-standards

Surak, J. G., and Wilson, S. (Eds.). (2007). The certified HACCP auditor handbook. ASQ Quality Press.

Surak J. , Wilson S., (2014) The Certified HACCP Auditor Handbook 3rd edition, ASQ Food Drug and Cosmetic Division, American society for Quality, Quality Press Milwaukee, 53203.

TIS (2009). Tyco Integrated Security, Food Safety Magazine, Signature Series, Recall: The Food Industry's Biggest Threat to Profitability, October 2012.
Accessed on April 1, 2017:
http://www.foodsafetymagazine.com/signature-series/recall-the-food-industrys-biggest-threat-to-profitability/

Taylor, E. (2001). HACCP in small companies: benefit or burden?. UK. Food control, 12(4), 217-222.

Taylor, E. (2008). A new method of HACCP for hospitality: changing behavior and proving success. UK. International Journal of Contemporary Hospitality Management, 20(5), 542-560.

Taylor, E. A., and Taylor, J. Z. (2004). Using qualitative psychology to investigate HACCP implementation barriers. International Journal of Environmental Health Research, 14(1), 53-63.

Taylor, J. (2012). HACCP Level three intermediate, Course Reference and Revision Book, TSI, United Kingdom.

Taylor, J., Akanji, T., Al Shaikh, A., Collison, F., and Whitehall, P. (2011). Barriers to HACCP in hospitality: a global problem with global solutions? Worldwide Hospitality and Tourism Themes, 3(5), 387-401.

Taylor-Powell, E., and Renner, M. (2003). Analyzing qualitative data. University of Wisconsin-Extension.

TDN (2010). Trade and Development Newsletter, News and Information on Lebanon's WTO Accession, Published by the WTO Unit at the Ministry of Economy and Trade. Downtown Beirut, Lebanon, September 2010.

Timeline, R., and Maps, C. C. (2012). Multistate Outbreak of Shiga toxin-producing Escherichia coli O121 Infections Linked to Farm Rich Brand Frozen Food Products (Final Update). CDC. USA.

Toma, B., Dufour, B., and Sanaa, M. (2002). Generalités sur l'analyse du risque. Paris, France. Article in French. Rev Epid San Anim, 41, 5-16.

Trafiałek, J., and Kołożyn-Krajewska, D. (2011). Implementation of safety assurance system in food production in Poland. Polish Journal of Food and Nutrition Sciences, 61(2), 115-124.

Trafiałek, J., Lehrke, M., Lücke, F. K., Kołożyn-Krajewska, D., and Janssen, J. (2015). HACCP-based procedures in Germany and Poland. Food Control, 55, 66-74.

FDA (2009). US Food and Drug Administration FDA food code. Center for Food Safety and Applied Nutrition.
Accessed on June 20, 2016:
http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/

Valder, P. (2009). GFSI Food safety standards. Quality Digest, 29(4), 20-23.

Vela, A. R., and Fernández, J. M. (2003). Barriers for the developing and implementation of HACCP plans: results from a Spanish regional survey. Food Control, 14(5), 333-337.

Wallace, C. A., Holyoak, L., Powell, S. C., and Dykes, F. C. (2012). Re-thinking the HACCP team: An investigation into HACCP team knowledge and decision-making for successful HACCP development. Food research international, 47(2), 236-245.

Wallace, C. A., Holyoak, L., Powell, S., and Dykes, F. C. (2014). HACCP – the difficulty with Hazard Analysis. Food Control, 35(1), 233-240.

Wallace, C., Sperber, W., and Mortimore, S. E. (2010). Food safety for the 21st century: Managing HACCP and food safety throughout the global supply chain. John Wiley and Sons.

Weber, R. P. (1990). Basic content analysis (No. 49). University of California, California, Sage.

Wilke, T., Belaya, V., and Pinior, B. (2012). How to measure food safety? A review of relevant literature. In 2012 International European Forum, February 13-17, 2012, Innsbruck-Igls, Austria (No. 144947). International European Forum on Innovation and System Dynamics in Food Networks.

Williams S., Roth E., Van Roekel J. (2005). Changing public and private food safety and quality requirements in Europe: challenges of fresh produce and fish exporters in developing countries - European Union Buyers Survey, Washington, DC, 1/1/2005.

Wissmann B, Klinc C, Schulze R, Wolf A, Schreiner H, Rabsch W, Prager R, and Hautmann W. (2010). Outbreak of salmonellosis after a wedding party, Bavaria, Germany summer 2010: the importance of implementing food safety concepts. Euro Surveill. 2012;17(6): pii=20076
Accessed on June 20, 2016:
http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20076

WHO (1998). Guidance on regulatory assessment of HACCP. The report of a Joint FAO/WHO Consultation on the Role of Government Agencies in Assessing HACCP. Geneva: World Health Organization; 1998. WHO/FSF/FOS/98.5.

WHO (1999). Strategies for implementing HACCP in small and/or less developed businesses. Report of a WHO Consultation in Collaboration with the Ministry of Health, Welfare and Sports, WHO Food Safety Program, the Netherlands.

WHO (2000). Surveillance Programme for Control of Foodborne Infections and Intoxications in Europe 8th Report 1999-2000 Country Reports: Germany.

WHO (2000). Surveillance Programme for Control of Foodborne Infections and Intoxications in Europe 8th Report 1999-2000 Country Reports: Poland.

WHO (2012). Food Safety: WHO Global Strategy for Food Safety.

WTO (2012). Understanding the WTO: The organization: Members and Observers. 157 members on 24 August 2012 (with dates of membership).

Yiannas, F. (2009). Food safety culture: Creating a behavior-based food safety management system. Springer Science and Business Media, Kissimmee, Florida.

Zhang, Y., and Wildemuth, B. M. (2009). Qualitative analysis of content, University of Texas.