

Master Thesis European Studies

Is our Food Safe?

An Assessment: on the European Union Food Safety Policy, Concerning the Safety of Meat & Animal-Derived Food Products in the EU.



Universiteit Twente & Westfälische Wilhelms-Universität Münster

April 2015

By Pawel Bonilla

Behavioural, Management and Social Sciences (BMS) & Institut für Politikwissenschaft (IfPol)

For the attainment of the Double Degree Master European Studies at the Westfälische Wilhelms-Universität in Münster (WWU) and at the Universiteit Twente (UT) in Enschede.

First Supervisor (WWU): Prof. Dr. Thomas Dietz

Second Supervisor (UT): Dr. Shawn Donnelly

Abstract

Since the 1990's BSE food safety crisis across the EU, a new food safety policy was formulated in order to improve the former European food and hygiene regulatory structure. The current EU food safety policy consists of three interrelated components namely: **(I)** legislation on the safety of food and animal feed and food hygiene; **(II)** scientific assessment and communication on which to base policy decisions and **(III)** regulatory measures of enforcement and control at EU level. To guarantee the safety of meat and animal-derived food products in the EU, the food safety policy uses: General Food law (GFL) Regulation 178/2002 and Hygiene Package (HP) Regulations 852/853/854/2004. By design, these regulations are the core foundation to food and hygiene safety in the EU. From GFL the European Food Safety Authority was established who has an important task in the scientific assessment of food and hygiene safety in the EU. In addition these regulations stipulate the regulatory measures of enforcement and control at EU level for the regulatory regime. Even though the present EU food safety policy was a major improvement in contrast to the former policy, it nevertheless failed to guarantee the public health in the EU, as numerous major food safety crises demonstrated. Consequently this raises the question whether these events were just incidental or systemic in their procedures and how this could have happened. A qualitative content analysis, guided by four regulatory assessment criterion was conducted; to assess from a public administration perspective if the EU food safety policy is effective or ineffective in order to guarantee the safety of meat and animal-derived food products in the EU. The research findings show that the EU food safety policy is partially effective in achieving its primary goal. On the other hand, there are also several important deficits concerning General Food Law, Hygiene Package and the regulatory regime unit; the European Food Safety Authority (EFSA). These deficits are ambiguous or unclear provisos; in addition to not enough transparency and expertise, which could unnecessarily, endangers the life of the general public in the EU if they are not improved.

Keywords: EU food safety policy, hygiene, regulations, GFL, HP, regulatory regime, the EC, EFSA, scientific assessment, enforcement & control, provisos as well as meat & animal-derived food products.

Table of Contents

LIST OF ABBREVIATIONS	6
INTRODUCTION	7
BACKGROUND OF RESEARCH	7
LITERATURE REVIEW	9
RESEARCH DEMARCATION, OBJECTIVE & QUESTIONS	11
MASTER THESIS STRUCTURE	12
CHAPTER 1: THEORETICAL FRAMEWORK	13
1.1 REGULATORY ASSESSMENT CRITERIA	13
1.1.1 CRITERION I: LEGITIMATION	14
1.1.2 CRITERION II: ACCOUNTABILITY	15
1.1.3 CRITERION III: TRANSPARENCY	17
1.1.4 CRITERION IV: EXPERTISE	19
1.2 ASSESSMENT MATRIX	20
CHAPTER 2: METHODOLOGY	21
2.1 QUALITATIVE RESEARCH APPROACH	22
2.2 RESEARCH DESIGN	22
2.2.1 RESEARCH STRATEGIES OF INQUIRY	23
2.2.2 CONCEPTUAL FRAMEWORK	25
2.2.3 QUALITATIVE RESEARCH MATERIAL	26
2.3 QUALITATIVE DATA ANALYSIS	27
CHAPTER 3: THE REGULATORY ORGANISATION OF GFL & HP REGULATIONS	28
3.1 GFL: REGULATION 178/2002	30
3.2 HP: REGULATIONS 852/853/854/2004	35
CHAPTER 4: ASSESSMENT	39
4.1 LEGITIMATION CRITERION	39
4.1.1 DEMOCRATIC & CONSTITUTIONAL	39
4.1.2 GOAL ORIENTED & FUNCTIONAL	43
4.2 ACCOUNTABILITY CRITERION	47
4.2.1 POLITICAL ACCOUNTABILITY	47
4.2.2 LEGAL ACCOUNTABILITY	49
4.2.3 ADMINISTRATIVE ACCOUNTABILITY	50
4.2.4 SOCIAL ACCOUNTABILITY	51
4.3 TRANSPARENCY CRITERION	52
4.3.1 VISIBLE & INFERABLE PROCESSES	52
4.3.2 OPENNESS OF INFORMATION & COMMUNICATION	54
4.3.3 INCLUSIVENESS OF ACTORS	55

4.4 EXPERTISE CRITERION	56
4.4.1 SYSTEM OF EDUCATION	56
4.4.2 STAFF AVAILABILITY & RESOURCES	56
4.5 REGULATORY ASSESSMENT FINDINGS	58
<u>CHAPTER 5: ASSESSMENT RESULTS</u>	59
5.1 CONCLUSION & SUGGESTIONS	59
5.2 LIMITATIONS & FUTURE RESEARCH	62
<u>BIBLIOGRAPHY</u>	63
<u>APPENDIXES</u>	68
I: EU SECONDARY LAW	68
II: EU CONSULTATION PROCESS	69
III: LIST OF FOOD SAFETY CRISES IN THE EU FROM 2002 TILL 2013	70

List of Abbreviations

EU	European Union
EC	European Commission
EP	European Parliament
ECJ	European Court of Justice
ECA	European Court of Auditors
GFL	General Food Law: Regulation 178/2002
HP	Hygiene Package: Regulations 853/854/2004
EFSA	European Food Safety Authority
FVO	Food and Veterinary Office
DG SANCO	Directorate General Santé (Health) & Consommateurs (Consumers)
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
TRACE	Trade Control and Expert System
HACCP	Hazard Analysis Critical Control Point
AVEC	Association of Poultry Processors and Poultry Trade in the EU countries
UECBV	European Livestock and Meat Trading Union
CLITRAVI	Liaison Center for the Meat Processing Industry in the European Union
BEUC	Bureau Européen des Unions de Consommateurs
SCFCAH	Standing Committee on the Food Chain and Animal Health
REFIT	Regulatory Fitness and Performance programme
RASFF	Rapid Alert System for Food and Feed
ESC	Economic and Social Committee
MS	Member State(s)
ENVI	Environment, Public Health and Food Safety EU Parliamentary Committee

Introduction

Background of Research

The first food safety legislation emerged in 1960; from this point the food safety was incrementally improved. One of the first major improvements was two food safety directives:

- (1) Directive 64/432 on animal health problems affecting intra-community trade in bovine animals and swine;
- (2) Directive 64/433 on health conditions for the production and marketing of fresh meat¹.

In 1960 these two directives were used to harmonise the many different food safety regulations across European Union (EU). In 1964 the EU also developed and adopted food hygiene regulations. However a problem with this legislation was that there were no specific provisos concerning fresh meat (E. Commission, 2007, p. 11). After several years additional hygiene legislations for other food groups were introduced such as: poultry meat, eggs, milk products and fishery products. The goal of these hygiene legislations was to improve the level of food safety via: prevention, elimination and the reduction of food contaminated with dangerous bacteria, parasites, chemical substances and unwanted debris² (E. Commission, 2007, p. 23). Because food production methods became more complex, thus the possibility of finding unwanted bacteria and other organism in consumer food products greatly increased. Also at the same time the hygiene systems as well as the microbiological testing were less developed in some EU Member States in comparison to others (see for more detail E. Commission, 2007).

The second food safety legislation emerged in 1990, because of the BSE crisis. This crisis caused a moratorium of cattle meat. Consequently millions of cattle were exterminated which created meat scarcity across the EU³. As response to the BSE crisis, the European Commission (EC) led by Jacques Santer (from 1995 to 1999) formulated a new supranational food safety policy, to replace the old one. In 1997 several years after the BSE crisis, the EU Commission published *the Green Paper on the general principles of food law*⁴. The EC led by Romano Prodi (from 1999 to 2004) used this Green Paper as a basis for a *White Paper on Food Safety*. The White Paper provided many food safety improvement recommendations for the EU and its Member States. The recommendations of the White Paper were translated into the current EU food safety policy⁵. The goal of this policy is to guarantee via a multitude of regulations⁶ and directives:

- a) safe, nutritious food & animal feed;
- b) a high level of animal health, welfare & plant protection and
- c) sufficient transparent information about the origin, content/labelling & use of food (Commission, 2014).

To realise this goal, the EU food safety policy comprised out of three interrelated components namely: *Food Legislation*, as the 'foundation of food safety' via General Food Law: Regulation 178/2002 (GFL) and Hygiene Package: Regulations 852/853/854/2004 (HP). Both GLF and HP regulations are used to: **(1)** regulate the safety of food and animal feed and food hygiene; **(2)** in order to guarantee a high level of protection of human life and health; **(3)** by means of protecting animal health, welfare plant health and the environment (Leibovitch, 2007; SANCO, 2014; van der Meulen,

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31964L0432:en:NOT>

² For example glass particles

³ See for detail figures and information http://ec.europa.eu/food/food/biosafety/tse_bse/monitoring_en.print.htm and <http://bmb.oxfordjournals.org/content/66/1/185.full>

⁴ See for more information: Commission Green Paper COM(97) 176

⁵ In this Master Thesis **public policy is conceptualise as** "an attempt by the government [national or supranational] to address a public issue by means of laws, regulations, decisions, and actions" (Venus, 2011 p.1).

⁶ In this Master Thesis **regulations are conceptualise as** "the organisation and control of economic, political and social activities by means of making, implementing, monitoring and enforcing rules" (Mattli & Woods, 2009a, p. 1; 2009j).

2009). To improve food safety in the EU, GFL introduce “farm to fork” an approach to monitor the entire food supply chain process by using the TRACE system. Moreover, HP regulations introduced the Hazard Analysis Critical Control Point or HACCP which serves to monitor the food hygiene (E. U. Commission, 2007; SANCO, 2014). Also, the GFL regulation established the European Food Safety Authority (EFSA). In sum: these regulations were meant to improve the food safety: **(a)** by harmonising the preceding food legislation structure, so that the free movement of food and feed in the EU is preserved; **(b)** by stipulating ‘transparent’ consumer rights at national and supranational level (SANCO, 2014; van der Meulen, 2009).

Scientific assessment and communication, as the ‘basis for food and feed policy decisions’ performed by the EFSA in the EU, (Alemanno, 2013; Commission, 2014). The EFSA is an independent operating EU institution situated in Parma Italy. The EFSA scientific panels are the ones in charge of risk assessment and communication at supranational level in collaboration with national food safety agencies of the Member States (Alemanno, 2013; SANCO, 2014). The role of the EFSA is to perform risk analyses vis-à-vis food, in order to inform risk management (i.e. EC, EU Parliament and Council of the European Union) concerning the current state of affairs of food safety in the EU. Thus the tasks of the EFSA are to provide independent scientific food advice concerning the drafting of food legislation or how to deal with food safety hazards in the EU; so that risk management at supranational level is able to act swiftly and make effective decisions when deemed necessary (Alemanno, 2013; SANCO, 2014).

Regulatory measures, as the ‘armaments’ to enforce and control the compliance of Member States and food operators at EU level (Europa.eu, 2013; Hartlapp, 2007). A regulatory measure that is often used by regulatory unit the EC is “checking” that is, controlling whether all EU Member States have incorporate EU food and safety legislation into their national law (Commission, 2014). Another regulatory measure used by regulatory unit the EC, is to instruct the Food and Veterinary Office (after this FVO) to “conduct on-the-spot examinations” at individual food production plants both in and outside the EU. The task of the FVO is to inspect and audit⁷ whether EU and non-EU countries alike, have the mechanisms in place to guarantee that their food business operators meet the highest food-safety standards set forth by the EU (Commission, 2014; Hartlapp, 2007).

The last food safety measures emerged in 2010, when the EC led by Jose Barroso performed a so-called “fitness check” to assess the food safety in the EU. The purpose of this assessment was to determine whether there exist: unnecessary burdens, overlaps, gaps, inconsistencies and/or outdated measures. Even though the current EU food safety policy was re-assessed for effectiveness, this was still not sufficient to guarantee the public health in the EU, as several major food safety crises ex post demonstrated. For instance, in 2012 a major food safety crisis happened, when a large fish producer in the Netherlands sold smoked salmon infested with salmonella and caused an outbreak of salmonella illnesses affecting 1000 consumers and three consumers died⁸. In 2013, another major food safety crisis occurred. National authorities discovered that several large food producers and traders of livestock produced and sold horsemeat under the disguise of beef or pork meat products in various Member States⁹. The results of these food safety crises were that it caused indignation across the EU public, because once again consumers became victims of: **(a)** fraudulent food schemes of companies; **(b)** incompetent food safety agencies at supranational and national level. All in all, the recent major food safety crises revealed that the EU food safety policy core components were and are not able to guarantee the safety of food in the EU as claimed.

⁷ These audits and inspection are vital in order to control for compliance with the requirements of EU food safety and quality, animal health and welfare and plant health legislation within the EU and on compliance with EU import requirements in third countries exporting to the EU http://ec.europa.eu/food/fvo/what_en.htm

⁸ <http://www.foodsafetynews.com/2012/10/nearly-1000-dutch-sickened-3-dead-from-salmonella-linked-to-smoked-salmon/>

⁹ See for detail information: http://ec.europa.eu/food/food/horsemeat/index_en.htm, <http://www.bbc.com/news/uk-21375594> and http://www.fsai.ie/uploadedFiles/News_Centre/Burger_results_2013_01.pdf

Literature Review

Earlier studies on EU food safety has been focused in understanding this topic from several academic disciplines such as: law, public administration, political science, health and food science and economics (e.g. Alemanno, 2013; Egeberg, 2006; Grunert, 2005; Millstone & Van Zwanenberg, 2002; Robinson, Holland, Leloup, & Muilerman, 2013). Even though, most academic studies so far (from 2002 till 2013) have written extensively concerning food safety in the EU. Their focus is generally grounded on researching the first four phases of the so-called policy cycle¹⁰ (for detail see Howlett & Cashore, 2014; Jann & Wegrich, 2007; Sabatier, 2007). As a result the research gap in present EU food safety literature can be found in the last phase of the public policy cycle namely, the assessment phase. According to several academic studies the last phase of the policy cycle is in general a complex and costly endeavour to carry out and thus not performed on a regular basis; and ‘as a rule’ based on the economics of cost-effectiveness (see Engel et al., 2011; Ingenbleek, Immink, Spoolder, Bokma, & Keeling, 2012; Jacxsens et al., 2011; Traill & Koenig, 2010). Therefore, the focus of this Master thesis is on researching the last phase of the policy cycle, concerning a specific policy area¹¹ that is governed by the EU food safety policy. To provide a descriptive and critical overview of contemporary research in EU food safety, the following studies are discussed.

The study from van der Meulen (2009) examined at supranational level the current EU food safety policy regulatory structure i.e. GFL: Regulation 178/2002 from a legal and institutional perspective. This study starts by describing the historical development of the EU food safety regulatory structure, followed by an explanation on how the current GFL functions. His research also makes legal comparison between the current GFL and the former regulatory structure that was based in general on directives. According to his study, the GFL was a response to the BSE crisis of the 1990s; and it functions as a holistic approach that applies to all businesses in the food chain. In other words, GFL regulates the practices and procedures of food business in order to guarantee the food safety in the EU. A new aspect of GFL is that it stipulates the establishment of a new EU institution i.e. EFSA, which task is to assess scientifically food products at supranational level. This author indicates in his study of (2009) that GFL has legal-flaws that are a potential danger to the food safety in the EU. His study concludes, by stating that a legal-flaw is observable in the GFL definition that is used to describe ‘food safety requirements’ at supranational level (van der Meulen, 2009, pp. 73-89).

The study from Leibovitch (2007) examined the HP: Regulations 852/853/854/2004, from a legal and public administration perspective in order to explain how it functions and what their provisos are. According to this study HP regulations are a new aspect in EU food safety policy, since such a complex hygiene regulatory structure did not exist prior to 2004 (Leibovitch, 2007). Leibovitch’s study from (2007) makes clear that HP functions primarily by means of regulations in order to guarantee the safety of meat and animal-derived food products in the EU. His study explains, that the HP regulations provisos stipulate what food business operators are permitted to do concerning: **(1)** the handling of food; **(2)** the safety of foodstuff processed and unprocessed products from animal origin and **(3)** the official controls on products of animal origin that are intended for human consumption. His study concludes, by stating that the HP regulations were introduced to: **(a)** simplify the existing food hygiene legislation and **(b)** to harmonised and improved were needed the many different hygiene rules and standards across the EU into one hygiene regulatory structure (Leibovitch, 2007).

The study from Lelieveld, Holah, and Napper (2014) examined and assessed at length from several academic perspectives the HP regulations that governed the safety of meat and animal-derived food products in the EU. In sum, this study describes that the HP regulations, principles and practices compel by law food operators to label their products. And at the same time it permits that these

¹⁰ The five policy cycles are: **1** agenda setting, **2** Formulation, **3** Implementation, **4** Budget and **5** Assessment or Evaluation

¹¹ **This Master thesis focuses explicitly on the policy area: the safety of meat and animal-derived food products in the EU.**

food operators develop and use their own set of standards and codes to regulate themselves (Lelieveld et al., 2014). In other words, the HP regulations are a mixture of command & control and self-regulation¹². Their study concludes, by stating that the regulatory stipulated penalties in the HP regulations are not sufficient to discourage food operators from conducting fraudulent schemes, because the profit gains outweigh the costs of being caught (Lelieveld et al., 2014).

The studies from Alemanno (2013) and Robison et al. (2013) examined from a legal and health perspective, EFSA's organisational structure. According to the Alemanno's study from (2013), this agency is organised as an independent operating EU institution, where risk assessment is separated from risk management to guarantee the science of food safety in the EU (Alemanno, 2013). His research also explained that the EFSA is responsible for food safety assessments and approvals of substances, products and claims in the food and feed sectors at supranational level (Alemanno, 2013). Alemanno's study from (2013) makes clear that the EFSA's main responsibility is to conduct scientific assessment and communication concerning food, feed as well as hygiene matters. This study concludes, by stating that in the case of conflicting scientific opinion between the EFSA and national food agencies, it will be up to the European Court of Justice to determine the balance between local, national and EU interests.

According to the Robison et al. study from (2013), the latest Seralini affair¹³ was yet another chain of controversies related to the EFSA's close relationship with the private industry. This study revealed that the former chair of EFSA's management board (i.e. Diána Bánáti), was closely connected to the industry-funded International Life Sciences Institute or ILSI (Robinson et al., 2013). In sum, this study demonstrates a vital organisational flaw within the EFSA structure i.e. poor screening procedures for the selection and appointing of managers and scientist, which has resulted in conflict of interest and biased scientific opinions. This study concludes, by stating that when industry scientists collaborate with publicly-funded scientists such as those from the EFSA to design risk assessment methodologies for pesticides and GM foods. The validity of the scientific findings and opinions of this agency cannot be regarded as independent and sound (Robinson et al., 2013).

Albeit these studies examined the EU food safety policy thoroughly; there are limitations due to their foci. First, most of these studies approached the safety of food in the EU from a specific academic discipline. Second, these studies apart from the one of (Lelieveld et al., 2014), do not focus explicitly on the assessment phase of the policy cycle. But on analysing and explaining how the EU food safety policy is developed, how it functions, and to some extent underlining the flaws it has. Third, more importantly these studies did not assess a specific policy area, with the exception of (Lelieveld et al., 2014). Even though there have been several major food safety crisis related to the safety of meat and animal-derived food products in the past decade across the EU. All in all, by systematically reviewing these studies it allowed me to identify, select and synthesise research evidence and arguments that were relevant to specify the policy area and formulate the research question(s) that are used in this Master thesis.

¹² For an overview of regulatory strategies see (Baldwin, Cave, & Lodge, 2012, pp. 134-136)

¹³ **This affair is about the health risks concerning the consumption of genetically modified (GM) plants that contain high levels of pesticide residues.** See: <http://www.counterpunch.org/2014/06/27/biosafety-and-the-seralini-affair/>

Research Demarcation, Objective & Questions

Due to assignment restrictions, I cannot research all of the areas which the EU food safety policy regulates such as: GMO, novel foods, fresh vegetables, fruits, process foods and drinks to name a few. Therefore, I will focus on one specific area of this policy namely, the safety of meat and animal-derived food products. This policy area is regulated by: **(a)** Legislation, General Food Law Regulation 178/2002 and Hygiene package Regulations 852/853/854/2004 and **(b)** the regulatory regime units the EC (enforcement & control) and EFSA (scientific assessment & communication) at EU level.

The **research objective** of this Master thesis is to examine from a public administration perspective if the EU food safety policy is capable of achieving its goal; by assessing whether it is able to guarantee the safety of meat and animal-derived food products (cattle and poultry) in the EU (28 Member States). To graphically illustrate the EU food safety policy interrelated core components that regulate the safety of meat and animal-derived food products in the EU; the taxonomy tree below is used:

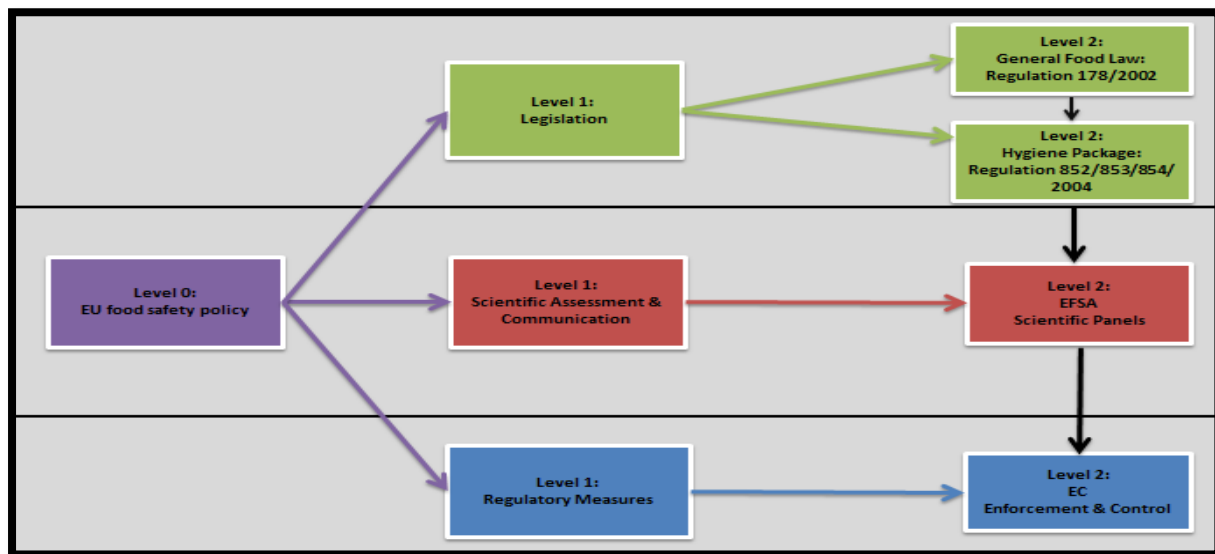


Figure 1: EU food safety policy levels

From the research objective the following two main research questions are formulated:

(a) "How does the EU Food Safety Policy, three interrelated core components: Legislation, Scientific Assessment & Communication in addition to Regulatory Measures contribute in order to achieve its goal?"

(b) "To what extent does the EU Food Safety Policy guarantees the safety of Meat and Animal-Derived food products (Cattle and Poultry) in the European Union (28 Member States)?"

Table 1: The main research question of this master thesis

To answer the main research questions the following three sub-questions are used:

- I. What regulatory assessment criteria can be derived from theories on regulations, institutions, political science, law and public administration, in order to determine whether a regulation and regulatory regime are effective or ineffective?
- II. How are the EU Food Safety Policy, legislation (GFL & HP); Scientific Assessment & Communication (EFSA) as well as Regulatory Measures (EC), organised to guarantee the safety of meat and animal-derived food products in the EU?
- III. To what extent do the EU Food Safety Policy General Food Law & Hygiene Package regulations in addition to regulatory regime units EC and EFSA fulfil these regulatory assessment criteria?

Table 2: The sub-research questions of this master thesis

Master Thesis Structure

This Master thesis is structured according to my research question(s). **Chapter 1** describes the theoretical framework that is used to assess the EU food safety policy regulations via four regulatory assessment criteria. **Chapter 2** describes the methodology that is used to collect, organise and analyse the qualitative research data systematically. **Chapter 3** describes how the main features of the EU food safety policy regulations GFL and HP as well as regulatory regime units; the EC and EFSA are organised and contribute in order to achieve its goal.

Chapter 4 assesses the extent to which the EU food safety policy regulations GFL and HP in addition to the regulatory regime units the EC and EFSA are effective or ineffective, to guarantee the safety of meat and animal-derived food products in the EU. Finally, **Chapter 5** assessment results conclude the research by answering the main research questions of this Master thesis as well as providing suggestions on how to improve it and discussing the limitations of this research.

Chapter 1: Theoretical Framework

This chapter describes the theoretical framework that is used in this Master thesis to assess the EU food safety policy regulations¹⁴ in addition to the regulatory regime. The theoretical framework of this Master thesis is divided into sections: 1.1 and 1.2.

1.1 Regulatory Assessment Criteria

This section outlines regulatory assessment criteria that are used to answer the first sub-research question.

Before I begin to describe the regulatory assessment criteria, it is important to note that in a complex institutional setting with less clear demand side conditions, the possibility to produce a weak regulatory outcome increases (Mattli & Woods, 2009a).

Therefore it is important to examine:

- (a) whether the institutional supply conditions i.e. regulatory processes of drafting of rules, implementation, monitoring and enforcement are properly organised in the institutional setting where it take place (Mattli & Woods, 2009a). From this perspective, one assesses the extent to which the ‘*internal environment*’ of a policy are based on public interest¹⁵ regulations (Baldwin et al., 2012; Mattli & Woods, 2009a).
- (b) whether the demand side conditions i.e. information, interest and ideas has an effect on the development of a regulation (Mattli & Woods, 2009a). From this perspective, one assesses the extent to which the ‘*external environment*’ of a policy are based on interest group¹⁶ regulations (Baldwin et al., 2012; Mattli & Woods, 2009a).

However, before one is able to assess regulations precisely, it is important to be clear and concise when choosing and developing such regulatory criteria¹⁷. Therefore, the following four criteria: *legitimation, accountability, transparency and expertise*, derived from several academic disciplines, are used; to assess the EU food safety policy regulations GFL and HP in addition to regulatory regime units the EC and EFSA more specifically.

In a nutshell: these four regulatory assessment criteria are used to determine the extent to which the EU food safety policy regulations¹⁸ in addition to regulatory regime¹⁹ are effective or ineffective, to guarantee the safety of meat and animal-derived food products (cattle and poultry) in the EU. Moreover to organise the results of the regulatory assessment, a matrix with ratings is used (see section 1.2). The next four sub-sections of this chapter describe in detail the regulatory assessment criteria that are used to carry out this research.

¹⁴ See appendix I: for explanation EU secondary law.

¹⁵ The public interest is conceptualised as “the notion of full information, perfect enforcement, benevolent, rational, trustworthy regulators that are disinterested and public spirited experts, that produce rules that guarantee the maximum social benefit and overall economic efficiency for society. (Baldwin et al., 2012; Mattli & Woods, 2009a).

¹⁶ The interest group is conceptualised as “actors or alliances that are intrinsically self-regarding and oriented towards maximising their personal and material utility (or self-interest), via the control of the regulatory process with the consequence that regulatory outcomes favour the narrow “few” or interest group, at the expense of the general public (Baldwin et al., 2012; Mattli & Woods, 2009a).

¹⁷ It is vital to note that to establish regulatory assessment criterion it is problematic endeavour, because it is subjectively and can be contested with regard to the weight and importance that is attribute to a criteria that is used for assessment. Therefore, I have read extensively through the literature in order to select the most suitable regulatory assessment criteria for this Master thesis topic.

¹⁸ In this Master Thesis regulations are conceptualise as “the organisation and control of economic, political and social activities by means of making, implementing, monitoring and enforcing rules” (Mattli & Woods, 2009a, p. 1; 2009j).

¹⁹ This Master thesis conceptualises a regulatory regime as “the set of interrelated units which are engaged in joint problem solving to address a particular goal; its boundaries are defined by the definition of the problem being addressed; and it has some continuity over time” (Black, 2009, p. 5).

1.1.1 Criterion I: Legitimation

In order to regulate effectively: This criterion stipulates that a regulation requires to have the support of the legislative authority, a clearly stipulated goal and scope, focused on a specific problem and consistently interpreted.

→ Thus to determine if a regulation fulfils this criterion, I assess specifically whether it is:

(1) Democratic & Constitutional: is the regulation **(a)** legitimised by the legislative authority; **(b)** supported by all the stakeholders involved (public and private) in the regulatory process; **(c)** founded in accordance to the rule of law; **(d)** proportional and necessary to develop by taking into consideration the many competing interests of different groups and **(e)** consistently interpreted by the Member States across the EU;

(2) Goal oriented and functional: are the goal(s)²⁰ and scope(s) of the regulation: **(a)** formulated in a detailed and concise²¹ manner; **(b)** targeted to solve a specific problem in addition to **(c)** systematically reviewed and assessed for effectiveness by the regulatory regime in charged (Baldwin et al., 2012, pp. 32-33; Black, 2009, pp. 14-16; Force, 1998; Malyshev, 2006, pp. 278-291).

Table 3: Regulatory assessment criteria legitimation

To have an effective regulation, this criterion indicates that a regulation is legitimate if it is: **(I)** approved and supported by the legislative authority e.g. national government, EP, EC and Council of the European Union as well as other stakeholders; **(II)** has clear identifiable stipulated regulatory goals and **(III)** is consistently interpreted by the actors that are involved and targeted to solve a specific problem (Baldwin et al., 2012; Black, 2009; Craig & De Búrca, 2011; Force, 1998; Malyshev, 2006).

(Black, 2008, 2009) complements this by explaining that the legitimation of a regulation is accepted socially if it is: **(a)** pragmatically founded, that is the regulatory regime in charge is able to realise their pursue of interest directly or indirectly; **(b)** morally founded, that is the general public perceives the goals and procedures of the regulation as morally proper and **(c)** cognitively based, that is, the regulation is accepted as necessary and thus unavoidable. Therefore, according to (Black, 2009, p. 9), legitimation intrinsically involves “*social credibility and acceptability a generalised perception or assumption that the actions of an entity are desirable, proper, or appropriate within a socially constructed system of norms, values, beliefs, and definitions*”. On the other hand, (Grant & Keohane, 2005, pp. 21-24) indicates that “*the chief sources of legitimacy at the domestic level, such as constitutional mandates, electoral processes, legality, tradition, and the services provided by effective government, are not [constantly] available to transnational organisations [UN]*”.

Nevertheless, legitimation at world level is to some extent similar to one of the EU, since both rest on: general norms of fairness, processes and on claims in order to improve the legitimation quality of outcomes (Grant & Keohane, 2005). The main problems with legitimation at supranational level is that often regulations are ambiguously framed concerning the goals it has to realised (Black, 2008, 2009). For example, regulations often have goals that are of mutual interest or double-edge formulated such as: protecting consumer interests and not damaging industrial interests at the same time (Baldwin et al., 2012, p. 28; Malyshev, 2006, p. 278). Also, legitimation at supranational level is often more susceptible to be influenced by industry lobbyist that are hired to adjust regulations and/or corrupt the regulatory regime into their advantage; at the cost of the general public and its resources (Black, 2009; Nestle, 2013).

²⁰ In this Master thesis the word goal has the same meaning as aim or objective.

²¹ **Specific** target a specific area for improvement; **Measurable** quantify or at least suggest an indicator of progress; **Assignable** specify who will do it; **Realistic** state what results can realistically be achieved, given available resources; **Time-related** specify when the result(s) can be achieved. See: Doran, G. T. (1981). "There's an S.M.A.R.T. way to write management's goals and objectives". *Management Review (AMA FORUM)* 70 (11): 35–36. and Moran, M. (2002). Review article: Understanding the regulatory state. *British journal of political science*, 32(02), 391-413.

Thus, to improve the legitimation of a regulation and regulatory regime, it is important to assess if it is approved by the legislative authority and supported by all the stakeholders involved in the regulatory process (ibid). So that all the stakeholders involved in the regulatory process can regulate in an effective and predictive manner.

1.1.2 Criterion II: Accountability

In order to regulate effectively: This criterion stipulates that a regulation requires to have an appropriate democratic system of accountability.

→ Therefore, to determine if a regulation fulfils this criterion, I assess specifically whether a regulation and regulatory regime are:

(1) Political accountable: does the regulation compel the regulators to render account to an elected parliament or selected commission, concerning the actions that are carried out in prior conduct or are planned for the future conduct;

(2) Legal accountable: does the regulation compel the regulators to be held to account for conducts that conflict with the stipulated obligations. Through courts judicial procedures of justification that are governed by the rule of law;

(3) Administrative accountable: does the regulation compel the regulators to be supervised and control by means of administrative and financial oversight. Using independent institutions such as: ombudsmen, auditors, and inspectors that report either directly or indirectly to parliament or other responsible institution or commission;

(4) Social accountable: does the regulation compel the regulators to account for their conducts to the public By means of forums, that are located in civil society (Baldwin et al., 2012; Bovens, 2007i; Curtin & Nollkaemper, 2005; Grant & Keohane, 2005; Wang, 2002).

Table 4: Regulatory assessment criteria accountability

To have an effective regulation, this criterion indicates that the regulatory regime must be subjected to public scrutiny, by means of: political, legal, administrative and social systems of accountability (Baldwin et al., 2012; Bovens, 2007i; Curtin & Nollkaemper, 2005; Schedler & Plattner, 1999). According to (Bovens, 2007i, pp. 106-108) accountability originates from accounting, and is conceptualised as *"a relationship between an actor and a forum, in which the actor has an obligation to explain and to justify his or her conduct, to a [specific] forum that can pose questions and pass judgment, and the actor may face consequences"*. In other words, accountability includes: **(a)** answerability, which is the obligation of the government, its agencies and public civil servants to provide information concerning their decisions and actions and to justify them to the public and **(b)** enforcement, which proposes that the public or the institution responsible for accountability have the possibility to sanction the offending actor or remedy the infringing conduct/behaviour (Schedler & Plattner, 1999).

Moreover, ideally accountability involves three elements namely: **(I)** the actor has to be obligated to inform the forum about its conduct, by providing several kinds of data concerning its performance of tasks, outcomes and procedures; **(II)** the possibility for debates in an open forum in order to interrogate the actor and to question its actions i.e. adequacy of provided information, legitimacy of conduct and **(III)** the forum has to be able to pass judgement on the conduct taken by the actor (Bovens, Curtin, & Hart, 2010, pp. 4-5). In other words, accountability *"is a relationship between an actor and a forum, in which the actor has an obligation to explain and to justify his or her conduct, the forum can pose questions and pass judgment, and the actor may face consequences"* (Bovens et al., 2010, p. 5). However, in many occasions accountability is often ex post facto, since the actors involved render account to a (specific) forum after prior conduct (Bovens et al., 2010). It is important to note that even though regulators can have an inaccurate regulatory mandate, they are in most occasions accountable and controlled by democratic institutions (Baldwin et al., 2012; Bovens,

2007i). However, complications can arise concerning the appropriate degree of accountability²², especially when the parliament or different elected institutions are not the specific forums that control the regulatory regime (units) actions during the regulatory process (Bovens, 2007a, 2007i; Schedler & Plattner, 1999). Than such an arrangement can be criticised as being un-representative and hence not accountable for the actions it carries out (Baldwin et al., 2012; Bovens, 2007i).

On the other hand, there are additional accountability measures that can be used to prevent that regulators abuse their powers. These measures are proposed by Grant and Keohane (2005) and involved: **(a)** hierarchical, supervisory, fiscal and legal accountability, which depend on delegation and **(b)** market, peer and reputational accountability, which depend on forms of participation in order to function accordingly (see for detail explanation concerning these mechanisms Grant & Keohane, 2005, pp. 24-27). It is important to note that in practice these additional accountability mechanisms are already regularly used in (world) politics; and they operate most effectively when standards are officially encoded in the law (Grant & Keohane, 2005). The following table below, that is borrowed from (Grant & Keohane, 2005, p. 42) summarises these seven measures:

<i>Mechanism</i>	<i>Accountability holder</i>	<i>Power-wielder</i>	<i>Cost to power-wielder</i>	<i>Examples</i>
<i>Hierarchical</i>	Leaders of organization	Subordinate official	Loss of career opportunities	Authority of UN Secretary-General
<i>Supervisory</i>	States	Multilateral organization and its executive head	Restraints on ability to act, loss of office	World Bank and IMF governance by their executive boards
<i>Fiscal</i>	Funding agencies	Funded agency	Budget restrictions	Withholding of UN dues
<i>Legal</i>	Courts	Individual official or agency	From restriction of authority to criminal penalties	International Criminal Court
<i>Market</i>	Equity and bond-holders, and consumers	Firm	Loss of access to, or higher cost of, capital	Refusal of capital markets to finance developing country governments during world financial crises
<i>Peer</i>	Peer organizations	Organizations and their leaders	Effects on network ties and therefore on others' support	Independent marine certification body's evaluation of the Greenpeace-Shell controversy
<i>Public Reputational</i>	Peers and diffuse public	Individual or agency	Diffuse effects on reputation, prestige, self-esteem	Effects on US "soft power" of unilateralism

Table 5: Additional accountability mechanisms

To improve the accountability of a regulatory regime, it is essential that accountability systems are: well-publicised, accessible, have fair and effective complaints and appeals procedures, clear lines of accountability to ministers, parliaments, assemblies and the public. In addition, regulators have to clearly explain how and why certain final regulatory decisions have been reached, so that they cannot abuse their powers and regulate effectively (Baldwin et al., 2012, p. 33). The figure on the right borrowed from (Bovens, 2007a) illustrates in a simplified manner how the accountability process can be organised.

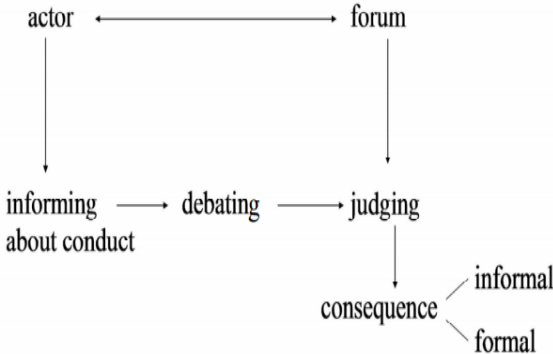


Figure 2: The accountability process

²² This includes the resources (human and financial) that have to be used for accountability and the acceptability of any trade-off among accountability and the effective pursuit of regulatory goals. See Baldwin, R., Cave, M., & Lodge, M. (2012). *Understanding regulation: theory, strategy, and practice*. Oxford University Press. Page 28.

1.1.3 Criterion III: Transparency

In order to regulate effectively: This criterion stipulates that a regulation requires to have an appropriate system of transparency.

→ Thus to determine if a regulation fulfils this criterion, I assess specifically whether a regulation and the regulatory regime provide:

(1) Visible and inferable processes: does the regulation compel the regulatory regime to guarantee a visible decision making process in the setting of rules and standards, so that the actors involved in the regulatory process are able to draw rational decisions;

(2) Openness of information and communication: does the regulation compel the regulatory regime to guarantee **(a)** the accessibility and disclosing of information concerning the actors involved in the regulatory process and **(b)** to communicate openly concerning its regulatory decisions and actions taken towards the public, industry or other affected parties through for example, government documents, websites, notes, reports etc. and;

(3) Inclusiveness of actors: does the regulation compel the regulatory regime to guarantee equal treatment participation concerning the actors involved in the regulatory process such as: NGO's, industry and others at all times or occasionally (Baldwin et al., 2012; Lodge, 2004; Michener & Bersch, 2011; Stiglitz, 2002).

Table 6: Regulatory assessment criteria transparency

To have an effective regulation, this criteria indicates that a regulation without high quality transparent and accurate due process, that are open fair and accessible; proper democratic influence cannot be guaranteed (Baldwin et al., 2012; Lodge, 2004; Michener & Bersch, 2011; Stiglitz, 2002). Moreover, Michener and Bersch (2011) explain that *“transparency at its core comprises of two dimensions: (a) visibility, as in light rendering an object entirely visible and (b) infer-ability, that is to infer with a high degree of accuracy”* (p.1-2). Consequently transparency requires to fulfil these two conditions in order to be regarded as transparent, because without them it result in information asymmetries instead of information symmetries (Michener & Bersch, 2011, pp. 3-4).

In other words, transparency refers to the access of timely and reliable information, concerning the performance and decisions made by the regulatory regime, government institutions or associated organisations that are in charge of the regulatory process (Michener & Bersch, 2011; Stern & Holder, 1999). Yet, one of the main common problems concerning regulatory transparency is the degree of actor participation. For instance, are the actors that are going to be affected indirectly by the regulation allow to participate or only those that are affected directly. Because when participation is extensive than it is possible that it leads to: in-effective decision making, less transparency and eventually the decline of the regulation and regulatory regime (Baldwin et al., 2012; Lodge, 2004).

An additional problem that often arises in a regulation is concerning the design of intentional or unintentional deficient due process, that in most cases results in: environmental degradation, health hazards, dis-functional markets, public resources misused, decrease investment and economic performance (Koedijk, Kremers, David, & Röller, 1996; Sacks et al., 2013). Consequently, transparency is of vital importance for a regulation, because this is associated as a hallmark for democracy and economic growth; and thus necessary for the proper functioning of government institutions or regulatory regime (Stern & Holder, 1999).

One of the key features of transparency that have an important and often direct effect on a regulation are open due process that will improve directly and indirectly the what, how, where and when, concerning the monitoring of regulatory activities by the regulatory regime in charge of the regulation (Jordana & Levi-Faur, 2004). Therefore it is important to establish proper due process so that it is possible to improve and extent the posting of information, but also the feedback loop through for example, allowing public comments and interaction (Jordana & Levi-Faur, 2004).

In a nutshell, transparency includes (Primova, p. 11):

<i>Institutional provisos</i>	<i>Open due processes</i>	<i>Involvement of the forum</i>	<i>Actor's responsiveness</i>
<ul style="list-style-type: none"> • Institutional arrangements for public participation and public scrutiny at EU level. 	<ul style="list-style-type: none"> • Openness if possible all of the EU-relevant and governmental documents to the general public. • Public reports and visibility of the policy-making process. 	<ul style="list-style-type: none"> • Involvement of relevant stakeholders such as NGO's, interest groups or citizens through consultations, stakeholders for a/forums or inquiries at EU level. • Balanced representation of all relevant stakeholders or citizens in the debate. • Questions, comments and critical concerns raised by the stakeholders. • Judgement is posed if necessary. 	<ul style="list-style-type: none"> • Providing information that is comprehensible and timely. • Reply, explanation and justification by the actor. • Policy output that is, consideration of the different stakeholders concerns and demands in the initial and final outcome.

Table 7: Transparency overview

To assess transparency it involves examining whether the regulatory regime: **(I)** publishes important regulatory documents, decisions or advice in the public domain and **(II)** informs civil society when decisions or advice are not published (Stern & Holder, 1999). But also if the regulatory regime allows the participation of various groups and whether it collaborates with civil society (Michener & Bersch, 2011). Therefore it is important that a regulatory regime regularly organises and post in open forums²³ what their plans are concerning a particular policy area. In addition to, requesting the public for opinion and revision on wording, clauses and mechanism that are stipulated in the preliminary regulation (ibid). To illustrate the interrelated transparency processes that are essential in order to have an open government system, concerning its regulatory operations; the figure below borrowed from DemocratieOuverte.org is used:

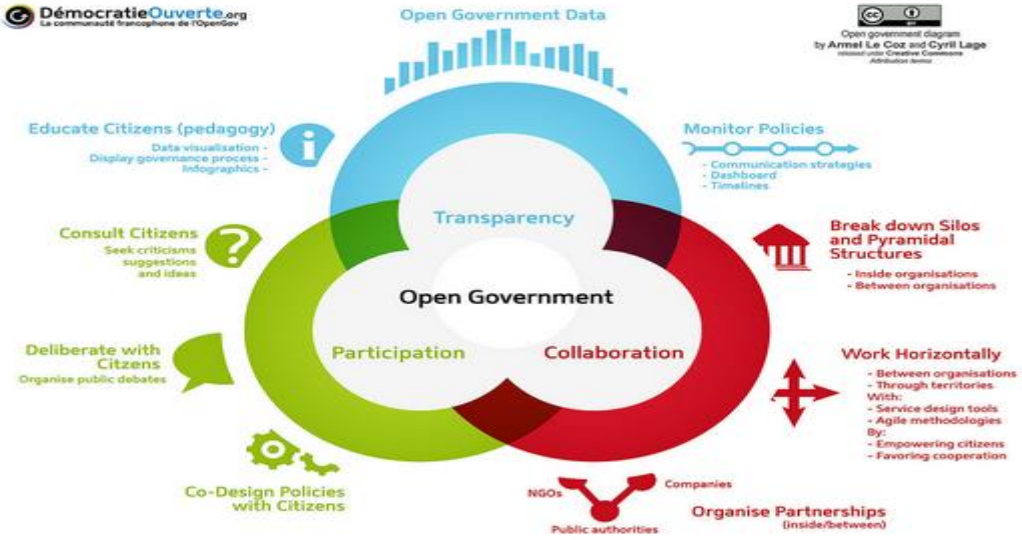


Figure 3: Transparency process

²³ The government of New Zealand has organises such an open forum for the public. This forum permits the public to comment on policies and bills in order to reconcile the comments into pros and cons positions by means of a so-called wiki pilot. However, this wiki pilot has so far not been used on a regular basis by the New Zealand public. See: <http://www.washingtonwatch.com/>

1.1.4 Criterion IV: Expertise

In order to regulate effectively: This criterion stipulates that a regulatory regime requires to have sufficient level of expertise and resources, so that a regulation is able to function appropriately.

→ Therefore to determine if a regulation fulfils this criterion, I specifically assess whether a regulation and the regulatory regime provide:

(1) System of Education: does the regulation compel the regulatory regime to schooling and training programmes in: legal, administrative, technical and scientific regulatory competence. So that the regulators levels of knowledge especially in a fast-space, overlapping and complex policy areas is up-to-date or improved when needed;

(2) Staff Availability & Resources: are there sufficient: **(a)** competent regulators employed in a regulatory regime to perform inspections and audits. So that regulatory control and compliance is achieved and **(b)** resources available such as funds (capital) and knowledge in order to regulate competently, so that the stipulated goal(s) are realised (Baldwin et al., 2012; Bourgeault & Grignon, 2013; Damro, 2012; Lin, 2010).

Table 8: Regulatory assessment criteria expertise

To have an effective regulation, this criteria indicates that regulators without sufficient levels of expertise and resources, will not be able to infer competently and justify their decisions (Baldwin et al., 2012). In many occasions regulatory regimes required the application of expert judgement, where the decision maker has to reflect several opposing choices (options) or values, and consequently has to balanced their judgment on inadequate and often shifting information (Baldwin et al., 2012; Bourgeault & Grignon, 2013). It is important to note that in such situations regulators can still claim support on the foundation of its expertise and the task at hand or *“trust to my expertise is the root of such claim”*, instead of providing rational reasons or justifications or procedural and documentary records (Baldwin et al., 2012, p. 29; Bourgeault & Grignon, 2013, pp. 202-211).

However in practice, it often occurs that regulators put emphasis on regulatory autonomy to improve their expertise in order to perform their tasks competently (Baldwin et al., 2012). This suggests that when regulators are liberated from their duties of justification, they will be able to infer the most suitable decisions, and thus realised the best regulatory outcome most swiftly (Baldwin et al., 2012). On the other hand, a major difficulty concerning expertise, is that it can be problematic for the public to assess or evaluate whether the public policy decisions that have been developed, are generated by the use of expertise or exclusively on the idiosyncratic judgement of the regulators (Baldwin et al., 2012; Bourgeault & Grignon, 2013). Therefore, to strengthen the regulators claim to expertise, legislative and administrative actions are necessary to assesses whether regulators have sufficient levels of: education, training and resources to perform their task effectively (ibid). Likewise, it is also important to assess the regulatory regime in charge of the regulation systematically both qualitative and quantitative in order to thoroughly examine and judge the state of performance (Baldwin et al., 2012, pp. 33-34).

1.2 Assessment Matrix

This section outlines the assessment matrix that is used in this Master thesis to summarise and organise the findings of the assessment. An assessment matrix is a means to objectively organise the possible outcome(s), derived from an assessment based on a set criterion²⁴. For that reason the matrix below is used in chapter 4.5 to graphically display the findings gathered from the four regulatory assessment criteria.

Assessment Rating:		Four Regulatory Assessment Criteria			
Effective + or Ineffective -		Criteria 1: Legitimation	Criteria 2: Accountability	Criteria 3: Transparency	Criteria 4: Expertise
EU Food Safety Policy Regulations used to guarantee the safety of meat and animal- derived food products in the EU.	General Food law: Regulation 178/2002				
	Hygiene Package: Regulations 852/ 853/ 854/ 2004				
	Regulatory Regime units the EC and EFSA				

Table 9: Assessment matrix

The assessment rating scores are as follows:

1. Effective	+	A regulation and regulatory regime are effective to guarantee the safety of meat and animal-derived food products in the EU, if they fulfil the requirements stipulated by each criterion: (a) to some extent ²⁵ (b) to a great extent ²⁶ and (c) all ²⁷ .
2. Ineffective	-	A regulation and regulatory regime are ineffective to guarantee the safety of meat and animal-derived food products in the EU, if they fulfil the requirements stipulated by each criterion: (a) to an extent ²⁸ and (b) not all ²⁹ .

Table 10: Assessment rating scores

²⁴ This assessment matrix is based upon the work of Linda G. Morra Imas and Ray C. Rist's, (2009) The Road to Results as presented in their International/European Program on Development Evaluation Training of 2010.

²⁵ For each criterion a regulation and regulatory regime must fulfil **at least half** of the stipulated requirements or conditions.

²⁶ For each criterion a regulation and regulatory regime must fulfil **more than half** of the stipulated requirements or conditions.

²⁷ For each criterion a regulation and regulatory regime must fulfil **all** of the stipulated requirements or conditions.

²⁸ For each criterion a regulation and regulatory regime fulfil **less than half** of the stipulated requirements or conditions.

²⁹ For each criterion a regulation and regulatory regime do **not** fulfil any of the stipulated requirements or conditions.

Chapter 2: Methodology

This chapter describes the research: approach, design and qualitative data analyses method; that I applied to systemically govern this study. The methodology of this Master thesis is divided into sections 2.1, 2.2 and 2.3 and is graphically illustrated by the following model below:

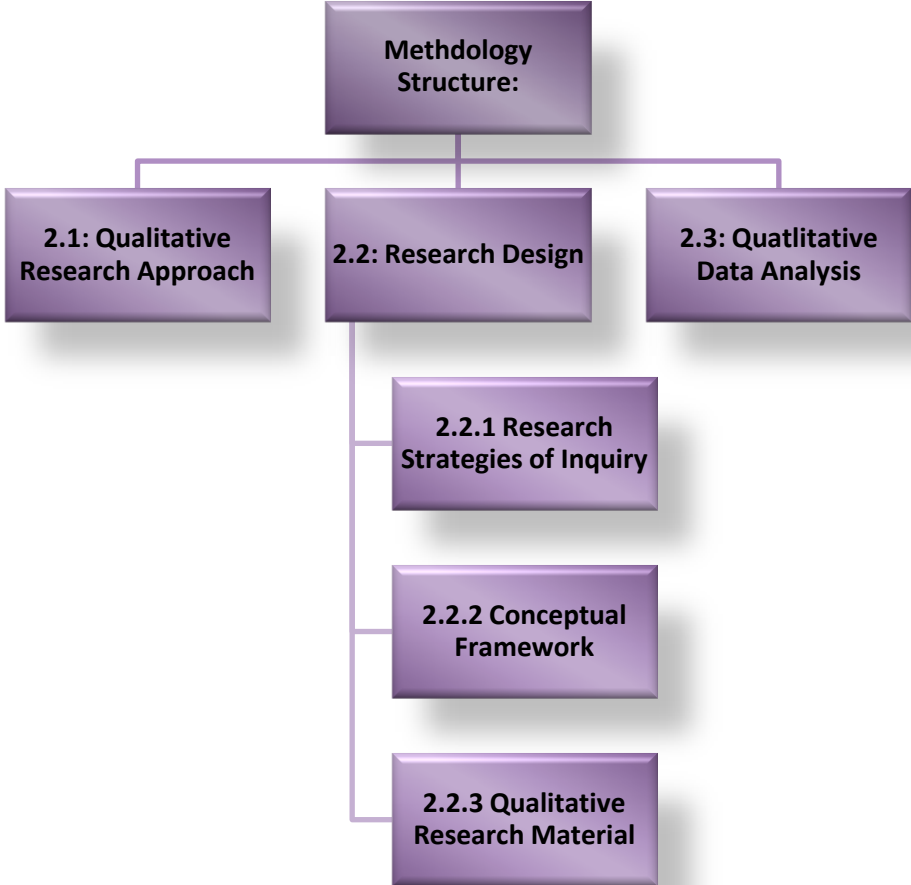


Figure 4: Methodology process

2.1 Qualitative Research Approach

Generally speaking a research approach is the plan and the procedures for conducting research in order to systematically study a topic (Creswell, 2013). To study the EU food safety policy three core components systematically, I use specifically in this Master thesis a **qualitative research approach**. This approach is *"any kind of research that produces findings [that are] not arrived at by means of statistical procedures or other means of quantification"* (Golafshani, 2003, p. 601; Strauss and Corbin, 1990, p. 17). In essence a qualitative research approach allows one *"(...) to understand phenomena [object] in context-specific settings, such as real world setting [where] the researcher does not attempt to manipulate the phenomenon of interest"* (Golafshani, 2003, p. 600; Patton, 2005, p. 39). Thus, qualitative research is an approach for exploring and understanding the meaning individuals or groups assigned or attributed to a social or human problem which in this case is the safety of meat and animal-derived food products in the EU (Creswell, 2013, pp. 16-19). All in all: a qualitative research approach is used in this Master thesis, because it allows one to obtain a comprehensive understanding of human behaviour and communication (textual data) and the reasons that govern these (Creswell, 2013; Gerring, 2011). Conversely, it also allows one to examine complex and sensitive topics such as food hygiene and safety, in order to become more experienced with the phenomenon or object under study (Creswell, 2013).

2.2 Research Design

The purpose of research design is to make certain that the evidence obtained allows the researcher to effectively address the problem at hand in a rational, systematic and unambiguous manner (De Vaus & de Vaus, 2001). In general research design refers to the selection and arrangement of evidence (Gerring, 2011). Thus research design involves identifying the type of evidence that is needed to for example, test a theory, evaluate a program or in this case: analyse, accurately describe and assess an observable object i.e. the EU food safety policy (Trochim, 2003). In other words, a research design is a systematic approach to study a scientific problem such as the crises concerning the safety of meat and animal-derived food products in the EU (Gerring, 2011). The research design that I use in this Master thesis is **descriptive study**, which is *"a scientific method that involves observing and describing the behaviour of a subject without influencing it in any way"* (Gerring, 2011, pp. 78-80). More specifically, I use descriptive-evaluation knowledge (Verschuren, Doorewaard, & Mellion, 2010). Descriptive-evaluation knowledge is used to generate knowledge by first describing and second assessing a particular object (i.e. EU food safety policy) and/or situation (i.e. food safety crises in the EU from 2002 till 2013) as accurately and comprehensively as possible (Verschuren et al., 2010, p. 107).

Furthermore, this Master thesis is based on an **idiographic description** of the EU food safety policy three core components that are used to guarantee the safety of meat and animal-derived food products in the EU. A description in line with (Gerring, 2011, p. 107) *"(...) can be understood as any empirical argument [question or theory] about the world that claims to answer a what question"*. Gerring (2011) clarifies that description comes before causation that is, one have to first describe a phenomenon or object in order to explain its causal relationship. Also to provide a detail description of EU food safety policy, the deductive reasoning³⁰ or top down approach is used (Gerring, 2011). Because my research begins from a general perspective i.e. EU food safety policy which is then narrowed down to a more specific perspective i.e. GFL, HP regulations as well as regulatory regime units the EC and EFSA. An important aspect of the research design is determining **the level of analysis**, because it is the what or who being studied (Babbie, 2012; Verschuren et al., 2010). Thus, the level of analysis in this Master thesis is at supranational level i.e. the EU food safety policy three interrelated core components: legislation, scientific assessment and communication in addition to

³⁰ That is, one firstly think about the theory of the topic of interest and subsequently narrow it down to more specific assumptions or questions that can be researched; in addition the evidence that is collected is used to support the deductive process (Gerring, 2011).

regulatory measures. Another important aspect of the research design, is determining what **the research object** or unit of observation is, where I will be making statements about and draw a conclusion (Babbie, 2012; Verschuren et al., 2010). Thus the research object or unit of observation of this Master thesis are the EU food safety policy regulations: **(1)** GFL Regulation 178/2002; **(2)** HP Regulations 852/ 853 /854/2004 and **(3)** the regulatory regime units the EC and EFSA, that together are used to guarantee the safety of meat and animal-derived food products in the EU. An additional important aspect of the research design is determining what the **research perspective** is. According to (Verschuren et al., 2010, pp. 72-74) the research perspective “(...) is the angle of approach towards the research object [or unit of observation], in order to specify which aspects will be examined or not”. Therefore depending on the type of research perspective (see for detail Verschuren et al., 2010, pp. 74-78); one will have to choose the perspective that is most appropriate, to realise the stipulated research objective. Hence, the research perspective that I use in this Master thesis is the evaluation (or assessment) perspective. Since my Master thesis focus is to determine whether the EU food safety policy is able to guarantee the safety of meat and animal -derived food products in the EU.

2.2.1 Research Strategies of Inquiry

The research strategies of inquiry that I use in the master thesis are the non-experimental single case study complemented by desk research. These strategies of inquiry together allows one to gain thorough understanding of complex subjects via a detailed contextual analysis of a limited number of events and their relationships (Gerring, 2007, 2011; Verschuren et al., 2010).

The **non-experimental single case study**³¹ (single case study) is according to (Gerring, 2004, p. 342; 2011, pp. 172-180) “an intensive study of a single unit a spatially bounded phenomenon [e.g. a policy, institution, organisation, nation-state or person] observed at a single point in time or over some delimited period of time”. Thus the single case study allows the researcher to gain in-depth insights into one or several objects or processes that are restricted in time and space (Gerring, 2011, pp. 224-232; Verschuren et al., 2010, p. 178).

This strategy is characterised by having a small research domain that consists of a limited amount of research units and observations, along with intensive data generation that is more in-depth than breadth (Gerring, 2011, pp. 233-236). Another characteristic of this strategy is that it is selective; and it uses qualitative data research methods, so that one is able to obtain a general idea of the object in order to make inferences about (Verschuren et al., 2010, pp. 178-185). The single case study is a research strategy that has noteworthy methodological advantages over for example experimental or survey research strategies (Exworthy & Powell, 2012; Verschuren et al., 2010).

Also from several epistemological and analytical perspectives this strategy is able to integrate both: **(1) idiographic** (i.e. the tendency to specify) unique cases, where the possibility for transferability or external validity is possible and **(2) nomothetic** (i.e. the tendency to generalise) case studies that are applicable or valid for the testing and development of causal hypotheses (Gerring, 2011; Golafshani, 2003; Thomas, 2011; Yin, 2014). Therefore to examining the EU food safety policy multifaceted interrelated core components and relationships, the single case study is the most rational option to choose. Also this strategy allows me to obtain a general idea/view of the research object; and this is needed to comprehend the complexity of the EU food safety policy three interrelated core components that are used to guarantee the safety of meat and animal-derived food products in the EU (Verschuren et al., 2010, p. 184).

³¹ **Robert Yin (2009, p.14)** conceptualises a single case study as “an empirical enquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident”. Also **Berg (2007, p.283)** conceptualises a single case study “a detailed examination of one setting, or a single subject or object, a single depository of documents, or one particular event”. According to **Robert Stake (2008, pp. 443, 445)** a single case study “is defined by interest in an individual case, not by the methods of inquiry used”, and that “the object of study is a specific, unique, bounded system”.

An often attributed advantage to the single case study has been its ability to obtain general picture of the research object or phenomenon that is being examined (Gerring, 2011; Verschuren et al., 2010; Yin, 2014). By having a general picture of the research object it allows the researcher to obtain in-depth knowledge hence understanding of complex objects (Verschuren et al., 2010; Yin, 2014). This is needed to examine the EU food safety policy. An additional advantage attributed to the single case study is that it does not require extensive pre-structuring as for instance, survey or experiment strategies (Gerring, 2011; Verschuren et al., 2010; Yin, 2014). By design a single case study is therefore a flexible strategy to use in comparison to a pre/post-test experiment or survey strategy that required extensive planning (Verschuren et al., 2010; Yin, 2014). Hence this strategy allows the researcher to adapt the research if needed, especially in fast shifting situations that often occur when conducting research. Other attributed advantages of the single case study are: **(1)** the extension or improvement of the knowledge concerning what is currently known, by using preceding completed research and **(2)** the strength to provide a comprehensive description of specific and rare case(s) that other strategies often cannot do (Gerring, 2011; Verschuren et al., 2010; Yin, 2014).

Nevertheless, the single case study has also been subject to a number of limitations (Gerring, 2004, 2011; Golafshani, 2003; Verschuren et al., 2010; Yin, 2014). An often attributed limitation has been its limited extent of transferability or external validity i.e. the extent to which the results of a study can be generalised to other objects, situations or persons (Gerring, 2011; Verschuren et al., 2010; Yin, 2014). This limitation arises due to the smaller amount of cases that are being studied; thus making it more difficult to apply the obtained results to a broader object of interest or to similar cases (Gerring, 2011; Verschuren et al., 2010; Yin, 2014). However, for my Master thesis the theoretical framework could be used for generalisation purpose by applying it on other policy areas that fall within the scope of GFL such as GMO, novel foods or pesticides. Another attributed limitation is reliability or the reproducibility of results i.e. can other researchers study the same (single) case and come to similar conclusions by using the same methods (Gerring, 2011; Verschuren et al., 2010; Yin, 2014). This limitation³² is in general associated with the possibility towards an interpretive foundation for meanings, reasons, and hence understandings by the researcher; due to the intense exposure to the examination of a single case, which could bias a researcher's interpretation of the findings (Gerring, 2011; Verschuren et al., 2010; Yin, 2014).

The second strategy is **desk research**, which according to (Verschuren et al., 2010, p. 194) is *“a strategy in which the researcher does not collect empirical data by itself, but uses material produced by other [researchers]”*. In general the researcher obtains data by collecting it behind a desk i.e. at home or library. This strategy in essence includes: **(a)** a literature review, the researcher uses knowledge produced by others i.e. knowledge sources and **(b)** secondary research namely, empirical data produced by others i.e. data sources (Verschuren et al., 2010, pp. 195-198). Furthermore the collection of data from existing resources is regarded as a low cost strategy³³ in comparison to for instance field research (Verschuren et al., 2010, p. 194). Desk research strategy makes use of a mixture of documentary and multiple-source data (Verschuren et al., 2010, p. 196). More specifically for this Master thesis I collect data from EU food safety regulation, public administration and institution literature i.e. books, journals, articles and documents from government officials/agencies (Verschuren et al., 2010). By using this strategy I can collect a large amount of data quickly, which is of vital importance due to time constraint. Nevertheless, it is important to note that most of the data concerning EU food safety is originally produced for other purpose than what I intend to conduct in this master thesis. Therefore, I will specifically focus on collecting data that is concerned with the food safety of meat and animal-derived food products in the EU.

³² This limitation is reduced by using triangulation methods. See for detail explanation (Verschuren et al., 2010, p. 184)

³³ In this Master thesis I will not conduct interviews or field observations.

2.2.2 Conceptual Framework

An additional important facet of the research design is the **conceptual research framework**. Which is a schematic depiction of the research objective and it consists of the estimated procedures, which need to be taken in order to realise the objective at hand (Verschuren et al., 2010). Also once such a depiction has been drawn up, the structure of the research plan becomes clearly visible for the researcher (Verschuren et al., 2010, pp. 65-70).

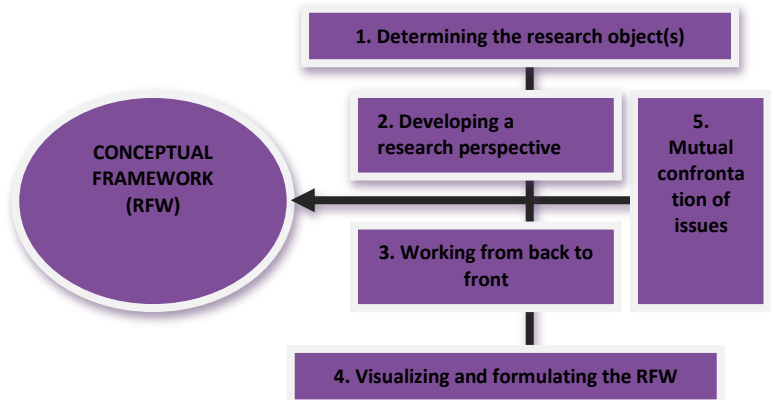


Figure 5: Research framework process.

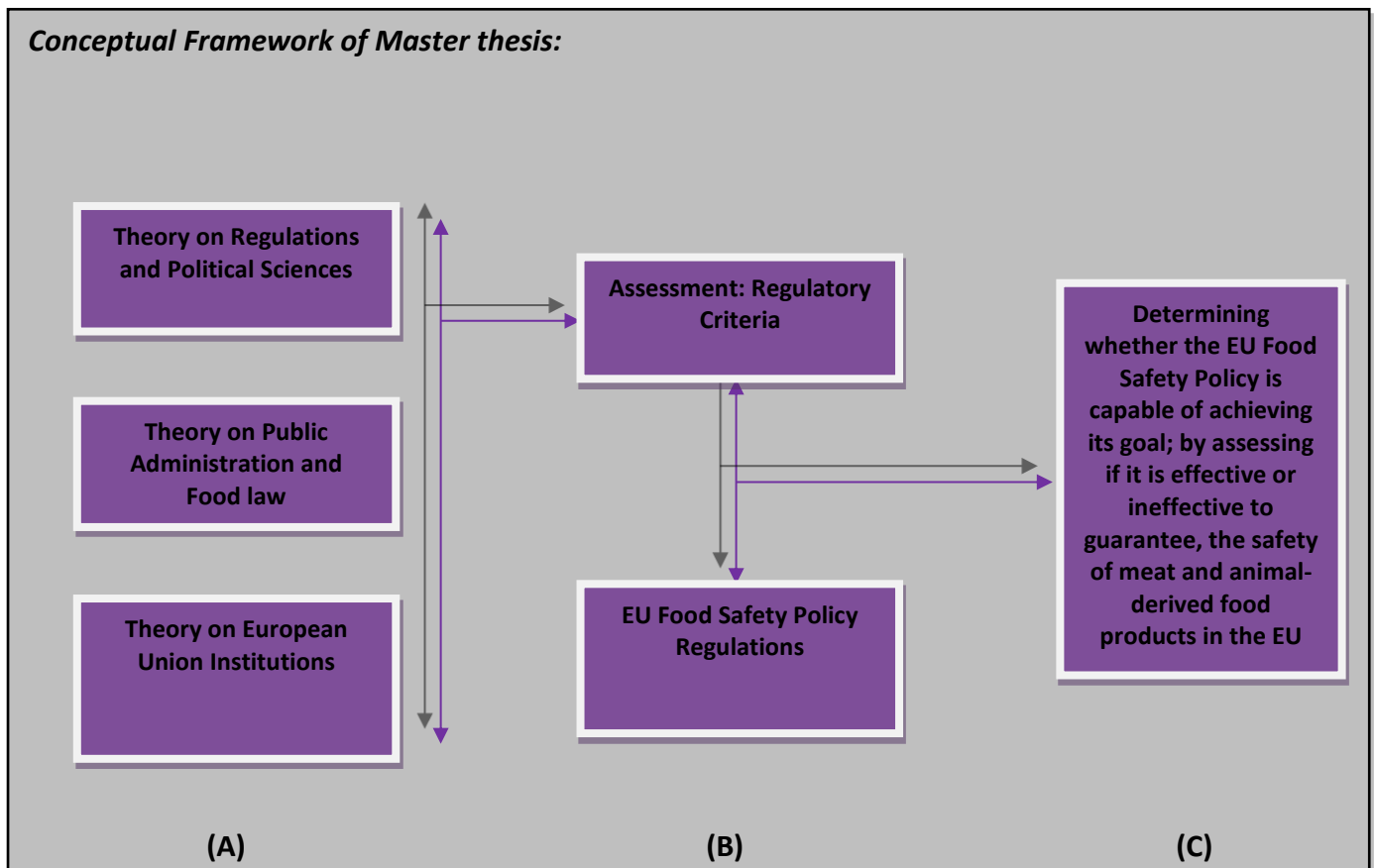


Figure 6: Conceptual framework process.

This master thesis is **(A)** a study based on recent and relevant scientific literature, in the fields of public administration, political science, law, European institutions and regulations, completed following a preliminary research, yields regulatory assessment criterion **(B)** on the bases of which the current EU food safety policy three interrelated core components are assessed **(C)** the results of this research are processed into the conclusion.

2.2.3 Qualitative Research Material

The purpose of qualitative research is not to generalise, but to develop an in-depth examination of a central phenomenon or object (Creswell, 2013). To examine the EU food safety policy interrelated core components, I therefore use **qualitative research material** that is collected by means of purposeful sampling. According to (Creswell, 2013, p. 206; Patton, 1990, p. 169), “*purposeful sampling, is when the “researcher intentionally select specific data sources [textual] that are information rich in order to learn or understand the central phenomenon [object] under study”.*

The qualitative research materials that I use for my Master thesis are produced between 2000 and 2014 and consist of: food policy documents from the EC, EFSA, DG Sanco and Member States. But also from EU food safety proposals and regulations, media newspaper articles, interviews, speeches and official statements of competent actors and relevant food operators and association reports. In addition, these data collection sources are unobtrusive. This means that the data is not collected directly from people, and this allows one to study the social behaviour of an object without affecting the process (Babbie, 2012).

Moreover, the qualitative research material that I used is mostly written in the English language. But this will be supplemented when needed by data sources that are written in the Dutch or German language from EU Member States the Netherlands and Germany³⁴. The secondary data are collected from scientific articles and journals that are used as supportive evidence. Since this kind of data has already analysed or assessed, for example similar or even the existing institutional setting, behaviour, interests and preferences of the regulations GFL and HP as well as regulatory units the EC and EFSA that are involved in guaranteeing the food safety in the EU. Furthermore, these secondary data sources were searched and collected through scientific indices such as: Jstor, google scholar and Eur-Lex, Web of Science and AGRIS.

To sum up: firstly the qualitative research material is used to describe what the current: governmental, academic and civil society discussion is concerning the EU food safety policy three interrelated components ability to achieve its goal. And secondly, to assess if the EU food safety policy is effective or ineffective in order to guarantee the safety of meat and animal-derived food products in the EU. The following table below illustrates a summarisation of the qualitative data sources that are used in this Master thesis:

<ol style="list-style-type: none">I. Draft Proposal and final version of General Food Law and Hygiene Package Regulations concerning the food and hygiene safety of animal derived food products(cattle and poultry);II. Member States government responses in consultation documents;III. Food industry interest and civil society responses in consultation documents;IV. Regulatory Scientific food safety books and articles;V. Media and newspaper articles;VI. Competent authorities interviews speeches and official statements.
But also the final food safety regulatory results concerning the safety of meat and animal-derived food products in the EU such as: <ol style="list-style-type: none">a. Food safety scandals concerning animal derived food products in the EU between 2002 and 2013;b. General Food Law: Regulation (EC) 178/2002 academic articles andc. Hygiene Package Regulations (EC) 852/853/854/2004 academic articles

Table 11: Summary of research material

³⁴ This is because regularly the national food safety comments concerning animal derived food products are written in national language.

2.3 Qualitative Data Analysis

To systematically analyse the collected qualitative research material, I used **qualitative content analysis** (content analysis). (Babbie, 2012) indicates that *“in content analysis the researcher examines a class of social artefacts that are generally written documents”*. By using this type of analysis, it allows me to understand how the collected qualitative research material reflects with the theoretical framework that is used, so that I am able to draw inferences from the data. Consequently, content analysis is *“a technique used to generate replicable, reliable and valid inferences from qualitative data to their context, by studying [or examining] recorded human communications [e.g. words, themes, characters, concepts, books, pages, paragraphs or lines]”* (Babbie, 2012, p. 320).

According to (Babbie, 2012, p. 333) content analysis is an appropriate data analysis technique when one intend to answer questions concerning: *“who says what, to whom, how and with what effect?”*. It is important to note that this data analysis technique consist of more than just: the counting of words, the extraction of objective content from texts, or the examination of the meaning, patterns and themes that could either be manifest³⁵ or latent³⁶ content or both in a specific text (Babbie, 2012). In other words, content analysis allows me to comprehend complex social reality in a subjective, although systematic manner based on science. An attributed advantage of this technique is that it is cost-effective, albeit depending on the data it could be time consuming to conduct due to coding (Babbie, 2012). Another attributed advantage of content analysis is *“its ability to not affect the subject (or object) under examination”* and; to examine processes that have occurred over a (long) period of time (Babbie, 2012, p. 344). An additional attributed advantage when using content analysis is that it uses unobtrusive measures, that is the researcher does not has any effect whatsoever on the object that is being examined(Babbie, 2012).

On the other hand, even though content analysis has several advantages, this data analysis technique also has its disadvantages. An often attributed disadvantage is concerning the examination of recorded human communication; because oral, written or graphic communication requires to be recorded in some fashion so that it can be analysed (Babbie, 2012). Another attributed disadvantage is concerning reliability, but this is more likely to occur when the researcher is solely examining communication processes (see for more detail Babbie, 2012, pp. 344-349).

All things considered, content analysis is used to: **(a)** formulated the research material into content analytical units; **(b)** fit the research material into a model of communication i.e. Master thesis in order to make inferences concerning the object under study and **(c)** control for biases via measures of: credibility, transferability, dependability and conformability along with data triangulation (see for more detail Babbie, 2012; Creswell, 2013; Guba & Lincoln, 1994; Mayring, 2004; Yin, 2014). Moreover, by including process tracing into content analysis it permits me to understand what has occurred concerning the development process of EU food safety policy from 2002 till 2013 and which actors (public and private) and competent authorities are responsible for what (Guba & Lincoln, 1994).

³⁵ The visible surface content or concrete terms contained in a communication: See (Babbie, 2012, p.338)

³⁶ The underlying meaning of communication: See (Babbie, 2012, p.338)

Chapter 3: The Regulatory Organisation of GFL & HP Regulations

This chapter answers the second sub-research question of this Master thesis and is divided into sections: 3.1 and 3.2.

Before describing the most important features that are used by the EU food safety policy regulations and regulatory regime, to guarantee the safety of meat and animal-derived food products in the EU; a brief background overview of this policy origin is provided. The EU food safety policy came into existence due to the **White Paper on Food Safety** of January 2000³⁷. This paper was designed to transform this policy into “*a pro-active, dynamic, coherent and wide-ranging apparatus*” in order to guarantee a high level of human health and consumer protection (van der Meulen, 2013, pp. 69-71). A very important feature of the present-day EU food safety policy is that it defined food legislation as “*the laws, regulations and administrative provisions [requirements or conditions] governing food in general, and food safety in particular, whether at Community or national level; it [food law] covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals*”³⁸.

Furthermore, the goal of the EU food safety policy is “*(...) to protect consumer health and interests while guaranteeing the smooth operation of the single market. In order to achieve this objective, the EU ensures that control standards are established and adhered to as regards food and food product hygiene, animal health and welfare, plant health and preventing the risk of contamination from external substances. It [EU food safety policy] also lays down rules on appropriate labelling for these foodstuffs and food products*”³⁹. It is important to comment that this goal is of mutual interest or double-edge formulated, since it is designed to both protect consumers and industry at the same time⁴⁰.

To realise the goal of the EU food safety policy, EU legislation was added to and amended in line with scientific and technological development. So that at present there is a wide-ranging set of regulations and directives that regulate the food safety (E. Commission, 2007; van der Meulen, 2013). The Directorate General (DG) responsible for food safety in the EU is **DG SANCO**. This DG is an important unit within the regulatory regime that is used to guarantee the safety of meat and animal-derived food products in the EU⁴¹. DG SANCO is a so-called **epistemic community**⁴² which is a group of professionals or experts with a legitimate claim to highly specified policy-relevant knowledge on scientifically complex subjects such as food safety and hygiene (Dunlop, 2010, p. 207).

³⁷ COMM (1999/2000). White Paper on Food Safety. 719, final. CEC. Brussels, European Commission and COMM (2001b). European Governance. A White Paper. Brussels, 25.7.2001. At its core the EU is built on Treaties which are based on the rule of law³⁷. These Treaties are the EU's primary laws where all Member States have voluntarily and democratically agreed to sign in order to be part of the Union (Craig & De Búrca, 2011). As such these primary laws are the impetus for the creation of: **(a)** supranational institutions such as: the EC, EP, ECJ and ECA and **(b)** secondary laws i.e. regulations, directives and decisions (ibid). Thus by signing these Treaties Member States has ceded parts of their sovereignty to the EU, which empowers the EU institutions to adopt secondary laws in order to govern a particular policy area (Craig & De Búrca, 2011).

³⁸ The definition of EU Food Law includes two aspects that are evidently accentuated namely: ‘food in general’ and ‘food safety’ in specific. See p. 1 and 2: regulation.upf.edu/dublin-10-papers/2F4.pdf

³⁹ See http://europa.eu/legislation_summaries/food_safety/index_en.htm

⁴⁰ See appendix III: List of food safety crises in the EU from 2002 till 2013

⁴¹ Communication of the European Commission on Consumer Health and Safety. Brussels: European Commission COM (97) 183 Final.

⁴² According to (Haas, 1992, p. 3) “*an epistemic community may consist of professionals from a variety of disciplines and backgrounds, they have (1) a shared set of normative and principled beliefs, which provide a value-based rationale for the social action of community members; (2) shared causal beliefs, which are derived from their analysis of practices leading or contributing to a central set of problems in their domain and which then serve as the basis for elucidating the multiple linkages between possible policy actions and desired outcomes; (3) shared notions of validity – that is, intersubjective, internally-defined criteria for weighing and validating knowledge in the domain of their expertise; and (4) a common policy enterprise – that is, a set of common practices associated with a set of problems to which their professional competence is directed, presumably out of the conviction that human welfare will be enhanced as a consequence*”.

In food safety, the relation between DG SANCO and the EC is of utmost importance and information between these two institutions is exchanged on a regular basis (ibid). Furthermore the main task of DG SANCO is to administratively manage the day-by-day consumer health operations in order to guarantee that the food and consumer goods that are sold in the EU market are indeed safe⁴³. Since the goal of DG SANCO is *“to make Europe a healthier, safer place where consumers can be confident that their interests are protected”*⁴⁴. Also due to the multi-level governance system of the EU, the regulatory regime unit the EC has to rely on a high number of expert groups to manage the many areas that are covered by the EU food safety policy.

Regarding stakeholders, such as lobby groups DG SANCO has set up three consultative groups:

- | |
|---|
| (1) European Consumer Consultative Group; |
| (2) Advisory Group on the Food Chain and Animal and Plant Health and |
| (3) EU Health Forum |

Table 12: DG SANCO consultative groups

These three consultative groups were created to make certain that the EC is consulting stakeholders such as consumers and lobby groups, in a transparent manner (ibid). Another function of these consultative groups is to provide the stakeholders, with relevant information in the policy-making process (ibid). DG SANCO also makes certain via stakeholder dialogues that these consultative groups have the opportunity to express their views and opinions on future planned food, feed and hygiene related policy areas (ibid). Even though the present EU food safety policy comprises of many regulations and directives that are used to regulate the entire food and feed supply chain. The core legislation of the EU food safety policy in order to guarantee the safety of meat and animal- derived food products in the EU is based on the following regulations:

- I. **General Food Law (GFL):** Regulation EC/178/2002, which stipulate the General Principles of Food Law that was adopted in January 2002 and lays down the general framework for food and feed businesses in order to guarantee that all foodstuffs, animal feed and feed ingredients are traceable through the entire food supply chain and
- II. **Hygiene Package (HP):** Regulations 852/853/854/2004, that was adopted in April 2004 and lays down the basic rules on food and feed hygiene that covers the food supply chain (E. U. Commission, 2007; Leibovitch, 2007; van der Meulen, 2013).

This means that the EU food safety policy uses GFL and HP regulations to guarantee the safety of meat and animal- derived food products. By means of general food safety rules and more specific food and feed hygiene rules, as well as the organisation of the official controls thereof. However, the present-day EU food safety policy legislation i.e. GFL and HP regulations emphasis, is on the so-called ABC or ‘Authorities, Business and Consumers’ that are legally distinctly addressed (Alemanno, 2006; van der Meulen, 2013). As a result, the food legislation concerning the safety of food products depends first of all on the food business operators themselves (van der Meulen, 2013). While competent national authorities or Member States have to enforce and control the former concerning EU food law stipulated obligations (Alemanno, 2006; van der Meulen, 2013). For consumers however, if they want to start a litigation they depend mostly on existing consumer protection laws and product liability legislation at national level (Alemanno, 2006; van der Meulen, 2013). As such, EU food law regulations such as GFL and HP do not offer consumers any innovative comprehensive rights or remedies in order to take legal action at EU level (Alemanno, 2006; van der Meulen, 2013).

⁴³ http://ec.europa.eu/about/ds_en.htm

⁴⁴ http://ec.europa.eu/dgs/health_food-safety/about_us/who_we_are_en.htm

3.1 GFL: Regulation 178/2002

This section describes the most important regulatory features of **General Food Law (GFL)** regulation that are used by the EU food safety policy, to guarantee the safety of meat and animal-derived food products in the EU. Before GFL was approved by the stakeholders that were involved in the regulatory process⁴⁵. It was subjected to a broad and continuing consultation process⁴⁶. Once GFL⁴⁷ was approved it was officially published in the Official Journal of the European Communities⁴⁸. While this regulation was adopted in 2002, some food law provisos became applicable in January 2007. For the reason that food and feed businesses required additional time to implement GFL (Articles 14 to 20) concerning enforcement measures on food and feed safety (EC, 2015a). By design, GFL⁴⁹ is a direct form of EU law, and thus binding across the EU (GFL, 2013; van der Meulen, 2013).

To realise the general goal and scope, GFL provided a number of modernisations concerning food safety in the EU, such as:

- 1) General principles and requirements of EU food law i.e. risk analysis, precautionary principle, and protection of consumer's interests and principles of transparency;
- 2) General framework of risk management, risk assessment and risk communication and the creation of an independent food safety authority (EFSA);
- 3) New general obligations for food business operators i.e. the general safety requirements, duty of compliance, traceability, the withdrawn of un-safe food products and product presentation and
- 4) General outline on food control within the EU which includes the import and export of foodstuffs (Commission, 2014; EC, 2015a; C. Regulation, 2002; van der Meulen, 2013).

One of the most important features of this regulation in order to guarantee the safety of meat and animal-derived food products in the EU is **risk analysis**. GFL (Article 6) stipulate that EU food law must be founded on science i.e. risk management, risk assessment and risk communication (GFL, 2013; Hansen, 2006). Risk analysis is the core foundation of food safety in the EU in order to make decisions concerning what are considered to be food risks and how to deal with such matters when the occur. Thus at EU level risk analysis is managed by the EC, because this institution is responsible for risk management⁵⁰. **Risk management** involves using a mixture of: socio, economic-political and scientific judgements to decide the extent to which society is prepared to accept food risks as well as the kind of actions that have to be adopted in order to decrease food safety risks (Hansen, 2006).

⁴⁵ COMM (2001). Food Quality in Europe an open debate about the future of agriculture, food production and food safety in the EU. Brussels, 25.7.2001 European Commission. And Byrne, D. (2003). Speech/03/494. Consumers in an Enlarged European Union. The Road Ahead. Consumer General Assembly 2003 Brussels, 28 October 2003. Brussels, European Commission.

⁴⁶ See appendix II for consultation process illustration.

⁴⁷ **REGULATION (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.

⁴⁸ See http://europa.eu.int/eur-lex/en/archive/2002/l_03120020201en.html

⁴⁹ GFL consists of: **chapter I** stipulates the general goal & scope (Article 1), definition of food or 'foodstuff' (Article 2) other definitions (Article 3); **chapter II** stipulates the general food law scope (Article 4), general principles of food law (Article 5 to 8), principles of transparency (Article 9 and 10), general obligations of food trade (Article 11 to 13) and general requirements of food law and procedures (Article 14 to 21); **chapter III** stipulates the establishment and organisational structure of EFSA (Article 22 to 49); **chapter IV** stipulates the Rapid Alert System, Emergencies and Crisis Management (Article 50 to 57); **chapter V** stipulates the procedures and final provisos (Article 58 to 65) (Alemanno, 2013; GFL, 2013; van der Meulen, 2013). According to GFL, the legal responsibility for guaranteeing the quality and safety at all stages of the food chain rest on the food business operator (Article 17 to 21); and the enforcement thereof GFL (Article 19) rest on the Member States supported by the FVO as a second line of defence (GFL, 2013; van der Meulen, 2013).

⁵⁰ **The EC is the guardian of the Treaties of the EU** and as such, this institution is responsible for guaranteeing that food legislation concerning the safety of meat and animal-derived food products in this case is correctly implemented and enforced. Albeit, in collaboration with the Member States. **Also the EC is due to its task as risk management the main authority at EU level to provide the market authorisation of food products in the EU.** See http://ec.europa.eu/food/fs/inspections/index_en.html

To perform effectively risk analysis, the EC is supported by EFSA who provides **risk assessment** alone and risk communication in cooperation with DG SANCO at EU level (GFL, 2013; Hansen, 2006). Moreover risk assessment is thought to be ‘the objective’ scientific part of the risk analysis process that comprises of “*hazard identification, dose-response assessment, exposure assessment, and risk characterisation*” (EFSA, 2015; Hansen, 2006). On the other hand, **risk communication** is the interactive exchange of information and opinions via the risk analysis process between: risk managers, the public, private industry, NGO’s, the academic community and other interested stakeholders (EFSA, 2015; Hansen, 2006; SANCO, 2014). The following figure below illustrates in a simplified manner the interrelated risk analysis process at EU level⁵¹:

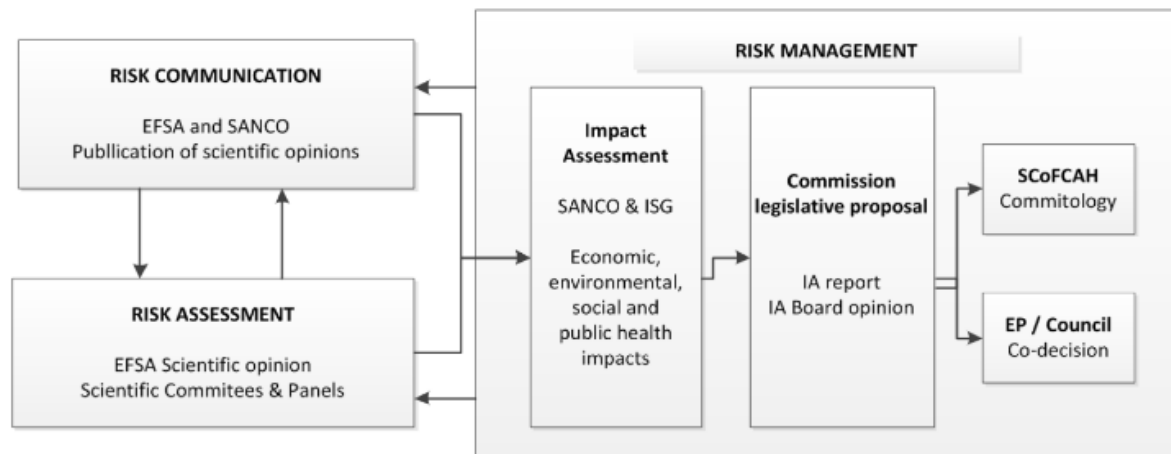


Figure 7: Risk analysis process

Another very important feature of this regulation is the creation of the regulatory regime unit the **European Food Safety Authority (EFSA)**. This agency was created to perform risk assessment and communication in order to guarantee the safety of meat and animal-derived food products in the EU. Moreover, EFSA is established as an independent operating food authority with a legal personality of its own (EC, 2015a, pp. 12-21). One of the obligatory tasks of EFSA is to maintain the European public informed concerning the safety of feed and food products (Alemanno, 2013; EC, 2015a; EFSA, 2015). Albeit this institution is branded as an authority it is in fact not one in the legal sense; because EFSA does not have the competences to make decisions that are binding to other parties (Alemanno, 2013, pp. 15-19; van der Meulen, 2013, pp. 88-89). The main responsibility of EFSA are providing scientific advice and technical support or risk assessment (Alemanno, 2013; van der Meulen, 2013). The scientific committees and panels of EFSA provide scientific advice and technical support to the decision makers at supranational level; so that the latter is able to make appropriate decisions concerning food and hygiene safety matters⁵². A majority of EFSA’s work begins in respond to specific requests from risk management (GFL, 2013).

EFSA also has the possibility to undertake scientific research by itself via self-tasking⁵³. It is important to note that EFSA is a so-called **network agency** that has to work closely with numerous stakeholders

⁵¹ **Impact assessment (IA)** concerning food safety is performed by DG SANCO and the **Indicators Sub-Group (ISG)** which task is to define and develop social indicators to monitor the progress of Member State countries via the so-called Open Method of Coordination for Social Protection and Inclusion. This group also performs analytical work and statistical research and it composes of national experts in this case that are concerned with the food safety (and thus also the safety of meat and animal-derived food products) See p. 8-9: http://ec.europa.eu/food/food/foodlaw/docs/st-17996_en.pdf <http://ec.europa.eu/social/main.jsp?catId=830&langId=en>

⁵² EFSA’s scientific advice supports the risk management via the process of adopting or revising EU legislation on food or feed safety. To decide whether to approve regulated substances, such as: pesticides and food additives, or, developing new regulatory frameworks and policies e.g. in the field of nutrition. However EFSA is not involved in these management processes, since its “independent advice gives them a solid scientific foundation” <http://www.efsa.europa.eu/en/aboutefsa/efsawhat.htm>

⁵³ **Self-tasking** procedure occurs when EFSA, during the course of its regular work, identifies particular issues which it believes requires further inquiry. See: <http://www.efsa.europa.eu/en/efsawho/mb.htm>

from the public and private sphere alike⁵⁴. However, ever since its inception in 2004 EFSA has been criticised by both civil society and other EU institutions such as EP, ECA and European Ombudsman for its lack of transparency (ibid). Likewise EFSA has been caught in major corruption and conflict of interest scandals in the last decade that involved leading staff members of the scientific panels and management board (see for more detail Observatory, 2013; Robinson et al., 2013). The figure below borrowed from PAN Europe (2012) illustrates EFSA's network structure and interrelated relationship with industry:

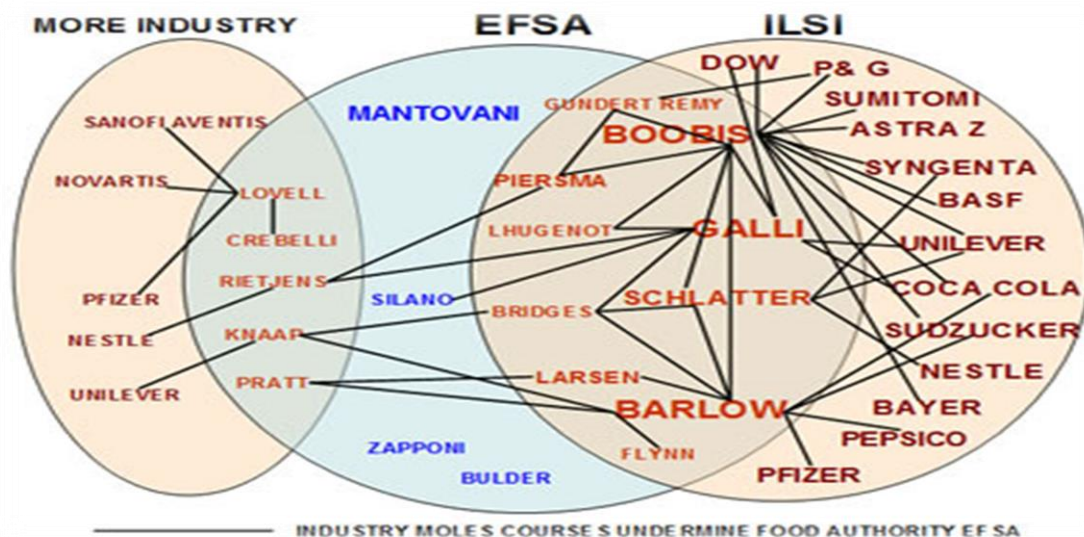


Figure 8: EFSA network structure

(Levi-Faur, 2011) indicates that agencies have replaced networks at the EU level, a process he refers to as 'agencification' where agencies make use of networking and become networked. By design EFSA is such a network agency that works in close co-operation with industry, NGO's and consumer organisations. For instance, EFSA possesses a mandate that includes direct interaction and communication with the European public (ibid). Hence EFSA is part of a network that consists of EU institutions, but also other stakeholders and individual groups (EFSA, 2014). An example of EFSA's network is the so-called advisory Forum, which consists of the national food authorities from all EU Member States plus Iceland and Norway. The advisory forum helps national authorities to share information and co-ordinate activities between themselves. Another example is EFSA's stakeholder's consultative platform where EU stakeholder organisations related to the food chain can discuss and exchange views. At present, this platform consists of twenty-four organisations, including 'NGOs representing consumers involved in public health, plant health, animal health and welfare and environmental protection; but also farmers and primary processors; food industry; trade and catering' (EFSA, 2014).

In addition there exist several networks of scientific organisations supporting EFSA. These consist of EU Member States food authorities or agencies, which are appointed at the national level and possess expertise in the relevant food policy field e.g. GMO, novel foods meat (EFSA, 2015). It is important to note that representatives of the EC and other food authorities, even those outside the EU framework can participate in EFSA networks as long as they can provide specific expertise on the policy field. These network meetings are chaired by EFSA and supported by one of the EFSA scientific panels and units (ibid).

⁵⁴ **Institutional Stakeholders** refers to those to whom this agency has a legal obligation to work with under EU rules: the EC, EP and Member States. This relationship is shown by the [EFSA Advisory Forum](http://www.efsa.europa.eu/en/networks/stakeholders.htm) and [Management Board](http://www.efsa.europa.eu/en/networks/stakeholders.htm), through formalised collaboration stipulated in GFL (Article 36) See: <http://www.efsa.europa.eu/en/networks/stakeholders.htm>

The goal of these network gatherings are to facilitate the scientific cooperation between those networks and the EFSA by: **(1)** coordinating activities, **(2)** Exchanging information, **(3)** developing and implementing joint projects, **(4)** exchanging expertise and best practises (ibid). According to article 36 of EFSA's founding regulation, it provides the legal basis for networking activities with and among relevant Member States organisations. In addition EFSA's Management Board updates the so-called Article 36 list on a regular basis, thus allowing competent organisations to support EFSA (EFSA, 2014). This means that the institutions that are stipulated by Article 36 are designated by EU Member States and include: universities, Institutions as well as authorities and agencies⁵⁵ (C. Regulation, 2002).

An additional important feature of this regulation in order to guarantee the safety of meat and animal-derived food products in the EU is the '**precautionary principle**'. This principle stipulates that in the event of scientific doubt, GFL (Article 7) is applied. This principle is used "*in specified circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection may be adopted, pending further scientific information for a more comprehensive risk assessment*" (EC, 2015a; C. Regulation, 2002; Simpson, 2005; van der Meulen, 2013). However, there is a problem with this principle namely that it was initially created to provide risk management (EC) with a means for decision-making on environmental risks and not concerning food safety or hygiene risks (Hathcock, 2001; Simpson, 2005). In addition, the precautionary principle was neither created nor defined to be applied as a food safety standard. Because when applying this principle, it will be very difficult if not impossible to prove that new food products or ingredients are safer since science cannot reduce risks to zero (Hathcock, 2001; Simpson, 2005).

Another important feature of this regulation in order to guarantee the safety of meat and animal-derived food products in the EU is the **Rapid Alert System (RAS)**. GLF (Article 50) established the Rapid Alert System and its goal is to provide risk management with information concerning direct or indirect risks to human health that are derived from food or feed products that are placed on the EU market (GFL, 2013; C. Regulation, 2002). This means in theory that every observed non-compliance, is 'at once notified' to risk management (EC) who has the power to withdrawal food from the internal market or recall it when deemed necessary (GFL, 2013; C. Regulation, 2002). Thus in the event that there are serious risks to human health, the EC is able to use suitable measures such as a moratorium of imports and the imposition of special conditions e.g. beef or pork meat without growth hormones (GFL, 2013; C. Regulation, 2002).

A different but nevertheless very important feature of this regulation in order to guarantee the safety of meat and animal-derived food products in the EU is the creation of the **Standing Committee on the Food Chain and Animal Health (SCFCAH)**. GFL (Article 58 and 59) established this important supporting body in order to support the EC with the development of food and hygiene legislation. Because of GFL⁵⁶, the comitology structure within the EU has changed. Prior to GFL there were several comitology Committees such as: the Standing Veterinary Committee, the Standing Committee on Foodstuffs, the Standing Committee on Animal Nutrition and part of the Standing Committee on Plant Health (plant protection products and pesticides residues). However, GFL changed this into a new single comitology namely the SCFCAH. Furthermore, GFL (Article 58 and 59) specified the procedures of these committees that comprises of representatives of the Member States that have an important task in decision-making on food, feed and hygiene safety matters⁵⁷. The SCFCAH is an expert group that is part of DG SANCO and comprises of representatives of both

⁵⁵ <http://www.consumersinternational.org/media/1402104/tacd-food-resolution-on-the-approach-to-food-and-nutrition-related-issues-in-the-ttip.pdf> and <http://farmfoundation.org/news/articlefiles/360-Djukes.pdf>

⁵⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF> and <http://www.eubusiness.com/topics/agri/standing-committees-food/>

⁵⁷ http://ec.europa.eu/food/fs/rc/index_en.html

the EU and Member States; that have an important task in decision-making concerning food, feed and hygiene safety legislation (GFL, 2013; C. Regulation, 2002). The task of SCFCAH is to support the EC in the development of food and feed safety legislation⁵⁸. Hence the SCFCAH is the comitology committee that is responsible for EU decisions and laws e.g. regulations or directives regarding the safety of meat and animal-derived food products⁵⁹.

A very important unit within the regulatory regime is the **European Commission (EC)**. The EC is responsible risk management and therefore in charge of the regulatory measures of enforcement in order to guarantee the safety of meat and animal-derived food products in the EU. Thus, in case that a Member State does not comply with the EU food safety and hygiene legislation i.e. GFL and HP regulations; than the EC is able to start the infringement procedure⁶⁰. By design this procedure is used to exert more direct pressure on non-complying Member States (Hartlapp, 2007, p. 663). Thus when a Member State does not follow commonly agreed rules, *“whether as a consequence of late or incorrect transposition [transfer], or incorrect application of a standard or failure to apply a standard, the EC starts enforcement by means of the infringement procedure”* (Hartlapp, 2007, p. 663). A good example occurred in 2010 when the EC started infringement procedure against Italy; because it did not transpose or transferred adequately the requirements of the Plant Protection Products Directive 2010/34/EU that are also governed by the EU food safety policy. Another example of an infringement procedure occurred in 2013; that due to the EP Agriculture and Rural Development Committee the EC had to start the infringement procedures against 9 non-compliant Member States concerning the sow stall ban set up by Council Directive 2008/120/EC which lays down the minimum standards for the protection of pigs and are also governed by the EU food safety policy⁶¹.

Furthermore, the regulatory regime unit the EC is supported by the **Food and Veterinary Office (FVO)**. The FVO is another important regulatory body that supports the EC, concerning regulatory measures of control at EU level; in order to guarantee the food, feed and hygiene safety⁶². Thus to support the EC, the FVO conducts on a regular basis audits and inspections at food business operators facilities, in order to guarantee that EU food legislation concerning food safety and hygiene is correctly implemented in addition to enforced⁶³. Like the SCFCAH comitology committee, the FVO is also part of DG SANCO and comprises of seven Units (ibid). it is important to comment that in practice, the EU relies on a so-called **hybrid governance approach** in order to guarantee the safety of meat and animal-derived food products and includes: **(1)** governance by information via EFSA, DG SANCO (FVO and SCFCAH); **(2)** self-regulation i.e. the core foundation of GFL and HP regulations food business operators are permitted to regulate themselves via so-called best practices codes in order to guarantee the food and hygiene safety; **(3)** C&C or Command and Control i.e. food business operators are by GFL and HP regulations obligated to include mandatory food labelling concerning the products that are placed on the EU market and the EC infringement procedure in case of Member State(s) non-compliance with EU food legislation and **(4)** cooperative decentralisation (i.e. agency autonomous structure or agencification) and proceduralisation (i.e. the scientific and administrative authorization process) by EFSA and other national food authorities such as: the Nederlandse Voedsel- en Warenautoriteit (NVWA), in the Netherlands or the Food Standards Agency (FSA) in the United Kingdom in order to guarantee the food and hygiene safety (see for more detail Hey, Jacob, & Volkery, 2007).

⁵⁸ See http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/regulatory_committees_en.htm

⁵⁹ http://ec.europa.eu/dgs/health_consumer/dgs_consultations/regulatory_committees_en.htm

⁶⁰ This procedure involves: **(1)** Letter of Formal Notice, **(2)** Reasoned Opinion, **(3)** Referral to the ECJ and **(4)** Judgment of the ECJ'. Moreover, in cases of continuing opposition to the ECJ judgment, a reiteration of the procedure with potential monetary sanctions as a consequence may be envisaged. **The legal bases are:** Article's 258 and 260-2-3 TFEU, but also Article's 4 and 17 TEU. see: http://ec.europa.eu/atwork/applying-eu-law/infringements-proceedings/index_en.htm and see examples infringement cases: http://ec.europa.eu/environment/legal/law/press_en.htm

⁶¹ See <http://lawyersforanimalprotection.eu/tag/infringement-procedures/>

⁶² See <http://lawyersforanimalprotection.eu/the-food-and-veterinary-office-fvo/>

⁶³ http://ec.europa.eu/food/fs/inspections/index_en.html

3.2 HP: Regulations 852/853/854/2004

This section describes the most important regulatory features of the **Hygiene Package (HP)** regulations that are used by the EU food safety policy, to guarantee the safety of meat and animal-derived food products in the EU. Before HP was approved by the stakeholders that were involved in the regulatory process⁶⁴. It was subjected to an extensive an ongoing consultation process⁶⁵. Once the HP was approved in April 2004, it was officially published in the Official Journal of the European Communities⁶⁶. Even though the HP was adopted in 2004, several food law hygiene provisos became applicable in January 2006. Because food and feed businesses as well as competent authorities required additional time to implement the new enforcement measures as well as obligations. By design HP regulations are the same as GFL, namely secondary EU law and thus binding across the EU (Leibovitch, 2007). To illustrate graphically how the HP regulations are structured within GFL framework, the following figure below is used⁶⁷:

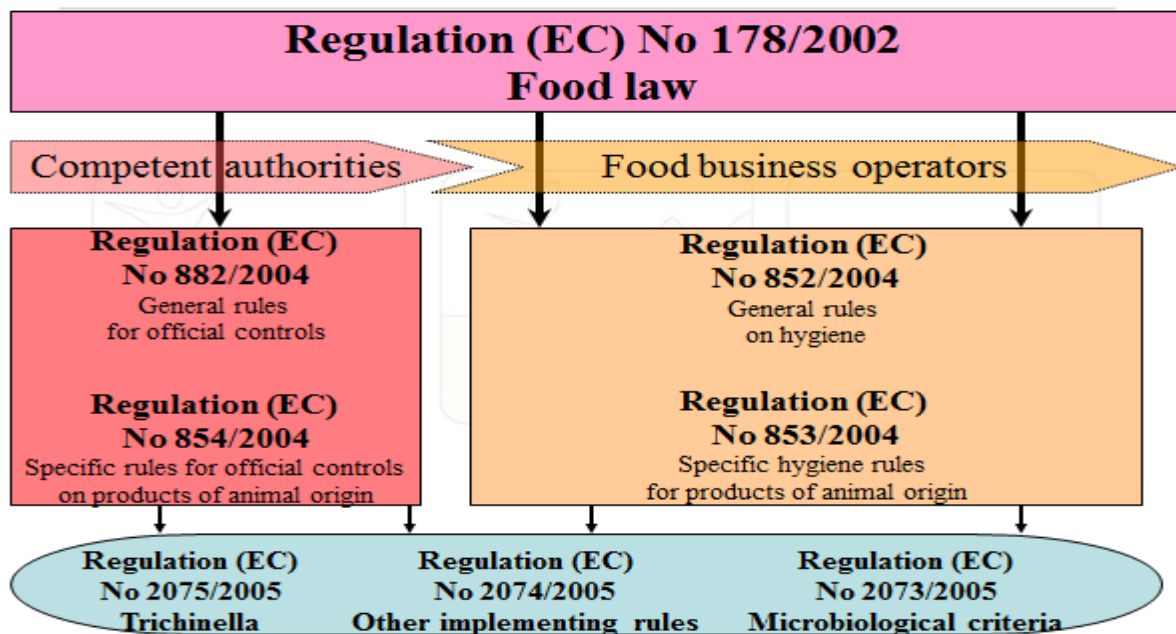


Figure 9: HP regulations function within the EU food safety policy

The goal of the HP is “to build ‘a single hygiene regime’ that covers the entire food and feed business operators sectors [thus also the meat i.e. poultry and cattle] sector; together with ‘effective instruments’ to guarantee the food safety and any potential food crises, through the food supply chain in the EU” (EC, 2015g; Lelieveld et al., 2014). Unlike GFL, the HP goal is not of mutual interest or double-edge formulated; since it is designed to exclusively guarantee the food and feed hygiene safety across the entire food supply chain. However, to realise the this goal HP stipulates that the food business operators will carry the principal responsibility for the safety of food and feed products in the EU (Lelieveld et al., 2014). This means that food business operators are first and foremost responsible in guaranteeing the safety of meat and animal-derived food products in the EU.

⁶⁴ (1) Regulation (EC) 852/2004 on the hygiene of foodstuffs, 29 April 2004; (2) Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin, 29 April 2004 and (3) Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, 29 April 2004.

⁶⁵ See appendix II for consultation process.

⁶⁶ In a nutshell, the HP focuses on the following seven food and feed hygiene principles: “(1) the primary responsibility for food safety borne by the food business operator; (2) food safety ensured throughout the food chain, starting with primary production; (3) general implementation of procedures based on the HACCP principles; (4) application of basic common hygiene requirements, possibly further specified for certain categories of food; (5) registration or approval for certain food establishments; (6) development of guides to good practice for hygiene or for the application of HACCP principles as a valuable instrument to aid food business operators at all levels of the food chain to comply with the new rules and (7) flexibility provided for food produced in remote areas (high mountains, remote island) and for traditional production and methods” (EC, 2015g; Leibovitch, 2007).

⁶⁷ See p.3: http://www.wetgiw.gov.pl/files/4623_1.5.Flexibility%20of%20the%20Hygiene%20Package.pdf.

On the other hand, the EU and Member State authorities are responsible to monitor or control the former for compliance with food and feed hygiene safety rules. The following figure below borrowed from (Žurek, 2011) provides an overview of EU Hygiene Package:

Action	Ref. Number	Description	Measures /Objectives	Who is regulated?	Legal basis
REGULATION (EC) European Parliament and Council	No 852/2004 of 29 April 2004 (especially Art. 3)	on the hygiene of foodstuffs	-human health -consumer interests -Internal market	-The manufacturers -Food business operators -All stages of production, processing and distribution of food and to exports, including sale to final consumer	TEC, Art.95 and 152(4)(b),Art. 251
REGULATION (EC) European Parliament and Council	No 853/2004 of 29 April 2004 (OJ 2004 L 139/55)	laying down specific hygiene rules for food of animal origin	-human health -consumer interests	-Food business operators.	TEC, Art. 152(4) (b) and Art. 251
REGULATION (EC) European Parliament and Council	No 854/2004 of 29 April 2004 (OJ 2004 L139/206)	laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption	-human health -animal welfare	Food business operators National control Authorities	TEC, Art. 152(4) (b) and Art. 251

Table 13: Complete Hygiene Package legislation

The first HP Regulation 852/2004 “lays down the general rules on hygiene of foodstuffs [products]” (EC, 2015g; E. Regulation, 2004a). The scope of this regulation (Article 1) stipulates the general hygiene rules for foodstuffs that have to be respected by food business operators throughout the entire food supply chain (EC, 2015g; E. Regulation, 2004a). An important feature of this regulation is that it applies an extensive definition concerning hygiene (Article 2 paragraph 1 point a) which stipulate that “*food hygiene, hereinafter called “hygiene”, means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use*” (E. Regulation, 2004a, p. 10). It is important to note that this regulation applies to food business operators with the exception of those in the primary production⁶⁸ that operate in the EU (EC, 2015g; E. Regulation, 2004a). Albeit there are exceptions in place, which are stipulated in (Article 1 paragraph 2) and are addressed to small quantities of primary products⁶⁹. Another important feature of this regulation is that it stipulates general obligations that food business have to comply to i.e. (Article 3) food business operators have to guarantee that at all stages of the production, processing and distribution of food that is under their supervision is in accordance with the hygiene requirements stipulated by this regulation (E. Regulation, 2004a, p. 13). An additional important feature of this regulation is that it also stipulates specific requirements for food business operators such as (Article 4), in addition to the hazard analysis and critical control points (Article 5) and official controls, registration and approval procedures (Article 6) (ibid). In other words, by design this regulation stipulates both general obligations and specific hygiene requirements the so-called ‘necessary technical requirements’ e.g. infrastructure and equipment,

⁶⁸ **Primary products are defined** in (Article 2), paragraph 1, point (b) read as follows: “*primary products means products of primary production including products of the soil, of stock farming, of hunting and fishing*”. In essence, it is the production, rearing or growing of primary products such as: *harvesting, milking and farmed animal production prior to slaughter. But also: hunting and fishing and the harvesting of wild products*”. The rules applicable to primary production are laid down in Annex I, Part a of Regulation (EC) No 852/2004. In addition, Annex I, Part A, point I (1) also covers the operations that are associated with primary production (E. Regulation, 2004a).

⁶⁹ **These are:** (a) private domestic use; (b) domestic preparation, handling, storage of food for private consumption; (c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer and (d) collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:139:0001:0054:EN:PDF>

water quality, pest control, personal hygiene; besides HACCP procedures in order to guarantee the safety of meat and animal derived food products in the EU⁷⁰.

(Dwinger, R. H et al., 2007) points out that ‘the foundation’ of food and feed hygiene safety in the EU; rest primarily on the necessary technical requirement in combination with the HACCP procedures which have to be implemented⁷¹. Because without these necessary technical requirements; HACCP procedures cannot to function accordingly (Dwinger, R. H et al., 2007, pp. 25). It is important to note that, this regulation allows food business operators to regulate themselves through so-called ‘guides to best practices’ for food and feed hygiene; in combination with obligatory HACCP (Dwinger, R. H et al., 2007). The main idea behind this major self-regulatory feature in this regulation; is to support at national and EU level food business operators to implement the HACCP procedures in a bespoke manner that is in accordance to their specific production, processing and distribution processes (Dwinger, R. H et al., 2007). One more important feature of this regulation is (Article 6) which stipulates that, food business operators are obligated to be registered with the competent authority i.e. Member State. For the reason that food business operators have to inform the competent authorities concerning the address of establishment and the particular food activity that is produced as well as placed on the EU market (Dwinger, R. H et al., 2007, pp. 25). Yet, the latest horse meat adulteration food safety crisis demonstrated that food business operators⁷², did not inform the competent authorities intentionally concerning their food activities or what they are placing on the EU market (Nicolaidis & Kearney).

The second HP regulation 853/2004 “lays down the specific hygiene rules for the hygiene of foodstuffs [products] of animal origin” (EC, 2015g; E. Regulation, 2004s). This regulation complements the former (852/2004) with reference to food hygiene specific obligations to business operators production and distribution of products of animal origin intended for human consumption (Dwinger, R. H et al., 2007). The scope of this regulation (Article 1) stipulate specific rules on hygiene of food of animal origin for food business operators; that applies to both un-processed and processed products of animal origin, at every stage of the food supply chain (EC, 2015g; E. Regulation, 2004s). An important feature, of this regulation is that the hygiene requirements have to be respected by food business operators that are handling food of animal origin at all stages of the food supply chain include: “*meat, live bivalve molluscs, fishery products, raw milk and dairy products, eggs and egg products, frogs’ legs and snails, collagen and gelatine at all stages of the food chain*” (Dwinger, R. H et al., 2007, pp. 25). In sum: this regulation stipulates: **(I)** general obligations on food business operators (Article 3); **(II)** the registration and approval of establishments by food business operators (Article 4); **(III)** health and identification marking of their products (Article 5) in addition to **(IV)** (Article’s 6 to 8) which have to be implemented by food business operators (Dwinger, R. H et al., 2007). (Dwinger, R. H et al., 2007) indicates that this regulation is a so-called ‘double-check’ with the purpose to further improve the food and feed safety within the EU. As a result food business operators that handle food of animal origin must implement the requirements of regulation 853/2004, along with the requirements laid down in regulation 852/2004 (Dwinger, R. H et al., 2007).

⁷⁰ HACCP comprises of seven principles: **(1)** identification of any hazards that must be prevented, eliminated or reduced to acceptable levels; **(2)** identification of the critical control points at the step(s) at which control is necessary to prevent or eliminate a hazard or to reduce it to acceptable levels; **(3)** establishment of critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; **(4)** establishment and implementation of effective monitoring procedures at critical control points; **(5)** establishment of corrective actions when monitoring indicates that a critical control point is not under control; **(6)** establishment of procedures, which shall be carried out regularly, to verify that [measures (1) to (5)] are working effectively; and **(7)** establishment of documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in [provisos (1) to (6)]” (Leibovitch, 2007, pp. 446-447).

⁷¹ See: Dwinger, R. H., Golden, T. E., Hatakka, M., Daelman, W., & Aland, A. (2007, June). THE “HYGIENE PACKAGE”—A NEW APPROACH TO FOOD SAFETY. In *Animal health, animal welfare and biosecurity. Proceedings of 13th International Congress in Animal Hygiene, Tartu, Estonia, 17-21 June, 2007. volume 1.* (pp. 24-25). Estonian University of Life Sciences, Jõgeva Plant Breeding Institute, Estonian Research Institute of Agriculture

⁷² <http://www.food.gov.uk/enforcement/monitoring/horse-meat/timeline-horsemeat> and <http://www.fda.gov.ph/attachments/article/155128/Draft%20IRR%20of%20Food%20Safety%20Act%2009%20May%202014.pdf>

Even though this regulation applies at all stages of the feed and food hygiene supply chain; there are nevertheless exceptions (Article 1 paragraph 3 and 5 point (a) (Dwinger, R. H et al., 2007). On the other hand, (Article 4) concerning the registration and approval of establishment compels by law without exceptions, food business operators that are handling food products of animal origin to register (Dwinger, R. H et al., 2007). This means that food business operators are only allowed to market food products of animal origin (cattle and poultry) if it is manufactured exclusively in their establishments or production facilities (Dwinger, R. H et al., 2007). To control food business operators this regulation stipulates specifically in (Article 4 paragraph 3 point a and b) that competent authorities have to perform on-site visits; in order to validate whether the establishment of the food business operator fulfils all of the requirements with regard to infrastructure equipment and hygiene in order to approve it (Dwinger, R. H et al., 2007).

The third HP regulation 854/2004 *“lays down the specific rules for the organisation of official controls on products of animal origin intended for human consumption”* (EC, 2015g; E. Regulation, 2004af). The scope of this regulation (Article 1) stipulates the specific rules for the organisation of official controls on products of animal origin sent for slaughter (Dwinger, R. H et al., 2007, pp. 26). An important feature of this regulation is (Article 1) which stipulate the specific rules concerning: fresh meat, fishery products, raw milk and dairy products in addition to the procedures concerning imports (Dwinger, R. H et al., 2007, pp. 26). According to this regulation official controls are defined by (Article 2 paragraph 1) and are performed by the competent authority e.g. Member State(s). Another important feature of this regulation is that it includes official controls vis-à-vis community establishments i.e. (Article 3) approval of establishment⁷³. In addition, this regulation stipulates that Member States are the appointed authorities to enforce and control food business operators through (Article 4), which stipulates the general principles for official controls in respect of all products of animal origin falling within the scope of this regulation. (Dwinger, R. H et al., 2007) points out that (Articles 5 to 8) of this regulation complement the former article by stipulating that Member States have to guarantee the control of: fresh meat, live bivalve molluscs, fishery products and raw milk and dairy products. In other words, this regulation stipulates clearly that the Member States are responsible for the official controls and enforcement of food and feed products in the EU. To realise this major task food business operators have to provide all the necessary support; so that the competent authorities are able to performed official controls successfully.

On the other hand, in case of non-compliance an additional important feature of this regulation stipulates (Article 9) that the competent authorities have to take action in order to guarantee that the food business operator solve the problem. According to (Dwinger, R. H et al., 2007 pp. 26) present-day meat inspection has to be founded on risks assessment so that possible risks of cross contamination in the slaughter hall can be prevented. Thus to prevent such risks, this regulation imposes stricter hygiene measures at farm level⁷⁴. All in all, even though the HP regulations harmonised and simplified the EU food and feed hygiene regulatory structure. There are nevertheless observable differences concerning the management of food safety hygiene official controls and enforcement in the EU (Lelieveld et al., 2014). For instance, some Member State countries apply different approaches to food hygiene safety of meat and animal-derived food products official controls and enforcement (Lelieveld et al., 2014). Where EU Member State countries such as: Germany and the Scandinavian ones (Finland, Denmark and Sweden) rely mostly on public control and enforcement procedures for this matter (Lelieveld et al., 2014). On the other hand, the United Kingdom (so far the only one in the EU) has placed almost the full responsibility of food and feed hygiene safety (and thus also the safety of meat and animal-derived food products), in the hands of food business operators (Lelieveld et al., 2014).

⁷³ See (E. Regulation, 2004af) p. 3 and http://www.fsai.ie/uploadedFiles/Consol_Reg854_2004.pdf

⁷⁴ See (E. Regulation, 2004af) p. 98-99 CHAPTER II: DECISIONS CONCERNING FOOD CHAIN INFORMATION and http://europa.eu/legislation_summaries/food_safety/veterinary_checks_and_food_hygiene/f84002_en.htm

Chapter 4: Assessment

This chapter answers the third sub-research question of this Master thesis and is divided into the following sections: 4.1, 4.2, 4.3, 4.4 and 4.5.

4.1 Legitimation Criterion

This section assessed the extent of legitimation of both GFL and HP regulations in addition to the regulatory regime, in order to determine whether they are effective or ineffective in guaranteeing the safety of meat and animal-derived food products in the EU.

4.1.1 Democratic & Constitutional

GFL and HP regulations were indeed established according to the **democratic and constitutional** foundations of the EU:

- (a) Title II Article 10 TEU *representative democracy*;
- (b) Title III Article 13 TEU *institutional framework*;
- (c) Chapter II Article 294 TFEU (ex-Article 251 TEC) the *ordinary legislative procedure* which is the principal law-making process at EU level in addition to
- (d) Articles 43, 114, 207 and 168 paragraph 4 point (b) TFEU (ex-Articles 37, 95, 133 and 152 paragraph 4 point (b) and 251 TEC) (Borchardt, 2010, p. 42; Žurek, 2011, pp. 116-117).

GFL and HP regulations were indeed **legitimated and supported** by the stakeholders involved in the regulatory process.

First, at EU level it was provided by the following legislative authorities that are responsible for food law development: **(1)** the **EC**⁷⁵ who started the adoption and consultation⁷⁶ process of GFL and HP regulations. This institution had to improve on several occasions these regulations due to opinions from the EP, Council of the European Union, Economic and Social Committee and Committee of the Regions; **(2)** the **EP**⁷⁷⁻⁷⁸ who as a co-legislator in the EU legislative process, approved GFL and HP regulations after several amendments. During this process the EP was supported by the Committee on the Environment, Public Health and Food Safety (ENVI) on food safety and hygiene matters and **(3)** the **Council of the European Union**⁷⁹ which at the time included all of the national ministers of health and agriculture of each EU Member State. This institution also approved these regulations after several discussions and amendments⁸⁰. Despite the fact GFL and HP regulations were democratic and constitutional founded, as well as legitimated and supported; there are nevertheless observable democratic deficits at EU level (Follesdal & Hix, 2006, pp. 535-547). For example, while the reforms made in the Treaties certainly enlarged the powers of the EP; this institution is still weak compared to the Council of the European Union or the 'non-elected ruled' EC (see for more detail Bovens et al., 2010; Follesdal & Hix, 2006).

Second, at national level the legitimacy and support was provided by the EU **Member States governments** (Holm & Halkier, 2009; Paul & Garnet, 2008). The impetus for their support was the BSE⁸¹ crisis in the 1990's which exposed the Member States inability to guarantee the food safety in the EU (Paul & Garnet, 2008). This resulted that the Member States delegated this large and complex regulatory task to the EC (Alemanno, 2006; GFL, 2013; Grunert, 2005). However, during the development phase of GFL the draft version of this regulation provided EFSA with regulatory powers

⁷⁵ See Article 17 TEU

⁷⁶ See **appendix II for consultation process**

⁷⁷ The EP played an vital part in resolving this food safety crisis; via a temporary Enquiry Committee, chaired by Manuel Medina Ortega that examined the actions of EU institutions involved in food safety and Member state food agencies that were involved in this crisis (van der Meulen, 2013, p. 76).

⁷⁸ See (Article 14 TEU)

⁷⁹ See (Article 16 TEU)

⁸⁰ See <http://eur-lex.europa.eu/legal-content/EN/HIS/?uri=CELEX:32002R0178>

⁸¹ See for more detail: Nathanson, N; Wilesmith, J; Griot, C (June 1997). "Bovine spongiform encephalopathy (BSE): causes and consequences of a common source epidemic"

but the Member States opposed this; and therefore it was omitted in the final version (Paul & Garnet, 2008).

Third, via the **Economic and Social Committee (ESC)**, a forum to discuss matters and express opinions concerning the single market that represents: employers, workers and various interests group⁸². During the development of GFL and HP regulations this forum included a variety of stakeholders such as: EU workers through EFFAT trade union and the primary sector (farmers and cooperatives) through Copa-Cogeca union (Nestle, 2013; Rademakers, 2000). Also during these consultations⁸³ the employers of the agro-food industry were represented by numerous large and powerful meat associations (cattle and poultry) from the Netherlands, Germany, France and Britain such as: Centrale Organisatie voor de vleessector, Zentralverband der Deutschen Geflügelwirtschaft e.V., Verband der Fleischwirtschaft e.V., Fédération des Industries Avicoles, Le syndicat des entreprises françaises des viandes, Vereniging van de Nederlandse Pluimveeverwerkende Industrie, British Poultry Council, British Meat Processors Association (akkanto, 2006; Deckwirth, 2005; Kerry & Kerry, 2011). But also by European meat associations such as: AVEC, UECEBV, CLITRAVI as well as UEAPME, EuroCommerce and BusinessEurope (Deckwirth, 2005; Nestle, 2013).

These meat associations welcomed GFL and HP regulations; because of their advantage of regulatory simplification and harmonisation which reduced considerable the costs of conducting business across the EU (Nestle, 2013; Rademakers, 2000). At the same time, these associations were also critical; concerning the new mandatory labelling requirement of GFL (Article 17). In their view the existing regulatory structure i.e. mandatory product of origin label was sufficient and therefore should not be changed⁸⁴. Moreover, these associations argued that additional labelling will increase the costs, especially for SME food business operators in Germany, Britain, France and Holland, the largest producers of animal-derived food products in the EU (ibid) Thus they recommended the EC to stipulate a voluntary labelling scheme instead of mandatory one; which did not come (akkanto, 2006). On the other hand, the EU consumers were represented by BEUC the largest umbrella consumer organisation in the EU.

While the BEUC⁸⁵, also positively welcomed GFL and HP regulations as a necessary regulatory overhaul in order to **(a)** improve the food safety in general and **(b)** recuperate the loss confidence of the EU consumers in public regulatory institutions⁸⁶. BEUC nevertheless criticised to great extent the emphasis of placing the food safety of the EU in the hands of food business operators themselves as first line of defence GFL (Article 17, 18, 19 and 20); instead of the competent (national or supranational) authorities⁸⁷. Another important critique by BEUC was that GFL did not include 'nutrition-related' matters; they argued that nutrition is not merely a matter of health advancement, but intrinsically related to food safety as well; therefore it should be included in food law (Quittkat & Finke, 2008; Spadaro, 2003). Moreover, BEUC recommend changing the name of EFSA to EFA (European Food Agency) because this institution is not an 'official authority' with binding legal powers. Thus using EFSA as name they it implies that it is a full fledged authority and this is not the case (Quittkat & Finke, 2008; Spadaro, 2003).

⁸² <http://www.eesc.europa.eu/?i=portal.en.about-the-committee>

and

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52001AE0404>

⁸³ There are other large and powerful food association from several food sectors that provided support and critique towards GFL and HP such as: FoodDrinkEurope, ESA, EDA, FEFAC and europabio, just to name a few (Van der Muelen & Freriks, 2006).

⁸⁴ It is noteworthy to note that these meat associations where extensively lobbying for more self-regulatory measures to be added into the GFL provisos; because this will reduce the government controls hence lowering the economic costs on the meat and food processing industry (akkanto, 2006; Mahoney, 2007).

⁸⁵ The BEUC is the largest consumer organisation in the EU, that represents and defends at EU level the interests of all Europe's consumers, concerning nancial Services, Food, Digital Rights, Consumer Rights, Sustainability, Safety, Health and Energy. <http://www.beuc.org/about-beuc/who-we-are>

⁸⁶ Burgess, A. (2001). 'Flattering Consumption: Creating a Europe of the consumer' Journal of Consumer Culture1: 93-117

⁸⁷ BEUC Comments on John Bowis' draft report on the Commission White Paper on Food Safety (COM (1999) 719 - C5-0136/2000 - 2000/2082(COS)).

Fourth, another important consultative body is the **Committee of Regions (CoR)**⁸⁸. This Committee represented only during the development of GFL regulation the interests of local and regional food sector that includes: farms, food processors, traders, warehouses, retail outlets and restaurants in the EU, which are often SME undertakings; that are imperative to the EU food market. While during the development of HP regulations this consultative body was excluded to participate. Moreover, this Committee provided important opinions concerning GFL. For example, an opinion of this Committee is that food safety is a growing local and regional matter; therefore it is imperative that this Committee is represented on the Management Board of EFSA and, so that it can request scientific opinions from it⁸⁹. However, in the final version of GFL this opinion was not realised (Vos, 2000c). An additional opinion of this Committee was that EFSA has to carry out its operations in full openness and transparency; and the decisions made by the Management Board as well as its documents must be accessible to all citizens. This opinion was partially realised, since GFL (Article 38 paragraph 2) permits the management board of EFSA to have leeway concerning disclosing of information.

To illustrate the approval process of the GFL and HP regulations in chronological order the figure below borrowed from Eur-Lex (2015)⁹⁰ is used:

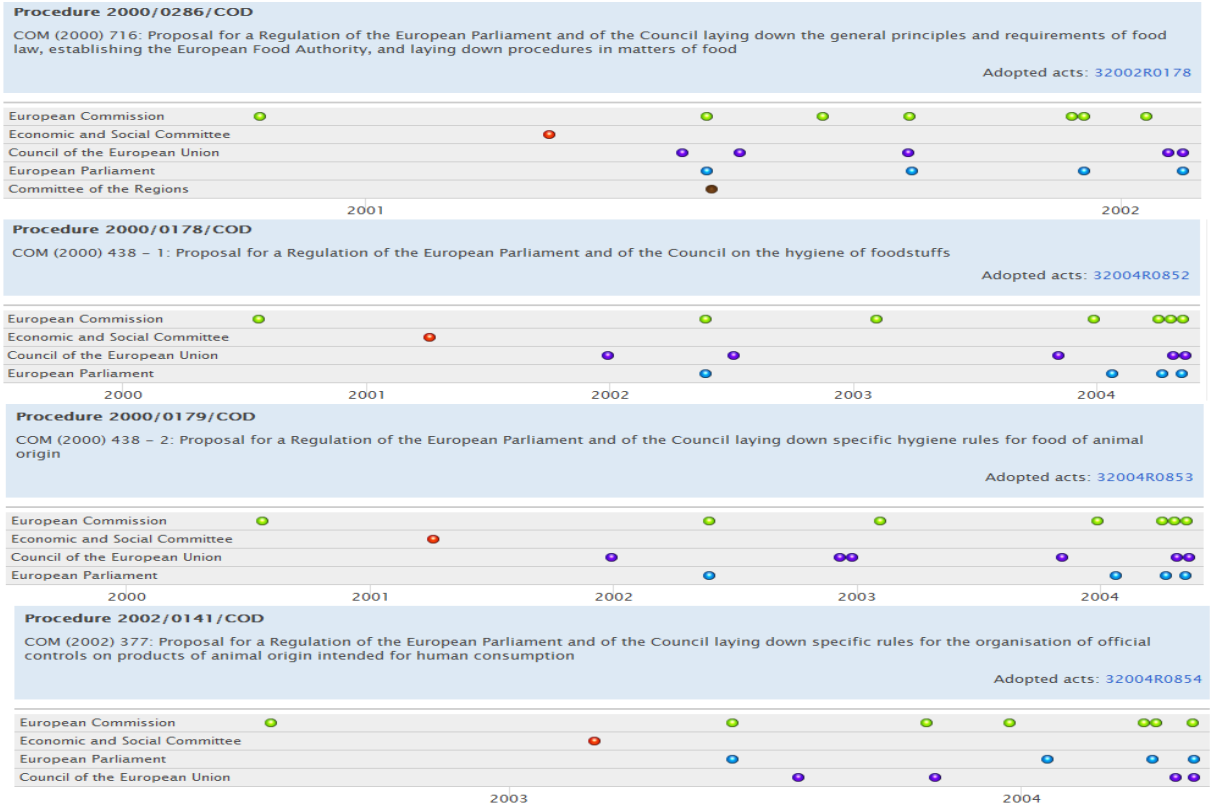


Figure 10: Approval procedure of GFL and HP regulations

The approval procedure shows that GFL and HP regulations passed through an extensive process of adoption, position, discussions, and amendments, opinions before they were eventually approved and implemented into the corpus of EU food legislation. Also this illustration shows that the ESC was only consulted ones during this process at the beginning; while CoR was only consulted during the GFL approval process, but not during the HP regulations approval process.

⁸⁸ This committee is an assembly for local and regional representatives that offer sub-national authorities such as: regions, counties, provinces, municipalities and cities a direct voice within the institutional framework of the EU. See <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52001AR0064>

⁸⁹ See for more comments of the Committee of Regions: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52001AR0064>

⁹⁰ This process involved several EU institutions. The coloured dots represent: adoption, position, discussions, amendments, opinions and final approval at the very end.

GFL and HP regulations were created according to the **rule of law**; since they are secondary EU laws derived from the primary laws of the EU i.e. its Treaties (Borchardt, 2010; Craig & De Búrca, 2011; EC, 2015a). In addition, GFL and HP regulations are to a great extent **proportional** and therefore effective. First, the objective of GFL and HP regulations are legitimate; since these regulations were supported by official authorities and additional stakeholders from private industry and civil society. Second, GFL and HP regulations were necessary due to the massive BSE crisis and the outdated food safety and hygiene regulatory structure which needed to be replaced. Third, while GFL and HP regulations took into account all of the different competing interest from the stakeholders involved in the regulatory. GFL (Article 17⁹¹ to 20) and HP regulations: 852/2004 (Article's 3 to 6) and 853/2004 (Article's 3 to 6) nevertheless reveal that there was more emphasises in developing regulations that are 'industry friendly' rather than consumer 'friendly'. Because these regulations are designed to be flexible and put the food and hygiene safety primarily in the hands of the food business operators instead of competent authorities⁹².

GFL and HP regulations are to some extent **consistently interpreted** across the EU and thus effective. However, the concept 'unfit for human consumption'⁹³ GFL (Article 14⁹⁴ paragraph 2) is ambiguous; and therefore not accordingly interpreted in the Netherlands (van der Meulen, 2009, pp. 160-162). For instance, because the Netherlands⁹⁵ has not interpreted the concept of 'unfit for human consumption' accordingly; the possibility of un-necessary food safety risks arises (van der Meulen, 2009). This raises the question whether the concept of unfit for human consumption is uniformly applied across the remaining EU Member States⁹⁶. Also, HP regulations 852/2004 (Article 6) and 853/2004 (Article 4) have not been consistently interpreted in the Netherlands because at EU level *"the system for the registration of the food business operators [that includes food traders, warehouses and storage facilities] is not clearly defined and not uniformly applied"*⁹⁷. This shows that the Netherlands interpreted the term 'supply' exclusively as the physical delivery of food and feed products. It is important to note that, the SCFCAH comitology committee that is one of the important bodies responsible for food safety legislation explicitly indicated that the term 'supply' *"refers more to the transfer of ownership of the food and feed or food producing animal. Additionally, brokers must be considered as a form of supplier for the purposes of some safety obligations [as traceability] whether or not they take physical possession of the goods"*⁹⁸. The misinterpretation of HP regulations 852/2004 (Article 6) and 853/2004 (Article 4) by the NVWA, shows that one of the Member States does not consistently applied this regulation. This suggests that the implementation of the HP regulations by the Netherlands was to an extent incorrectly performed.

⁹¹ **GFL Article 17 paragraph 1:** *" stipulate Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met; 2 Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution (...)"* (see for more detail Articles 18, 19 and 20 C. Regulation, 2002, pp. 11-12).

⁹² The studies of (Coen, 2007, pp. 335-343; Mahoney, 2007, pp. 48-53) indicate that extensive lobbying towards the EC and EP has influence certain policy areas in the benefit of lobbyist and their clients in Brussel. Their work revealed that Brussel has a concentration of approximate 15.000 lobbying firms; which raises questions concerning the high possibility of influence by industry on EU policy decision-making (Coen, 2007; Mahoney, 2007).

⁹³ **GFL (article 14 paragraph 2 point (b) and paragraph 5)** definition concerning unfit for human consumption *"in determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay"* (GFL, 2013, p. 10)

⁹⁴ EU Food regulators make use of: GFL (Article 14) to ascertain whether food is unfit for human consumption.

⁹⁵ **The Nederlandse Voedsel- en Warenautoriteit** is the food regulatory authority of the Netherlands. According to NVWA definition *"food is unfit for human consumption in case of a deviation unacceptable for consumers such as the presence of a chemical or micro-organism, deviations in taste or smell or mistakes in labelling with possible health consequences"*. See: <http://www.nvwa.nl/onderwerpen/levensmiddelen/dossier/vlees-en-vleesproducten>

⁹⁶ If this was a directive or decision instead of a regulation; than each Member State could formulate slightly different laws, but this can result in divergent administrations (Leibovitch, 2008).

⁹⁷ DG (SANCO) 2009-8222, Final report of a mission carried out in the Netherlands from 09 to 20 March 2009 in order to assess the official controls over infant formulae, follow-on formula and baby foods, including the supply chain.

⁹⁸ See Lex Alimentaria Food Law Office report p.16 *regulation.upf.edu/dublin-10-papers/2F4.pdf*

4.1.2 Goal Oriented & Functional

The goal of GFL is extensively formulated and at the same time well-demarcated in order to guarantee the general food safety in the EU. For example, (Article 1 paragraph 1) stipulate that *“this regulation [GFL] provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It [GFL] establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety”* (C. Regulation, 2002, pp. 6-7).

Similarly **the scope** of this regulation is also extensively and well-demarcated, as stipulated in (Article 1 paragraph 2 and 3): *“for the purpose of paragraph 1, this regulation [GFL] lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level. It [GFL] establishes the European Food Safety Authority. It [GFL] lays down procedures for matters with a direct or indirect impact on food and feed safety. This Regulation [GFL] shall apply to all stages of production, processing and distribution of food and feed. It [GFL] shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.”* (C. Regulation, 2002, pp. 6-7). In other words, the goal and scope of GFL are designed to be general in order to provide a framework from farm to fork that is able to guarantee a coherent approach in the development of food law, by stipulating: *“general definitions, principles and obligations covering all stages of food/feed production and distribution”* (GFL, 2013; van der Meulen, 2013). An example of this is GFL (Article 2), which stipulates a definition of ‘food’ (or ‘foodstuff’) that covers a wide range of food products in the EU⁹⁹.

Likewise, GFL (Article 3) stipulates ‘other definitions’ such as **(a)** *“food law [which] means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it [GFL] covers any stage of production, processing and distribution”* in addition to **(b)** more precise definitions concerning: food business, food business operators, feed (or feeding stuff), feed business, feed business operators, retail, placing on the market, risks, risk analysis, risk assessment, risk management, risk communication, hazard, traceability, stages of production, processing and distribution, primary production and final consumers (C. Regulation, 2002, pp. 7-8). As a result, the goal in addition to the scope of GFL is to a great extent detailed and concise formulated; and therefore effective to guarantee the safety of meat and animal-derived food products in the EU.

Furthermore, GFL is to great extent **targeted to solve a specific problem**; namely to improve the food safety of the EU, by taking into account a wide range of food products. Through: **(I)** common principles and requirements of EU food law i.e. risk analysis, precautionary principle, and protection of consumer’s interests and principles of transparency and **(II)** general obligations for food business operators i.e. the general safety requirements, duty of compliance, traceability, the withdrawn of unsafe food products and product presentation (C. Regulation, 2002).

On the other hand, there are observable deficits concerning the stipulated goal of GFL. For instance, they are of mutual interest or ‘double-edge’¹⁰⁰ and not time-related formulated that is, they do not specify when the results required to be realised. In addition GFL does not stipulate specifically how or when it requires to be assessed e.g. periodically or every 3 or 5 years (C. Regulation, 2002).

⁹⁹ *“(…) any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. ‘Food’ includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC”* (C. Regulation, 2002, p. 7).

¹⁰⁰ **Double-edge formulated** goals and scope it means that GFL on the one hand protects consumers interest and on the other hand the internal market at the same time; albeit the focus is more on internal market functioning (industry) than consumers.

Moreover, because GFL is by design a horizontally centred regulation, its goal and scope are therefore formulated in a general manner; in order to address a wide-range of food products that have ‘common characteristics’ (van der Meulen, 2013, pp. 77-80). In other words, food products that have common characteristics such as cattle (cow and horse meat products) similar to poultry (chicken and duck products) are grouped together. This for instance, can result that by accident (or intentionally) animal derived food products are mixed-up in the food supply chain by the food business operators. A good example, are the recent fraudulent food practices that were investigated by the Committee on the Environment, Public Health and Food Safety; which revealed that food business operators have in some occasions systematically mixed-up animal derived food products for profit schemes across the EU¹⁰¹.

Additional deficits concerning risk analysis which is ‘the foundation’ to guarantee the food safety in the EU as GFL (Article 6 paragraph 1) stipulates “*in order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure*” (C. Regulation, 2002, p. 6). Albeit risk analysis GFL (Article 6), stipulates the division between risk management i.e. policy matters and risk assessment and communication i.e. science matters. Yet, there is a problem because “*(...) risk assessment and management are so complex, uncertain, and controversial that they cannot be conducted without reference to normative social values*” (Vos, 2000a, p. 230). Likewise, it is important to highlight that risk management and risk assessment are frequently entangled, making a separation difficult if not impossible (Hansen, 2006; Houghton et al., 2008). Because under the decision-making process concerning GFL (Article 6) risk analysis; science is regarded to be ‘rational, value-neutral, objective and independent’ but in reality this is often not the case. A good example of risk analysis lack of objective and independent science can be found in the EU chemical policy development, where problems concerning GFL (Article 6) were revealed; due to “external hands that were influencing the risk analysis process” (Hansen, 2006, p. 13). In line with (Hansen, 2006, p. 14) which points out that “*(...) decision-making concerning risks in the face of ambiguity are difficult, value-laden and extremely controversial*”.

This highlights that the problem here is that GFL (Article 6) does not stipulate precisely what risk management actions prior to risk assessment have to be, such as: deciding what kind of protection goals are critical and hence needed, since this defines how effects and exposures are eventually assessed at EU level (Hansen, 2006). Therefore in absence of precise formulated risk analysis proviso¹⁰² it is very difficult if not impossible to realised objective and independent decisions. For example, at present the risk management decisions made by the EC that include a mixture of socio-economic and political judgements influences directly or indirectly the scientific risk assessment procedure performed by EFSA; thus making the theoretical division between risk management and assessment unclear in reality (Hansen, 2006, p. 14).

The goal of HP is equally extensively formulated and at the same time well-demarcated in order to guarantee the food and feed hygiene safety in the EU. For example, the goal of HP is “*(...) to build ‘a single hygiene regime’ that covers the entire food and feed business operators sectors [including the meat sector i.e. poultry and cattle]; together with ‘effective instruments’ to guarantee the food safety and any potential food crises, through the food supply chain in the EU*” (EC, 2015g; Lelieveld et al., 2014). Similarly, **the individual scope(s)** are also well-demarcated. While regulation 852/2004 (Article 1) does stipulate general rules for food business operators on the hygiene of foodstuffs¹⁰³ it does

¹⁰¹ See full report: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARG+PE-519.759+02+DOC+PDF+V0//EN&language=EN>

¹⁰² A legal proviso is a condition, stipulation, limitation, provision or requirement inserted in a legal document. See Black's Law Dictionary Free Online Legal Dictionary 2nd Ed

¹⁰³ “*(...) to ensure the hygiene of foodstuffs at all stages of the production process, from primary production up to and including sale to the final consumer. It does not cover issues relating to nutrition or to the composition or quality of foodstuffs. This Regulation [852/2004]*”

stipulate precisely to whom it applies and whose responsibility it is to guarantee the food hygiene safety in the EU (E. Regulation, 2004a). On the other hand, regulations 853/2004 (Article 1) stipulate specific rules on the hygiene of food of animal origin for food business operators that apply to both unprocessed and processed products of animal origin¹⁰⁴. Likewise, regulation 854/2004 (Article 1 paragraph 1) stipulate specific rules concerning the official controls on products of animal origin that are intended for human consumption¹⁰⁵. As a result, the goal in addition to the individual scopes of HP regulations 853/854/2004 are to a great extent detailed and concise formulated; and therefore effective to guarantee the food hygiene safety in the EU.

The HP stipulated goal and individual scopes are to a great extent **targeted to solve a specific problem**; namely, the food and feed hygiene safety via specific rules to address: **(a)** food and feed hygiene safety and **(b)** the organisation of official controls for products of animal origin intended for human consumption. Yet, there are problems observed concerning the stipulated goal and scope(s) of HP regulations; because like GFL, HP was designed to be ‘double-edge’¹⁰⁶. This means that, the HP goal and (scope(s) are developed to protect the food and feed hygiene of animal derived food products intended for human consumption and at the same time the interest of the meat industry. Also, the stipulate goal and individual scopes of HP regulations do not have any time-related indicators to specify when the results required to be realised. There are additional deficits concerning HP regulation 852/2004 (Article 6) the ‘official controls, registration and approval’¹⁰⁷ and regulation 853/2004 (Article 4) the ‘registration and approval of establishments’¹⁰⁸

For instance, both (Article 6 and 4) of regulations 852/853/2004 stipulates that food business operators are obligated to registered themselves, so that the competent authorities know: **(1)** where they are established, **(2)** what they are producing as well **(3)** placing on the EU market (Biglia & Pisanello, 2013). However, several food safety crisis’s from 2007 to 2009 that included food and feed hygiene matters; exposed that food business operators and in particular food traders, warehouses and other food facilities regularly did not notify the competent authorities at all (Pisanello, 2010, pp. 6-15). Also according to the ENVI committee on fraud in the food chain report there are more problems concerning HP regulations¹⁰⁹. One of these problems is that, the HP regulations do not stipulate a common definition of ‘food fraud’ and this is of utmost important for the food hygiene safety in general; but also for the safety of meat and animal derived food products in the EU (ibid).

applies to food businesses but not to the primary production of food for private domestic use or the domestic preparation of foodstuffs for private consumption” see

http://europa.eu/legislation_summaries/food_safety/veterinary_checks_and_food_hygiene/f84001_en.htm

¹⁰⁴ “(...) Regulation [853/2004] applies to unprocessed and processed products of animal origin, but not to foods consisting of both products of plant origin and processed products of animal origin, unless expressly indicated to the contrary. Furthermore, this Regulation does not apply to the retail trade or to primary production for private consumption, for which the provisos of the above-mentioned Regulation on the hygiene of foodstuffs are sufficient”.

See http://europa.eu/legislation_summaries/food_safety/veterinary_checks_and_food_hygiene/f84002_en.htm

¹⁰⁵ The complete scope of regulation 854/2004 includes the following paragraphs: “2. It shall apply only in respect of activities and persons to which Regulation (EC) No 853/2004 applies; 3. The performance of official controls pursuant to this Regulation shall be without prejudice to food business operators’ primary legal responsibility for ensuring food safety, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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 and any civil or criminal liability arising from the breach of their obligations” (E. Regulation, 2004af).

¹⁰⁶ **Double-edge formulated or mutual interest** goals and scope it means that HP on the one hand protects consumers interest and on the other hand the internal market at the same time; albeit the focus is more on internal market functioning (industry) than consumers.

¹⁰⁷ **Paragraph 1** “Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law; 2 in particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment and 3 . However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required”(see for more detail E. Regulation, 2004a, pp. 17-18).

¹⁰⁸ **Paragraph 1** “ food business operators shall place products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments”(see for more detail E. Regulation, 2004s, pp. 14-16)

¹⁰⁹ See: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A7-2013-0434+0+DOC+XML+V0//EN> and
<http://www.euractiv.com/video/meps-want-tougher-sanctions-over-food-fraud-after-horse-meat-scandal-307729> and
<http://www.globalmeatnews.com/Industry-Markets/Report-calls-for-more-policing-in-EU-food-controls>

It is important to comment that food fraud is the intentional act and adulteration that is committed for monetary profit (ibid). To solve this problem GFL could for example utilise and modify where needed the definition of food fraud that is used by for instance the FSA¹¹⁰. Also the same report points out additional problems concerning the enforcement and controls measures used by HP regulations; because they are administrative and veterinary based¹¹¹.

Another problem, are the (monetary) penalties for fraudulent schemes across the EU which varies from Member State to Member State: because they individually decide what the appropriate penalties are. For example, in Ireland, alone the recent horsemeat scandal included four companies, from which only one company could be prosecuted by the Irish authorities. However, the maximum monetary penalty, which this company could receive if it is prosecuted, is 30.000 euros¹¹². And this is not sufficient to deter fraudulent schemes; because one container alone of horsemeat that is labelled and marketed in the EU as beef can at present make a profit of 65.000 euros (ibid).

GFL and HP were **reviewed and assessed for effectiveness** but only once in 2010, by the so-called 'fitness check' or REFIT¹¹³. While EFSA is by law obligated to be assessed every six year for effectiveness as GFL (Article 61) stipulates *"before 1 January 2005 and every six years thereafter, the Authority [EFSA], in collaboration with the Commission, shall commission an independent external evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission (...)"* (C. Regulation, 2002, pp. 30-31). On the other hand, GFL and HP regulations do not have any specific provisos concerning food and hygiene assessment. Also the REFIT was first and foremost focused in reducing administrative burdens instead of improving food and hygiene safety (Observatory, 2013; Robinson et al., 2013). For instance, REFIT is part of the EU Smart-Regulation programme and as such its *"(...)evaluation focuses on potential simplification and regulatory cost reductions, taking into account the administrative burden, but also the impact on cost competitiveness, capacity for innovation and international competitiveness, while ensuring consumer choice and public health and safety"*¹¹⁴. In other words, REFIT is by design 'double-edge' focused i.e. taking into account consumer health safety and industry interest at the same time; albeit with more emphasis on the former than the later.

This means that REFIT was firstly used to reduce the administrative burden for the food industry and competent authorities by simplifying food legislation even further; and secondly concerned with consumer welfare. Despite this assessment for effectiveness, GFL and HP were not improved in order to guarantee the food and hygiene safety in the EU, as several large crises afterwards across the EU revealed such as: *E. coli*, Salmonella in the Netherlands, Germany, France and Sweden in 2011 and 2012 and the horse meat adulterations in 2013 have exposed (ibid)

¹¹⁰ **The British Food Standards Agency (FSA) applies an extensive definition of what food fraud is, namely:** *"food fraud is committed when food is deliberately placed on the market, for financial gain, with the intention of deceiving the consumer. Although there are many kinds of food fraud the two main types are: (1) the sale of food which is unfit and potentially harmful, such as: recycling of animal by-products back into the food chain; packing and selling of beef and poultry with an unknown origin and knowingly selling goods which are past their 'use by' date; (2) the deliberate misdescription of food, such as: products substituted with a cheaper alternative, for example, farmed salmon sold as wild, and Basmati rice adulterated with cheaper varieties and making false statements about the source of ingredients, i.e. their geographic, plant or animal origin and (3) food fraud can also include the sale of meat from animals that have been stolen and/or illegally slaughtered, as well as wild game animals like deer that may have been poached"*. See <https://www.food.gov.uk/enforcement/foodfraud>

¹¹¹ The report suggest to changed this to a policing approach that is ex-ante with an emphasis on preventing food fraud by placing more tasks and responsibility in the hands of the competent authorities i.e. Member States (Pisanello, 2010). See also MB 4 15.12.2005 - 4 EFSA Evaluation European Food Safety Authority Management Board 15 December 2005 State of play – EFSA Evaluation and <http://www.reading.ac.uk/foodlaw/news/eu-05104.htm>

¹¹² FOOD CHAIN EVALUATION CONSORTIUM(FCEC), Study on fees or charges collected by the Member States to cover the costs occasioned by official controls, Framework Contract for evaluation and evaluation related services - Lot 3: Food Chain (awarded through tender no 2004/S 243-208899)

¹¹³ http://ec.europa.eu/smart-regulation/refit/index_en.htm

¹¹⁴ See REFIT report p. 47-49: http://ec.europa.eu/food/food/foodlaw/docs/st-17996_en.pdf

4.2 Accountability Criterion

This section assessed the extent of accountability of both GFL and HP regulations in addition to the regulatory regime, in order to determine whether they are effective or ineffective in guaranteeing the safety of meat and animal-derived food products in the EU.

4.2.1 Political Accountability

GFL and HP regulations do not stipulate any specific proviso concerning this matter; only that the responsibility of food and hygiene safety rest on the hands of food business operators and Member States to control and enforce (C. Regulation, 2002; E. Regulation, 2004a, 2004s, 2004af). However, the regulatory regime¹¹⁵ unit the EC is to a great extent **political accountable**. Because the regulatory regime unit the EC “(...) [is] subjected to various accountability regimes simultaneously, such as a regime of political accountability to the European Parliament and the Council [of the European Union]” (Bovens et al., 2010, pp. 5-7). In other words, the regulatory regime unit the EC has to render account for the actions it carries out in prior and future conduct concerning the stipulated obligations of GFL or HP regulations to: **(a)** the Council of the European Union via a principle-agent¹¹⁶ and **(b)** the EP formally (Bovens, 2007a, pp. 15-16). Consequently, in notion the EC is one of the foremost controlled institutions in the EU, because it is located between the Council of the European Union and the EP (Magnette, 2003, p.51). Also, as a result of the Treaties¹¹⁷ the political accountability at EU level has been improved incrementally (Moravcsik, 2008; Řiháčková, 2007). Since these Treaty improvements provided the EP, with more accountability powers such as: questioning, blocking, censure and budget freeze (ibid).

Despite the growing powers of the EP towards the EC as a political accountability forum; the EP has also political accountability deficits of its own (System Report, 2013, p.13). For example, the EP has “*Loopholes in integrity safeguards concerning MEPs' assistants; weak rules and practice regarding the monitoring and sanctioning of MEPs' conduct and governing their contacts with third parties [lobby firms] and less well-developed internal whistle-blowing provisos*”¹¹⁸. For additional deficits concerning the EP (see Bovens, 2007a, p. 18). At the same time there questions concerning the credibility of the EP as an accountability forum; due to **(a)** absence of interest from EU constituents on EP elections and **(b)** less well-developed EU party system at supranational level (Bovens et al., 2010). On the other hand, there are important deficits in the existing political accountability system of the EC (Van Gerven, 2005, pp. 18-25). An often attributed deficit is that the EC consist of members who are de facto selected by the Member States government's, thus lacking any citizen participation either directly or indirectly via political parties; albeit the EC members are indeed after selection screened and approved by the EP. An additional political accountability deficit concerning the EC is the commissioners' 'code of conduct' which is a form of soft law; and it also does not have sufficiently detailed and concise stipulated anti-corruption provisos¹¹⁹. The EU Integrity System (2013) report, suggests that the decisions concerning conflict of interest are not taken into the College meetings; since they are not mention in the commission's minutes. This means that, if an EC official is corrupted; this will most likely not come to light through the existing accountability procedures (code of conduct) of the EC itself.

¹¹⁵ **The regulatory regime** in charge of GFL and HP regulations comprises of the following units: EC, MS, EFSA, DG SANCO (SCFCAH and FVO) but also food business operators. **However the focus in this Master thesis will be on the EC and EFSA units.**

¹¹⁶ The Council of the European Union also has deficits; for instance, this institution and its individual members are not political accountable to any forum whatsoever at supranational level (see Van Gerven, 2005, pp.85- 91).

¹¹⁷ The Treaty of **Maastricht** harmonised the EC term in office with that of the EP. The Treaty of **Amsterdam** main emphasis is on citizenship and the rights of individuals; by improving at supranational level democratic process through the enhancement of the EP powers. The Treaty of **Nice** improved further the political accountability concerning the election of the EC President by replacing unanimity voting in the European Council with the so-called Qualified Majority Voting or QMV; which permits an increase in the number of EC nominees. Yet, there are problems concerning the system of nominations; because it is still consensual based thus allowing too many actors to be part of the process. The Treaty of **Lisbon** established the ordinary legislative procedure or co-decision, improve the rights of EU citizens i.e. right to petition (Article 227 TFEU) and improve the role of national parliaments in EU legislation (Moravcsik, 2008; Řiháčková, 2007)

¹¹⁸ See EU Integrity System report p. 17 www.transparencyinternational.eu/wp.../EU_Integrity_System_Report.p

¹¹⁹ See EU Integrity System report p. 106-107.

An example of this occurred in 2012, when Glencore an Anglo-Swiss commodity trader corrupted an EC official with currency and additional gifts in exchange for confidential information concerning the agro-market; yet, the EC did not report this conflict of interest that was eventually exposed by a Belgium court¹²⁰. Another case of political accountability deficit is concerning comitology committees (Bovens et al., 2010, p. 11). For example, the political accountability of a powerful comitology committee such as the SCFCAH on food safety and hygiene matters is at EU level limited; because political accountability forums at EU level in many occasions cannot check “(...) *the many and invisible hands*” that take part in such committee (Bovens et al., 2010, pp. 16-18).

It is important to note that a comitology committee, permits experts to take hold of powers that “*in principle’ belong to the parliaments*” (Bovens, 2007i, p. 114). Thus in absence of political accountability (Bovens, 2007b, p. 144; Lord, 2004, p. 188) indicates that a “*comitology [committee like the SCFCAH] slips through the net of a wide range of mechanisms of parliamentary scrutiny, and not just those of the EP*”. Albeit a powerful comitology committee such as, the SCFCAH on food safety and hygiene matters is less well known than for instance, the regulatory regime units the EC or EFSA. It is by no means less important in the regulatory process that regulates the safety of meat and animal-derived food products in the EU. Especially taking into consideration that “*the shaping and implementing of policies and decisions that bind the governments, companies, and private citizens of its Member States*” is developed by comitologies (Bovens & Curtin, 2010, p. 17).

EU agencies such as EFSA have to an extent political accountability (Busuioc, 2012; Holland, Robinson, & Harbinson; Observatory, 2013; Robinson et al., 2013). The reason for this is that only in limited cases, do the regulations offer the EP with the option to invite the director of an EU agency such as EFSA to a hearing prior to his nomination or to report on its operations. For instance, GFL (Article 24 to 26) stipulate that EFSA is managed by the Executive Director, who has to report to an independent Management Board (C. Regulation, 2002). This board is independent due to GFL (Article 37) which provide this board the power to select the members of the scientific panels GFL (Article 28)(C. Regulation, 2002). Nevertheless, due to independence structure questions are raised concerning its political accountability; because to who is the management board accountable if they are independent by EU law. It is important to note that every scientist that works in the scientific panels is appointed by the EFSA management board. In October 2013 more than half of the 209 EFSA’s scientist sitting on the scientific panel had a direct or indirect relationship with the industry they regulate (Observatory, 2013, pp. 14-15).

Thus EFSA failed to act in accordance with the stipulate responsibilities of GFL (Article 6) risk analysis but also with GFL (Article 29 to 34 and 37) (Observatory, 2013; C. Regulation, 2002). Yet, no action was undertaken by either the EC or the EFSA management board itself to address this problem. In addition the scientific panels of EFSA have also in some occasions not complied with EU regulations. For instance, in 2009 the scientific panels of **EFSA undermined an EU pesticide regulation**¹²¹ by permitting industry to conduct chemical tests themselves; and this is prohibited by EU law (Robinson et al., 2013). Even despite this non-compliance the EC and the management board of EFSA did not start an investigation. So far the only EU institution that has expressed its distrust to EFSA on several occasions has been the EP. This institution has on several cases: **(1)** postponed for six months the budget release of EFSA in 2012; **(2)** requested EFSA for stronger improvements concerning its internal organisational structure in 2013; and **(3)** it has voted a very clear resolution demanding that EFSA had to improve its independence policy in 2014 by stating that “[EFSA] should apply a two-year cooling-off period to all material interests related to the commercial agro-food sector, including research funding, consultancy contracts and decision-making positions in industry-captured

¹²⁰ See EU Integrity System report p. 110

¹²¹ This Regulation stipulates that pesticides cannot longer be assessed solely on the basis of industry tests see: European Parliament and Council. Regulation (EC) No 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Off J Eur Union 2009:1–50

organisations"¹²². Yet, regardless of all of the demands made by the EP to improve the political accountability system of EFSA, the management board has so far disregarded almost all of the demands (Observatory, 2013).

4.2.2 Legal Accountability

GFL (Article 21) does stipulate a liability proviso but, HP regulations do not provide any specific proviso concerning this matter (C. Regulation, 2002; E. Regulation, 2004a, 2004s, 2004af). Nevertheless, the regulatory regime unit the EC is to a great extent **legal accountable**. Because the regulatory regime unit the EC can be held legally to account by important legal forums such as the ECJ for conducts that conflict with the stipulated obligations of GFL or HP regulations through court judicial procedures governed by the rule of law (Borchardt, 2010; Bovens, 2007i; Bovens et al., 2010). For instance, at supranational level¹²³ the regulatory regime unit the EC can be held accountable through specific responsibilities that are either formally or legally conferred on competent authorities such as the ECJ¹²⁴ (Bovens, 2007a; Bovens et al., 2010). This means that, the legal accountability at supranational level is one of the foremost forms of accountability towards the regulatory regime in charge of GFL and HP regulations; because the legal scrutiny is founded (in most cases) on very thorough and precise legal standards (Bovens, 2007a, pp. 16-17). A good example of this, is the judicial oversight of the EC, which is covered under Treaty provisos both individually (Article 245 TFEU) and collectively (Article 234 TFEU).

Even though the EC has to answer to question posed by the EP by law (Article 314 and 312 paragraphs 2 TFEU); there are observable legal accountability deficits (Louis Hancisse, 2014). For instance, the EC has: **(1)** limited legal accountability in important areas of its operations such as: advisory committees, expert groups and trade negotiations; **(2)** lack of solid legal rules concerning the use of external expertise and the systematic disclosure of meetings with third-parties and **(3)** no clear and concise formulated legal definition of what precisely conflict of interest and lobbying is¹²⁵. Moreover, from 2009 to 2010 six from the thirteen departing commissioners moved from public office into industry or lobbying occupations; and this raises concerns with possible conflicts of interest (ALTER-EU Report, 2011). Another legal accountability deficit can be found at EFSA because GFL did not take into consideration the possibility for EFSA to submit its acts to legal examination;

¹²² See <http://corporateeurope.org/efsa/2014/11/efsas-credibility-loopholes>

¹²³ For example, Article 228 TFEU (ex 195 TEC); Article 245 TFEU (ex -Article 213 TEC); Article 247 TFEU (ex -Article 216 TEC); Article 25 (ex -Article 225a TEC); Article 251 TFEU (ex -Article 221 TEC); Article 256 (ex -Article 225 TEC); Article 258 TFEU (ex -Article 226 TEC); Article 260 TFEU (ex 228 TEC); Article 261 TFEU (ex-Article 229 TEC); Article 263 TFEU (ex 230 TEC); Article 263 to 267 TFEU. See <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:12012E/TXT>

¹²⁴ **(1) Actions for failure to fulfil obligations** (Article 258-260 TFEU) which stipulate that the EC is able to start proceedings against a Member State when the latter does not comply with stipulated obligation. Examples concerning the safety of food and hygiene are: "Food Safety: Commission urges Spain to transpose provisos of the Animal Feed Directive; Food Safety: Commission requests Austria to transpose provisos of the Directive on control of potato cyst nematodes; Food Safety: Commission urges Italy to transpose provisos of the Plant Protection Products Directive and European Commission v. Belgium: foodstuffs contaminated by dioxin" and **(2) Proceedings for failure to act** (Article 263 and 265 TFEU) which stipulate that in case that an EU institution such as the EC failed to comply with its obligations to act, it is possible to start a proceeding against the EC by either a Member state or another EU institution and possibly individuals [NGO's]. Good examples are occurred in November 1993, the EP, on the basis of Article 175 of the EEC Treaty (Article 265 TFEU), put forward an action against the EC for failure to present the proposals required for the establishment of the free movement of persons within the internal market. But also "environmental organisations and scientists jointly bring the case to the European Court of Justice and Munich/Luxembourg, 25 September 2013. Monsanto, the British Government, the European Food Safety Authority (EFSA) and the EU Commission are joining forces in EU Court proceedings to prevent risky genetically engineered soybeans from being withdrawn from the food market". See for detail: <http://www.ensser.org/media/0413/> and <http://www.testbiotech.org/en/node/781>

¹²⁵ According to (ALTER-EU Report, 2011, pp. 11-16; EU Integrity System Report, 2014, p. 87), the problem of not having a clear legal definition of what lobbying is, results that there is no possible manner to decide on what ex-commissioners' activities constitute lobbying; in addition the interpretation of this matter is at present left to the Ad hoc ethical committee. This committee has also come under negative spot light as the, inquire of the EU Ombudsman shows. See <http://www.ombudsman.europa.eu/en/cases/summary.faces/en/53404/html.bookmark>

thus the role of EU courts is very limited (Alemanno & Mahieu, 2008). As such, at present the EU court's jurisdiction exclusively covers 'contractual and non-contractual' legal accountability matters concerning EFSA due to GFL (Article 47) (Alemanno & Mahieu, 2008, p. 321).

This means that the administrative acts, opinions or scientific advice provided by EFSA are very difficult to challenge before EU courts, because "(...) *these are exclusively governed by the classic rules relating to actions for annulment [Article 230 of the EC Treaty]*" (Alemanno & Mahieu, 2008, pp. 321-322). In other words, even when using (Article 230 EC) actions for annulment, with reference to the scientific opinions of EFSA, there are two main problems. The first problem is that (Article 230 EC) does not refer clearly and concisely to the acts of EFSA, scientific committee or source of expertise, between the EU institutions that can be subject to annulment (Alemanno & Mahieu, 2008, p. 322). The second problem is that the scientific opinions of EFSA are so-called 'preparatory acts'; as such it is in the 'procedural' stage of the decision-making process¹²⁶ (ibid). Therefore the scientific opinions of EFSA do not appear to be covered within the acts of (Article 263 TFEU ex 230 TEC) in order to be subjected to an action for annulment. Also (Article 263 TFEU ex 230 TEC) just covers those acts that are "(...) *intended to produce legal effects vis-à-vis third parties*". A good example of this problem is shown in: **(a)** "*Case T-454/05 R Sumitomo Chemical AGRO Europe and (b) Philagro France v Commission, paragraph 50*" (Alemanno & Mahieu, 2008, p. 322). In sum: the deficit here is that EFSA has very limited legal accountability concerning its administrative acts and scientific opinions. Therefore in order to legally contest a scientific opinion of EFSA, it is a very difficult and complex process due to limitations in present-day EU law (Alemanno & Mahieu, 2008, pp. 324-328).

4.2.3 Administrative Accountability

GFL (Article 21) does stipulate an administrative proviso, while HP regulations do not (C. Regulation, 2002; E. Regulation, 2004a, 2004s, 2004af). Yet, the regulatory regime units the EC and EFSA are to some extent **administrative accountable**. Because these regulatory regime units are supervised and controlled for their conducts concerning the stipulated obligations of GFL or HP regulations, by auditors, inspectors and controllers such as: ECA¹²⁷, OLAF¹²⁸ the European Ombudsman¹²⁹, and also by the EP¹³⁰ (Bovens, 2007a, 2007i; Bovens & Curtin, 2010). An important administrative/financial accountability forum is ECA (European Court of Auditors). It is important to note that ECA, due to its "*comprehensive infrastructure of basic integrity rules and an extensive access concerning information on EU financial management for audit purposes*" is able to investigate EU institutions (Louis Hancisse, 2014, pp. 136-156). Likewise, ECA acts as an external auditor, that controls both the reliability of the EU financial accounts, as well as the legality and regularity of the transactions that are performed by EU institutions such as the EC and EFSA (Louis Hancisse, 2014). Another important administrative/financial accountability forum is OLAF (European Anti-Fraud Office), that due to its strong "*legal mandate with extensive investigative methods at its disposal*" is able to also commence investigations on EU institutions (Louis Hancisse, 2014, pp. 158-182).

Moreover, OLAF is authorised to investigate and combat fraud and corruption that affects the financial interests of the EU; and it can also investigate serious misbehaviour or unlawful activity by members or staff of the EU institutions (Louis Hancisse, 2014). The investigations performed by ECA, OLAF in addition to European Ombudsman have exposed administrative/financial accountability deficits concerning the regulatory regime units the EC and EFSA. For instance, the investigation of the

¹²⁶ See for example the argument of EFSA in Case T-311/06, FMC Chemical and Arysta Lifesciences/ EFSA (2008), paragraph 27.

¹²⁷ Article 287 TFEU (ex -Article 148 TEC). The ECA who has the power to: investigate the revenues of agencies such as EFSA to determine if the annual accounts are valid and reliable and whether the transactions are legal and regular (ibid).

¹²⁸ Article 325 TFEU (ex -Article 280 TEC). OLAF's responsibilities are to investigate fraud that affects the EU budget, in addition as corruption and any other irregular action or activity, such as the misconduct, within the EU institutions such as the EC and EFSA (ibid).

¹²⁹ Article 228 TFEU (ex -Article 195 TEC). The European Ombudsman has investigation powers on EU institution agencies such as the EC and EFSA concerning "*administrative irregularities, unfairness, and discrimination, abuse of power, and failure to answer, but also the refusal of information or unnecessary delay thereof*" (ibid).

¹³⁰ EFSA is administratively accountable to the EP; because the latter has substantial power over its budget via the budgetary discharge procedure as numerous agencies like EFSA depend on fully or partly Community funding (ibid).

European Ombudsman confirmed conflict of interest at EFSA because of the maladministration of its rules and procedures concerning staff member's hiring and resignations processes¹³¹. This investigation shows that a top GMO scientific staff member of EFSA was able to work directly after resigning for a large biotechnology company a so-called 'revolving doors' case (ibid). Due to such practise question are raised concerning the validity and objectivity of EFSA scientific opinions and thus putting at risk the food and hygiene safety and public health in the EU.

Another example is the anti-fraud investigation performed by OLAF¹³² in 2012 that resulted in the resignation of commissioner Dalli due to fraud and corruption allegations; who at the time was responsible for health and consumer affairs, including GMOs. Even though administrative forums such as the European Ombudsman and financial forums such as ECA and OLAF are able to exercise a range of external and independent financial, administrative supervision and control via specific status and set standards; these institutions also have limitations of their own (see for detail Bovens, 2007i; Bovens et al., 2010; Louis Hancisse, 2014).

4.2.4 Social Accountability

GFL (Article 9) does stipulate a social accountability proviso, while HP regulations do not (C. Regulation, 2002; E. Regulation, 2004a, 2004s, 2004af). Nevertheless, the regulatory regime units the EC and EFSA are to an extent **socially accountable**. Because these regulatory regime units are compelled; although limited to render account for its conducts to forums located in the public sphere concerning the stipulated obligations of GFL and HP regulations¹³³. (Reale, 2003, p. 3) indicates that at EU level the concept of "participation" is, actually the core foundation of the White Paper on Governance, where the EC identified five principles of good governance i.e. "*openness, participation, accountability, effectiveness and coherence*". However, these principles accentuates that the EU¹³⁴ governance legitimacy firstly "*depends on involvement and participation*" since "*the Union has moved from a diplomatic to a democratic process*" (Höreth, 2001, pp. 10-11). This means that, at EU level social accountability involves on regular bases various stakeholders via: "*public consultations, stakeholder forums, specialised ad-hoc committees, expert groups in addition to informal meetings*" but it depends on policy matters (Tanasescu, 2009, p.79).

However, in practice the regulatory regime unit the EC has limited socially accountable to civil society; because at EU level it is founded on general principles and a set of minimum standards that are not legally binding (Bovens, 2007a, pp. 460-466; 2007i, pp. 109-113). The reason for this is that social accountability provisos are indeed formulated in an ambiguous manner and are also non-binding at EU level (Nickel, 2005; Tanasescu, 2009). A recent example whereby civil society was excluded is the current TTIP trade negotiations. In 2014 the 'Stop TTIP Coalition' that comprises of more than 300 civil society organisations across the EU, filed a lawsuit against the EC, because it was excluded to participate in the trade negotiations as well as lack of transparency thereof¹³⁵. Civil society and academia are concerned; because the food sector is one of the most important sectors that will be substantially affected by the TTIP¹³⁶. Since the TTIP will have a direct impact on the food safety of animal derived food products and thus the public health; because "*the US authorises slaughterhouses to use decontamination treatments on carcasses, on a massive scale*"¹³⁷.

¹³¹ See: <http://www.ombudsman.europa.eu/en/cases/draftrecommendation.faces/en/11089/html.bookmark>

¹³² See: European Anti-Fraud Office, The OLAF report 2012, (2013) (Luxembourg; Publications Office of the European Union), pg. 19

¹³³ See p. 3-12 COMMUNICATION FROM THE COMMISSION: *Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties* by the Commission Brussels, 11.12.2002 COM(2002) 704 final

¹³⁴ "*The Union is built on the rule of law; it can draw on the Charter of Fundamental Rights, and it has a double democratic mandate through a Parliament representing EU citizens and a Council representing the elected governments of the Member States.*" (p. 7).

Commission of the European Communities: European Governance. A White Paper. COM (2001) 428 final. Brussels: CEC

¹³⁵ Other deficits in social accountability at EU level are observed in the ordinary legislative procedures; which cannot guarantee the public examination of such processes by NGOs, interest groups or other social partners (ibid).

¹³⁶ See <http://www.beuc.org/press-media/news-events/food-ttip-what-stake-eu-consumers>

¹³⁷ See <http://www.beuc.org/press-media/news-events/food-ttip-what-stake-eu-consumers> and <http://www.euractiv.com/sections/health-consumers/ttip-will-sacrifice-food-safety-faster-trade-warn-ngos-308025>

For instance, slaughterhouses in the US are permitted to use chemicals such as chlorine and peroxyacids in order to wash meat (both of cattle and poultry) at the end of the production line (ibid). Such practices are forbidden by law in the EU; therefore the BEUC argued that the *“TTIP should not be used as a vehicle to allow these treatments within the EU”* (ibid).

Other social accountability deficits can be found in regulatory regime unit EFSA concerning the participation of stakeholders. Albeit EFSA is obligated by law i.e. GFL (Articles 38, 39 and 42) to include stakeholders; in the past 10 years alone civil society¹³⁸ has been excluded on several occasions to participate in the 'scientific colloquiums' of this agency. For example, EFSA often organises these colloquiums in co-operation with ILSI an industry lobby association; and as such they are full of industry representatives and industry-related individuals, whereas civil society was not represented. Example of such cases occurred in: *“(1) the 2005-colloquium on genotoxic carcinogens, (2) the 2006-colloquium on pesticide mixtures and (3) the 2011-joint EFSA/ILSI/CEFIC-workshop on TTC, an industry-tool to classify chemicals as 'safe' but without testing the chemicals”* (ibid). Moreover, many of the industry-related individuals present at these scientific colloquiums have work for the scientific panels of EFSA; thus emphasising the interrelated relation of this agency with the industry it has to regulate. On the other hand, additional mechanisms such as hierarchical, supervisory and professional accountability are indeed present in EU institutions; and so-called 'performance base mechanisms' that were introduced by the Prodi commission (from 1999 to 2004) to improve the working methods of EU institutions¹³⁹. Yet, these mechanisms are not legally binding; instead they are for a great extent founded on informal codes of conducts (see for more detail Commission, 2000, 2001). This is a major concern; because the internal organisation of agencies such as EFSA are built on such informal ethical and management based codes of conducts which have proven to be insufficient to guarantee the food safety and hygiene in the EU (Holland, Robinson, & Harbinson, 2012; Robinson et al., 2013).

4.3 Transparency Criterion

This section assessed the extent of transparency of both GFL and HP regulations and the regulatory regime, in order to determine whether they are effective or ineffective in guaranteeing the safety of meat and animal-derived food products in the EU.

4.3.1 Visible & Inferable processes

GFL (Article 38) does stipulate a transparency proviso concerning visible and inferable processes with regard to EFSA, while HP regulations address this matter exclusively in the preambles paragraphs 16, 19 and 7 (C. Regulation, 2002; E. Regulation, 2004a, 2004s, 2004af). Nevertheless, the regulatory regime units the EC and EFSA do provide to some extent **visible and inferable processes**. Because these regulatory regime units are compelled by EU laws to make certain the accessibility and disclosure of information concerning most of its decision making processes (Louis Hancisse, 2014). For example, the EC is compelled by EU laws to have a visible and inferable regulatory processes via the so-called 'principle of open Union decision making' which compels this institution to be 'as open as possible' towards EU citizens (Louis Hancisse, 2014, pp. 94-95). In addition, the EC has to make certain that it has transparent proceedings (Article 15 paragraph 3 TFEU); and it also has to make public the agendas and minutes of the College of Commissioners (Article 9 paragraph 2) EC ATD rules, Annex. However, (Louis Hancisse, 2014, p. 94) points out that the EC meetings themselves are not open to the public and its discussions are confidential due to (Article 9) Rules of procedure of the Commission. But via the so-called adaptation access (Article art 9 paragraph 3) EC ATD rules, Annex, it is possible to have admission to the preparatory documents that are sent to the College concerning legislative acts in addition to official EC documents. Although there are EU laws in place to make

¹³⁸ Pesticide Action Network (PAN) is a network of over 600 non-governmental organisations, institutions and individuals in over 60 countries; that were founded in 1982 see. <http://www.pan-europe.info/News/PR/121112.html>

¹³⁹ See for more detail: Wille, A. (2010) 'The European Commission's Accountability Paradox', in M. Bovens, D. Curtin, P 't Hart (eds) The Real World of EU Accountability, Oxford: Oxford University Press, 63-86

certain that there are visible and inferable processes, limitations are indeed observed. For instance, the provisos in place to disclose documents related to the inter-service consultations are formulated in an ambiguous manner (Louis Hancisse, 2014); as a result it is not at all times possible to have full disclosure concerning EC documents.

Additional major transparency deficits concerning the regulatory regime unit the EC are regarding the often limited visible and inferable processes of: trilogues¹⁴⁰, advisory committees, expert groups and trade negotiations¹⁴¹ (Louis Hancisse, 2014, p. 96). A good example of lack of transparency due to un-visible and inferable processes is the TTIP trade negotiations; that will have a considerable effect on the food and hygiene safety in the EU (ibid). In respond to this, for lack of transparency as well as refusing to take into account the European Citizens Initiative, a lawsuit was started in 2014 against the EC¹⁴². Due to this lack of transparency organisations such as the Ecologist (2015) are concerned that the TTIP “(...) is a Trojan Horse that will threaten our food safety and environment. Trade officials whose primary objective is to increase trade and boost corporate profits will have a first say over future food safety rules”¹⁴³. The BEUC complement this by emphasising that the present farm-to-fork approach has “greater public health benefits than ‘end-of-line’ pathogen reduction treatments focussed only on the food pathway” that is used in the US¹⁴⁴. In addition, the BEUC points out that the goal of the TTIP is trade and therefore it requires that EU food and hygiene safety standards are changed to meet those of the US, and this is not permitted by GFL (Article 13 point e) in order to prevent possible food safety and hygiene risks for EU consumers.

EFSA has come under attack since its inception by numerous food, consumer, agricultural associations¹⁴⁵ across the EU; because of having limited visible and inferable processes concerning its scientific opinions (Alemanno, 2013; Observatory, 2013; Robinson et al., 2013). Although EFSA is by law GFL (Article 23) tasks, (Article 38) compelled to provide high levels of transparency concerning its operations and GFL (Article 39 point b) compels it to provide a visible decision making process concerning scientific opinions; contrary to practices (Observatory, 2013; C. Regulation, 2002; Robinson et al., 2013). For example, the practices of EFSA indicates that it does very limited research on its own since most of their files, studies and analyses are either sponsored or made by the very same industry they are regulating (Observatory, 2013; Robinson et al., 2013). As a result, a majority of these files and studies in addition to raw data are in many occasions maintained undisclosed by using ambiguous formulated proviso such as those of GFL (Article 39) as well as additional commercial confidentiality agreements in order to avert possible research duplication (ibid). It is important to note that such practices are dangerous to the food and hygiene safety of products in the EU. Because the validity of the authorisation processes which the EC has to provide before food products can be placed in the EU market; depends to a great extent on the scientific opinions of EFSA and these are questionable (Munro, Renwick, & Danielewska-Nikiel, 2008; Robinson et al., 2013; Séralini et al., 2012; Whaley, 2012).

¹⁴⁰ Dr. Raya Kardasheva (a lecturer at the European politics at King’s College London) describes that even though the legislative process has been improved, the trilogues permits the Council of the European Union to negotiate directly with majority party leaders of the EP, at the cost of minority parties. See <http://www.euractiv.com/future-eu/trilogues-boost-influence-majority-analysis-515205>

¹⁴¹ At supranational level the EC is the solely institution that receives the largest number ATD or access to documents requests which are for the majority replied; even so the European Ombudsman does criticise the handling of these requests by the EC For instance, the EC responded after 30 days to 1143 ATD cases and 178 days later to other 219 ATD cases (ibid). In addition, the EC positions, agendas and minutes from on-going trilogue discussions are not made public; because of limited checks and balances, lack of formality and transparency. See D. Chalmers, G. Da vies & G. Monti, European Union Law 2nd edition (Cambridge: CUP, 2010) p. 109.

¹⁴² See <http://ec.europa.eu/citizens-initiative/public/basic-facts?lg=en> and <http://www.globaljustice.org.uk/blog/2014/nov/10/lawsuit-served-against-european-commission-%E2%80%98stifling-debate%E2%80%99-ttip>

¹⁴³ http://www.theecologist.org/blogs_and_comments/commentators/2741624/ttip-is-a-lethal-attack-on-food-safety-and-animal-welfare.html

¹⁴⁴ <http://www.beuc.org/press-media/news-events/food-ttip-what-stake-eu-consumers>

¹⁴⁵ Association pour la suppression des OGM dans l'alimentation (APSODA), Cancer Prevention and Education Society, ClientEarth, Corporate Europe Observatory (CEO), Earth Open Source, European Environmental Bureau (EEB), Fondazione Italiana per la Ricerca in Agricoltura Biologica e Biodinamica (Firab), Friends of the Earth Europe (FoEE), GMWatch, Groupement International d'Etudes Transdisciplinaires (GIET), Inf'OGM, Pesticide Action Network Europe (PAN Europe), TestBiotech. <http://corporateeurope.org/agribusiness/2013/10/minimum-efsa-can-do-restore-public-trust>

4.3.2 Openness of Information & Communication

GFL (Article 10, 39, 40 and 41) does stipulate transparency provisos concerning openness of information and communication especially towards EFSA, while HP regulations 852/853/2004 exclusively address this matter in the preamble and annex II and III and 854/2004 in (Article 5) (C. Regulation, 2002; E. Regulation, 2004a, 2004s, 2004af). Despite that, the regulatory regime units the EC and EFSA are to some extent required to provide **openness of information and communication**. Because these regulatory regime units are compelled by hard and soft laws¹⁴⁶ to make certain the accessibility and disclosing of information and communication (Louis Hancisse, 2014; C. Regulation, 2002). For example, the EC is compelled by GFL (Article 10) to guarantee that EU citizens have access to public information (ibid). Also several international and EU laws compel the EC to guarantee that documents of the accessible to the public¹⁴⁷. Basically, the EC is compelled to disclose information by means of secondary EU laws such as regulations in order to provide the public with access to all documents it has¹⁴⁸.

Nonetheless, there are exceptions due to ATD Regulation (Article 4 paragraph 7) (Louis Hancisse, 2014). Likewise, additional limitations are observed concerning this matter in supporting bodies such as a comitology. For instance, even though there is a comitology register in place this register is restricted, and as such it cannot provide full disclosure of information to the public (Louis Hancisse, 2014). According to (Louis Hancisse, 2014, p. 97) a comitology, such as the SCFAH in food safety and hygiene matters, does not have to provide information concerning: the names of individuals who were present in the committee, the discussions that took place, the rules of procedure and the meeting documents¹⁴⁹. Thus, this impedes the openness of information and communication which has been criticised extensively by civil society and the EP (Louis Hancisse, 2014, p. 97).

Even though EFSA is compelled by law i.e. GFL (Article 39, 40 and 41) to provide openness of information and communication; it has not always meet these stipulated obligations (Observatory, 2013; Robinson et al., 2013). For example, EFSA has systematically refused to disclose information concerning their scientific opinions i.e. files, studies, analysis and raw data (ibid). This resulted that NGO's such as CEO, Beelife, Earth Open Source, Fondation Sciences Citoyennes, GM Watch, Pesticides Action Network Europe, have been pushing via open letters and legally for several years to disclose this information; in order to perform independent analysis and testing of EFSA's scientific opinions. Also, Corporate European Observatory (2014) points out *"that EFSA's opinions cannot be reproduced without access being given to commercially sensitive elements, their red line (one could however imagine that scrutiny by competitors could be quite efficient from a public interest perspective)"*¹⁵⁰. Thus, in order to guarantee the food and hygiene safety in the EU it is important to disclose the scientific opinions of EFSA; so that the public can be fully informed on how these

¹⁴⁶ **Hard law** refers to actual binding legal instruments and laws; while **Soft law** does not have any or very weak binding force. See for more detail Christians, Allison (Summer 2007). "Hard Law & Soft Law". Wisconsin International Law Journal 25 (2).

¹⁴⁷ International (Aarhus convention); Article 1 TEU (Consolidated version 2012) [2012] OJ C326/13. But also other EU legislation such as: regulations 178/2002, regulation 1049/2001, 1367/2006 and regulation 503/2013) which make it mandatory for EU authorities such as the EC to permit citizens access to documents and information it has, where exceptions are clearly stipulated and limited (ibid).

¹⁴⁷ Dr. Raya Kardasheva (a lecturer at the European politics at King's College London) describes that; even though the legislative process has been improved, the trilogues permits the Council of the European Union to negotiate directly with majority party leaders of the EP, at the cost of committees and minority parties. See <http://www.euractiv.com/future-eu/trilogues-boost-influence-majority-analysis-515205>. But also via Article 15 TFEU (Consolidated version 2012) [2012] OJ C326/47

¹⁴⁸ Regulation (EC) 1049/2001 regarding public access to the EP, Council of the European Union and EC documents [2001] OJ L145/43; (ATD Regulation) Exceptions relate to the protection of public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making processes (Louis Hancisse, 2014).

¹⁴⁹ Rules of procedure 2011/C 183/05 for the appeal committee, Regulation 182/2011 (Articles 12 paragraph 2 and 3); and the Standard Rules of Procedure EC 2011/C 206/06 for Committees (Articles 13 paragraph 2 and 3)

¹⁵⁰ The present risk assessment operations performed by EFSA work as follow: first food, pesticide, GMO etc. studies are provided by the very own industry producers; secondly EFSA then assess whether these studies fulfil the relevant regulatory standards; thirdly this is the foundation of EFSA's scientific opinion over the said product, which is in many occasions followed by the EC who is the one to permit the market authorisation decision for industry food products. see <http://corporateeurope.org/food-and-agriculture/2014/10/towards-transparent-efsa>

assessment were performed in addition to how EFSA gathered the data to assess food and hygiene product risks and whether this is objective grounded science (Observatory, 2013; Robinson et al., 2013). Conversely, industry strongly competes against such demands by suggesting that in an event that EFSA discloses such information; they might take legal action against it (ibid). This disclosure debate is similar to the one in clinical trials for drugs; where many NGO's and academics such as (Goldacre, 2010, 2014; Lo, Wolf, & Berkeley, 2000; Perlis et al., 2014; Ridker & Torres, 2006) indicates that the public has the right to know who funded and supplied these studies as well as how they are assessed¹⁵¹.

4.3.3 Inclusiveness of Actors

GFL (Article 9, 36 and 42) does stipulate transparency provisos concerning the inclusiveness of actors, while HP regulations do not (C. Regulation, 2002; E. Regulation, 2004a, 2004s, 2004af). On the other hand, the regulatory regime units the EC and EFSA do to some extent provide **inclusiveness of actors**; because they are compelled by EU law to do so (C. Regulation, 2002). For instance, the EC is compelled by GFL (Article 9) to include in a transparent manner all the actors involved in the regulatory process through representative bodies during the preparation phase, assessment and revision of EU food law; with the exception of urgencies¹⁵² to the matter which does not permit to include all the actors (C. Regulation, 2002). Additional EU law (Article 11 paragraph 2 and 3 TEU) compels the EC to carry out a broad and inclusive consultations in order to make certain that the actions taken in the EU are coherent and transparent (Louis Hancisse, 2014). Nevertheless, the EC has not always included all the actors into food safety and hygiene regulatory process. The present TTIP negotiations are a good example of this, because it covers greatly food and feed matters; but is has continued to stay unnoticed. So far the meetings and discussions were and still are occurring behind closed doors; whereby EU citizens and civil society across the EU are excluded from participation¹⁵³.

EFSA is by law GFL (Article 36) compelled to include the Member States competent food agencies/authorities in order to improve scientific cooperation and therefore to realise its mission (C. Regulation, 2002). Also GFL (Article 42) compels EFSA to include consumers, produces and other parties so that it can maintain an effective relationship with these actors (C. Regulation, 2002). Yet, the practice of EFSA indicates a different tendency; because it does not always include all the actors into the regulatory process. For instance, the EFSA working group on TTC or Threshold of Toxicological Concern that is organised together with ILSI, excluded in 2005 and 2011 environmental NGO's such as PAN to participate¹⁵⁴. Due to this exclusion PAN (Pesticide Action Network) made in 2011 a formal complaint to the European Ombudsman, who after investigating this matter came to the verdict that EFSA has failed to dismiss doubts concerning its efforts to make certain that all stakeholders are included into its external meetings¹⁵⁵. These practices of EFSA raises concerns whether this agency systematically also excludes NGO's in food and hygiene safety matters in addition to consumer and other animal wellbeing organisations across the EU.

¹⁵¹ See <http://www.euractiv.com/sections/health-consumers/ben-goldacre-pharma-industry-has-destroyed-its-own-reputation-309355>

¹⁵² These have to be justified by Protocol (No. 2) on the application of the principle of subsidiarity and proportionality [2012] OJ C326/206, art 2. The exception applies only in cases of extreme urgency, and the EC must give reasons for why it has not undertaken consultation(s) in such cases (Louis Hancisse, 2014, p. 94).

¹⁵³ European Union Ombudsman opened an own-initiative inquiry towards the European Commission concerning transparency and public participation in relation to the TTIP negotiations (OI/10/2014/RA. See <http://www.ombudsman.europa.eu/en/cases/correspondence.faces/en/56100/html.bookmark>

¹⁵⁴ See <http://www.pan-europe.info/News/PR/140328.html>

¹⁵⁵ "In 2011, PAN Europe started a complaint at the Ombudsman on the EFSA Working Group on TTC (Threshold of Toxicological Concern), a statistical approach for risk assessment substituting safety testing. PAN Europe analyzed the work and the members of the group in a report and showed that 10 out of 13 members had been involved in promoting TTC in the past and many links with industry. PAN Europe concluded that EFSA failed to protect the interest of the public and promoted the interests of industry" <http://www.pan-europe.info/News/PR/140328.html#ftn1>. See [Decision of the European Ombudsman closing the inquiry into complaint 2522/2011/\(VIK\)CK against the European Food Safety Authority \(EFSA\)](#)

4.4 Expertise Criterion

This section assessed the extent of expertise of both GFL and HP regulations and the regulatory regime, in order to determine whether they are effective or ineffective in guaranteeing the safety of meat and animal-derived food products in the EU.

4.4.1 System of Education

GFL and HP regulations stipulate some provisos but not specifically concerning the obligation for the regulatory regime to provide for a **system of education** to its staff; in order to guarantee the food and hygiene safety in the EU. For instance, GFL (Article 43 paragraph 1 and 2) stipulate that EFSA can use its budget for staff training purposes in, scientific, administrative, technical and operational matters (C. Regulation, 2002). While HP regulations emphasises that it is the food business operators and competent authorities (Member States) responsibility to provide for a system of education concerning its staff in order to guarantee the food and hygiene safety at EU level (E. Regulation, 2004a, 2004s, 2004af). For example, regulation 852/2004 (II Hygiene provisos paragraph 4 point d) stipulates that food business operators have to make certain that the handlers that are working with foodstuffs receive training on health risks. Likewise, (Chapter XII Training paragraph 1 to 3) stipulates that food business operators have to make certain that the food handles e.g. employees are supervised and trained concerning food hygiene matters (E. Regulation, 2004a). Moreover, regulation 853/2004 (Chapter I Training of Hunters in Health and Hygiene paragraph 5) stipulates that the competent authority have to encourage hunter organisations to provide training to hunters of wild game (E. Regulation, 2004s). On the other hand, regulation 854/2004 (Article 4 paragraph 4 point e) stipulates that the competent authorities have to make certain by means of audits that food business operators have good hygiene practices such as performing training in hygiene and work procedures; (Article 5 paragraph 6 point a) stipulates that the official veterinarian has to receive training in order to perform audits in the production of meat and poultry in accordance with Annex I, Section III, Chapter III (A) in addition CHAPTER IV: PROFESSIONAL QUALIFICATIONS A. OFFICIAL VETERINARIANS paragraph 1, 2 and 4 (E. Regulation, 2004af).

Nevertheless EFSA does provide training and schooling to its staff members on a regular basis¹⁵⁶. An example of such staff training to improve the competence of EFSA scientific staff is the “*EFSA’s food and feed crisis preparedness training: 2012 Crisis Training Exercise*” which is a four-year preparedness training¹⁵⁷. During this comprehensive training the staff members of EFSA that are involved in the Emerging Risk Unit or EMRISK undertake a four year food and feed safety crisis training¹⁵⁸ that includes: workshops involving case studies, table-top exercises and command-post simulation exercises¹⁵⁹. Another example of staff training performed by EFSA is the PROMETHEUS project or Promoting Methods for Evidence Use in Science¹⁶⁰. This staff training is used to improve the: methodological rigidity, transparency, harmonisation and evidence that are acquired through the scientific assessments that are performed by this agency (ibid).

4.4.2 Staff Availability & Resources

GFL and HP regulations do not stipulate any proviso concerning the regulatory regime required amount of **staff availability and resources** necessary to guarantee the food and hygiene safety in the EU (C. Regulation, 2002; E. Regulation, 2004a, 2004s, 2004af). However, to guarantee the food and hygiene safety and thus also the safety of meat of and animal derived food products, the staff of the regulatory regime at supranational level is as follows organised. DG SANCO has a staff of 960¹⁶¹.

¹⁵⁶ Staff Regulations of Officials (SR) and the Conditions of Employment of Other Servants of the European Communities (CEOS), in particular Art. 27-34 (SR), Art. 12-15 (CEOS) and Art. 82-84 (CEOS) <http://www.efsa.europa.eu/en/efsajournal/pub/e1051.htm>

¹⁵⁷ See: EXTERNAL SCIENTIFIC REPORT EFSA’s food and feed crisis preparedness training: 2012 Crisis Training Exercise and four-year training strategy College Hill Ltd and www.efsa.europa.eu/en/search/doc/388e.pdf

¹⁵⁸ www.efsa.europa.eu/en/supporting/pub/388e.htm

¹⁵⁹ www.efsa.europa.eu/en/search/doc/388e.pdf

¹⁶⁰ www.efsa.europa.eu/en/mb141023/docs/mb141023-ax7.pdf

¹⁶¹ http://ec.europa.eu/dgs/health_food-safety/about_us/who_we_are_en.htm

While EFSA has a staff of 474 from which 344 temporary agents and officials, 110 contract agents, 20 seconded national experts in addition approximate 1500 external experts support this unit¹⁶². The Food and Veterinary Office (FVO) has a staff of 180 from which a majority are qualified as auditors i.e. veterinarians, agronomist and other specialists¹⁶³. Moreover, the annual report of EFSA from 2014 showed that it had a budget of €79.82 million from which 52% was allocated to staff, 36% to operations and 12% to infrastructure¹⁶⁴. The annual budget of EFSA has gradually increased since it was established; while at the same time the staff members have been decrease as the annual reports from 2004 till 2013 showed¹⁶⁵. It is important to note that the EC by means of the ‘zero-growth human resource strategy’ that commenced in 2013; plans to reduce its working staff incrementally till 2017 (Louis Hancisse, 2014). The result of this strategy is to cut human resource costs by means of ending approximate 250 posts each year¹⁶⁶. Also, the EC is reducing its operation resources regarding its capacity to examine the quality of entries in the joint Transparency Register, which is used to respond to questions from the EP as well as those of the public (Louis Hancisse, 2014, p. 112). It is important to note that in the event that the EU signs the TTIP with the USA and Canada, and these countries start to export meat products without growth promoter to the EU (Bánáti, 2014; Bennet, 2014; Jarman, 2014; Young, 2014). At present there are insufficient inspection possibilities to control whether this is actually the case. Due to insufficient staff availability of the FVO; this makes it almost impossible to perform effective inspections across the EU.

Also, because HP regulations provisos emphasis that it is the responsibility of: **(1)** food business operators to have sufficient staff and resources to guarantee the food and hygiene safety in the EU and **(2)** competent authorities control the former and enforce EU food law in case of breach. However, making food business operators comply with both EU and national food law has in some occasions proven not possible to realise. For example, in the Netherlands the NVWA is the competent national authority that has to control and enforce EU food law, besides national food laws. Yet this authority has come under severe national criticism due to several food safety and hygiene crisis e.g. salmon infected with salmonella as well as adulteration horse meat fraud which involved Dutch food business operators, warehouses and trader¹⁶⁷. Furthermore, soon after these crises the NVWA was assessed and the auditor’s report of 2013 discovered that due to structural resources cuts from the Rijksoverheid (or central government) in the past 10 years, this food authority has become a “toothless tiger” that cannot sufficiently control and enforce the food and hygiene safety at national level (FNV, 2013; Veiligheid, 2013). As a result of these funding cuts, the NVWA has to carry out more work with less staff¹⁶⁸. This raises questions concerning the extent to which national food authorities are able to guarantee the food and hygiene safety both at EU and national level. Since GFL and HP regulations do stipulate that the responsibility to control and enforcement rest on the hands of the competent authorities. To compensate the lack of staff availability due to insufficient resources, the NVWA was able to outsourced a great part of their meat (cattle and poultry) inspection to VERIN an independent private Dutch inspection company that provides certificates of food safety and hygiene (ZEMBLA, 2013). However, this private meat inspection company is part of the holding Comore BV¹⁶⁹ which has close ties with large Dutch meat producers such as VION Food Group; this raises questions concerning the objectivity of VERIN when performing inspections at food business operators establishments (ZEMBLA, 2013).

¹⁶² www.efsa.europa.eu/en/jobs/docs/faqsrecruitment.pdf and [www.efsa.europa.eu › Publications › Corporate publications](http://www.efsa.europa.eu/Publications/Corporate%20publications)

¹⁶³ http://ec.europa.eu/food/food_veterinary_office/audit_programmes/index_en.htm

¹⁶⁴ www.efsa.europa.eu/en/.../doc/scientificcooperationroadmap1416.pdf

¹⁶⁵ See <http://www.efsa.europa.eu/en/publications/corporate.htm>

¹⁶⁶ European Commission, Human Resources Report of the European Commission – 2013, (2013),(Luxembourg; Publications Office of the European Union), pg. 9 (EC HR Report 2013)

¹⁶⁷ <http://content1d.omroep.nl/urishieldv2/l27m13d72d381d2409ef0052efe75b000000.a8698c46cd181b466bcf0c932ff5fc88/kro/documents/journalistiek/zembla/kamerbrief-over-toezicht-slachterijen-nvwa.pdf>

¹⁶⁸ The working staff of NVWA has been reduced from 3700 to 2175 employees; while the workload has increase substantially. See:

http://www.eerstekamer.nl/behandeling/20130625/verslag_houdende_een_lijst_van_document3/f=-/vlast3ydk2d3.pdf

http://www.joop.nl/leven/detail/artikel/23086_voedsel_en_warenautoriteit_dreigt_tandeloze_tijger_te_worden/

¹⁶⁹ <http://www.verin.nl/Comore/Over-CoMore.aspx>

4.5 Regulatory Assessment Findings

This section organises the findings of the assessment. The assessment findings indicates that the EU food safety policy regulations GFL, HP and regulatory regime are effective, in guaranteeing the safety of meat and animal derived food products in the EU. To graphically illustrate this, the following assessment matrix below is used:

Assessment Rating:		Four Regulatory Assessment Criteria			
Effective + or Ineffective -		Criteria 1: Legitimation	Criteria 2: Accountability	Criteria 3: Transparency	Criteria 4: Expertise
EU Food Safety Policy Regulations used to guarantee the safety of meat and animal-derived food products in the EU.	General Food law: Regulation 178/2002	++	+++/-	++/-	+/-
	Hygiene Package: Regulations 852/ 853/ 854/ 2004	++	+/- - - -	- - -	- -
	Regulatory Regime units the EC and EFSA	++	+++/-	+/- - -	+/-

Table 14: assessment outcome

Firstly, the legitimation criterion findings indicates that GFL and HP regulations in addition to regulatory regime units the EC and EFSA are to a great extent able to guarantee the safety of meat and animal derived food products in the EU; and thus can be said to be effective. Even though these regulations are legitimated and supported by the stakeholders involved in the regulatory process; there are also visible deficits concerning the formulation of some important provisos of GFL and HP regulations. **Secondly**, the accountability criterion findings indicates that GFL regulation and the regulatory regime are great extent able to guarantee the safety of meat and animal derived food products in the EU; and can therefore be called effective. Even though GFL does stipulate several provisos to address this matter; and the regulatory regime units the EC and EFSA are compelled by EU laws to render account for their conducts to various, political, legal and administrative accountability forums at EU level. On the other hand, HP regulations only have provisos which stipulate that the responsibility of food and hygiene safety and the organisation of official controls thereof, rest on the food business operators and competent authorities i.e. Member States. Nevertheless, there are also several visible important accountability deficits due to ambiguous formulated provisos and soft law internal organisational accountability procedures from the EC and EFSA e.g. code of conduct or ethical codes which are not legally binding.

Thirdly, the transparency criterion findings indicates that GFL and HP regulation in addition to the regulatory regime are to an extent able to guarantee the safety of meat and animal derived food products in the EU; and can therefore be called ineffective. While GFL indeed stipulate several provisos to address this matter more specifically, HP does not. And the regulatory regime units EC and EFSA are by EU laws compelled to provide transparency. Their practices have revealed that they often do not provide or comply with the obligation stipulated by GFL and other EU laws; especially concerning its internal decision making processes. **Fourthly**, the expertise criterion findings indicates that GFL and HP regulations in addition to the regulatory regime are to an extent able to guarantee the safety of meat and animal derived food products in the EU; and can thus be called ineffective. Even though, GFL and HP regulations do stipulate several provisos concerning the use of a system of education; these are not specifically formulated concerning the amount of available staff or resources. Also GFL and HP regulations solely stipulates that it is the food business operators and competent authority to provide for staff availability and resources, to guarantee the food and hygiene safety in the EU. But this becomes a problem when the competent authority that also has to control and enforce EU food law, does not have sufficient expertise and resources to realise its task.

Chapter 5: Assessment Results

This chapter answers the main research questions of this Master thesis and consist of sections 5.1 and 5.2.

5.1 Conclusion & Suggestions

The **research objective** of this Master thesis is to examine from a public administration perspective if the EU food safety policy is capable of achieving its goal(s); by assessing whether it is able to guarantee the safety of meat and animal-derived food products (cattle and poultry) in the EU. The main research questions are: **(a)** *“how does the EU Food Safety Policy, interrelated core components: Legislation, Scientific Assessment & Communication in addition to Regulatory Measures contribute in order to achieve its goal?”* and **(b)** *“to what extent does the EU Food Safety Policy guarantees the safety of Meat and Animal-Derived food products (Cattle and Poultry) in the European Union (28 Member States)?”* To answer these questions, I firstly described how the EU food safety policy is organised to guarantee the safety of meant and animal-derived food products; and secondly I assessed this policy by means of four regulatory assessment criteria. These criteria are: legitimation, accountability, transparency and expertise. Using these criteria, I assessed the EU food safety policy regulations GFL and HP in addition to the regulatory regime units the EC and EFSA. The research findings of this Master thesis indicate that, the EU food safety policy achieved partially its goal and is thus effective, although to some extent in guaranteeing the safety of meat and animal-derived food products in the EU.

First, I assessed the legitimation of the EU food safety policy regulations GFL and HP. The research findings indicate that GFL and HP regulations in addition to regulatory regime units the EC and EFSA are to a great extent legitimised; and thus effective, to guarantee the safety of meat and animal-derived food products in the EU. These regulations and regulatory regime were legitimatised and supported by the stakeholders involved in the regulatory process. However, important forums such as the ESC and CoR were permitted to provide only once opinion concerning the development of these regulations. The research findings also indicate that GFL and HP regulations are to a great extent goal oriented and functional. Moreover, GFL and HP regulations as well as the regulatory regime unit EFSA were reviewed and assessed for effectiveness; once in 2010, through the REFIT. However, despite the assessment for effectiveness these regulations as well as regulatory regime unit EFSA were not improved. Because the main focus of REFIT was primarily to reduce the regulatory and administrative burden and to further simplify EU food legislation.

Second, I assessed the accountability of the EU food safety policy regulations GFL and HP as well as that of the regulatory regime units the EC and EFSA. The research findings indicate that GFL regulation and the regulatory regime unit the EC are to a great extent accountable; and therefore effective, to guarantee the safety of meat and animal-derived food products in the EU. While the HP regulations solely stipulate that the food business operators and competent authorities (Member States) are responsible for the food and hygiene safety in the EU. The research findings indicate that the regulatory regime unit, the EC can be held to a great extent accountable at EU level. Because additional EU laws compel this institution to render account for the actions it carry out in prior and future conduct to political, legal and administrative forums. While the regulatory regime unit EFSA can be held to an extent accountable at EU level. Even though EFSA is compelled by GFL to render account for the actions it carries out in prior and future conduct. The research findings indicate that it is very difficult to hold EFSA accountable through the existing accountability forums. Because of its network agency or independent organisational structure; in addition to ambiguous formulated provisos concerning the degree of accountability of the management board and scientific panel staff members.

Third, I assessed the transparency of the EU food safety policy regulations GFL and HP as well as that of the regulatory regime units the EC and EFSA. The research findings indicate that these regulations in addition to the regulatory regime to an extent provide transparency; and thus ineffective, to guarantee the safety of meat and animal-derived food products in the EU. Although GFL to some extent does provide transparency provisos; on the other hand the HP solely address this matter to an extent exclusively in the preambles and annexes. The research findings also indicate that the regulatory regime unit the EC is to some extent compelled by EU laws to provide transparency concerning: visible and inferable processes, openness of information & communication as well as inclusiveness of actors. Through the so-called 'principle of open Union decision making' which compels this institution to be 'as open as possible' towards the general public of the EU. Although in important trade negotiation and expert group(s) such as the SCFCAH concerning food and hygiene safety matters, this institution has demonstrated a conflicting tendency. Moreover, the research findings indicate that the regulatory regime unit EFSA is to some extent compelled by GFL to make certain the accessibility and disclosing of information and communication. Even though GFL stipulate provisos that compels EFSA to provide transparency towards all of its stakeholders; its practices showed a contradictory an in some occasions a non-complying trend.

Fourth, I assessed the expertise of the EU food safety policy regulatory regime units EC and EFSA. The research findings indicate that the regulatory regime to an extent provide expertise; and therefore ineffective, to guarantee the safety of meat and animal-derived food products in the EU. Even though, GFL regulation stipulate a proviso which permits the regulatory regime unit EFSA to use its budget for the training of its (scientific) staff members; on the other hand this regulation does not stipulate anything concerning the other unit the EC. Likewise, the HP regulations stipulate that it is the responsibility of food business operators themselves and competent authorities (Member States) to provide for a system of education to its staff in addition to staff availability and resources; and nothing concerning the EC or EFSA. The research findings also indicate that the regulatory regime units the EC and EFSA have started to gradually reduce their staff member capacity in the past years; and the former institution its resources as well. Further reducing staff availability and resources is detrimental to the food and hygiene safety in the EU, especially in an ever increasing and complex food supply chain which requires more expertise to regulate effectively. Thus it is highly likely that more food safety crises could occur again.

Fifth, even though the EU food safety policy is indeed effective in guaranteeing the safety of meat and animal-derived food products in the EU; its goal(s) however are partially achieved due to several important deficits that include:

- I. Both GFL and HP regulations have double-edge or mutual interest formulated goals and scopes as well as ambiguous provisos such as: the concept of risk analysis GFL (Article 6) and unfit for human consumption GFL (Article 14 paragraph 2). But also the HP regulations 852/2004 (Article 6) and 853/2004 (Article 4) concerning the system for the registration of food business operators; that are not consistently applied by Member State the Netherlands (see chapter 4.1).
- II. Both GFL and HP regulations do have a common definition of 'food fraud' and harmonised monetary penalties against fraudulent schemes at EU level. In addition, HP regulations place too much emphasis on administrative enforcement and control measures that are ex post instead ex ante. Also there is at EU level no proviso concerning nutritional value of food and this is a very important aspect in order to maintain a healthy population (see chapter 4.1).
- III. The regulatory unit the EC has predominantly soft law based internal accountability procedures, as well as ambiguous formulated: anti-corruption provisos and legal definition of conflict of interest and lobbying at EU level. But also ineffective social accountability provisos

that are founded on general principles and a set of minimum standards; and therefore not binding which permits the EC to exclude civil society in some cases (see chapter 4.2).

- IV. The regulatory regime unit EFSA's management board and scientific panels are difficult to hold to account by existing: political, legal, administrative and social accountability forums because of ambiguous or lack of provisos to address this matter precisely. In addition to lack of precise and concise formulated administrative rules and procedures concerning the hiring and resigning of staff members of the management board and scientific panels (see chapter 4.2). Likewise, because of ambiguous formulated provisos concerning the inferable processes of EFSA; it permits this institution to not provide full disclosure of its internal management and scientific process documents. Also because of ambiguous formulated provisos concerning the inclusiveness of actors, EFSA is able to exclude civil society (see chapter 4.3).
- V. The lack of any proviso of GFL and HP regulations concerning the regulatory regime required amount of staff availability and resources necessary to guarantee the food and hygiene safety in the EU. Also if there is an increase in animal derived food products imports into the EU; the FVO cannot control this due to insufficient staff availability. The present staffs of the FVO consist of 180 this makes it almost impossible to perform effective inspections across the EU. In addition, both GFL and HP regulations addressed the competent authorities (Member States) to control and enforce EU food law. However, if the food agency of a Member State cannot perform its tasks as a result of lack of staff and resources; this puts at risk the food and hygiene safety of the general public in the EU (see chapter 4.4).

Finally, it is important to accentuate that if these deficits are not improved then there is a possibility that the EU general public will be exposed to more food safety crisis in the future. Therefore I suggest the following improvements concerning the EU food safety policy regulations GFL and HP as well as Regulatory regime unit EFSA.

A possible option to improve the safety of meat and animal-derived food products are: **(a)** to amend the current goals of GFL and HP regulations, so that these are explicitly focused in protecting the food and hygiene safety of the EU general public; **(b)** to amend GFL and HP regulations so that these include a clear and concise proviso of food fraud in order to harmonise this throughout the EU and **(c)** to increase the present-day food fraud monetary penalties (e.g. a percentage of the food business operators revenue or profits or to exclude them from subsidies or the EU market) at supranational level to a substantial quantity, in order to deter and hence reduce the possibility of fraudulent schemes by food business operators.

Another option to improve the safety of meat and animal-derived food products are: **(d)** to amend GFL regulation to include a proviso concerning the nutritional value of the food products that are placed into the EU market for human consumption. For example, by amending GFL (Article 16 presentation and 17 responsibilities) to include this matter as well. Through such an amendment it is possible to compel food business operators to include in their labelling the nutritional value of food products; and not just an often vague numerical account of sugar, fats, additives or calories which in many occasions' consumers cannot interpret correctly. This is in particular crucial to food safety, so that the EU general public (or consumers) is able to distinguish what nutritional foods are and thus to improve the public health.

An additional option to improve the safety of meat and animal-derived food products are: **(e)** to amend the regulatory regime unit EFSA soft-law based rules, regarding the hiring and discharging of the scientific staff as well as that of the management board members into hard laws. Through such an amendment it is possible to include both criminal and administrative penalties in case of non-compliance (e.g. conflict of interest) by EFSA. This could be achieved by placing EFSA under the direct supervision of the European Court of Justice (ECJ); since this institution has the expertise, power and the means to force EFSA in to compliance. This is of utmost importance to food safety, because ever

since EFSA was established it has shown not to be able to operate independently nor objectively, in order to guarantee the food safety in the EU.

Also to improve the reliability and validity of EFSA's scientific work, it is crucial to prohibit that the scientific staff of this agency performs research for other parties' i.e. food business operators as well as the use of their laboratories to conduct research. Therefore it is of vital importance that the screening of the scientific staff is performed thoroughly. A possible option to achieve this is by placing the screening of all of the head members of the scientific panels in addition to management board members under the supervision of the European Court of Auditors (ECA). Because the auditors of ECA have the skill and know-how to provide objective supervision to EFSA in order to prevent additional conflicts of interest cases. In the end, it is of utmost importance that the scientific studies and hence recommendations provided by EFSA concerning the safety of meat of animal-derived food products in the EU are bona fide an independent of external influences.

5.2 Limitations & Future Research

It is important to note that this Master thesis also suffers from limitations primarily caused by a lack of existing data and specific supportive studies on: GFL and HP regulations, as well as regulatory regime units: DG SANCO (FVO and SCFCAH) and Member State(s) food agencies. Another limitation is concerning the scope of this Master thesis which is solely focused on one area of the EU food safety policy. Therefore, it is difficult to generalise the results; because it is possible that the EU food safety policy is performing ineffective in other policy areas. An additional limitation is concerning the selected regulatory assessment criterion. Albeit I have read extensively through the literature in order to select the most appropriate regulatory assessment criterion for this Master thesis. These criterion are not the solely ones that can be used to assess a policy area.

It is recommended that future research should focus on conducting empirical studies on other policy areas that are covered by the EU food safety policy, such as: novel foods, GMO, fresh fruits and vegetables which were not included in this Master thesis. In order to compare the many different policy areas for effectiveness; through for instance, comparative case studies that are, both qualitative and quantitative. Also to measure more accurately the effectiveness of the food safety policy areas, longitudinal studies could be used which are very useful to gather extensive data. Through further studies it should be possible to discover whether there are discrepancies or similarities concerning the effectiveness of ineffectiveness of the EU food safety policy. Furthermore, because of the limited scope of this Master thesis, future research should include Member States food agencies in addition to the DG SANCO (FVO and SCFCAH) into the assessment of the EU food safety policy, since they have an important role in guaranteeing the food and hygiene safety in the EU.

Bibliography

- akkanto, C. P. P., Kohl PR and Schuttelaar Partners. (2006). What's cooking in the EU? Current and upcoming trends in food policy. In E. f. p. report (Ed.).
- Alemanno, A. (2006). Food safety and the single European market. *What's the Beef*, 237-258.
- Alemanno, A. (2013). Foundations of EU Food Law and Policy-Ten Years of European Food Safety Authority. A. Alemanno-S. Gabbi, *Foundations of EU Food Law and Policy-Ten Years of European Food Safety Authority (London: Ashgate, 2013), Forthcoming*.
- Alemanno, A., & Mahieu, S. (2008). European Food Safety Authority before European Courts, *The Eur. Food & Feed L. Rev.*, 320.
- Babbie, E. (2012). *The practice of social research*: Cengage Learning.
- Baldwin, R., Cave, M., & Lodge, M. (2012). *Understanding regulation: theory, strategy, and practice*: Oxford University Press.
- Bánáti, D. (2014). European perspectives of food safety. *Journal of the Science of Food and Agriculture*, 94(10), 1941-1946.
- Bennet, N. (2014). Health concerns raised over EU–US trade deal. *The Lancet*, 384(9946), 843-844.
- Biglia, C., & Pisanello, D. (2013). Enforcement of the food hygiene package: role and requirements from a recent European Union Court's judgement. *Italian Journal of Food Safety*, 2(3), e42.
- Black, J. (2008). Constructing and contesting legitimacy and accountability in polycentric regulatory regimes. *Regulation & Governance*, 2(2), 137-164.
- Black, J. (2009). Legitimacy and the competition for regulatory share.
- Borchardt, K.-D. (2010). *The ABC of European*.
- Bourgeault, I. L., & Grignon, M. (2013). A comparison of the regulation of health professional boundaries across OECD countries. *The European Journal of Comparative Economics*, 10(2), 199-223.
- Bovens, M. (2007a). Analysing and assessing accountability: a conceptual framework1. *European law journal*, 13(4), 447-468.
- Bovens, M. (2007i). New forms of accountability and EU-governance. *Comparative European Politics*, 5(1), 104-120.
- Bovens, M., & Curtin, D. (2010). *The real world of EU accountability: what deficit?* : Oxford University Press.
- Bovens, M., Curtin, D., & Hart, P. t. (2010). Towards a more accountable EU: retrospective and roadmap. *Amsterdam Centre for European Law and Governance Working Paper(2010-04)*.
- Busuioc, M. (2012). European agencies and their boards: promises and pitfalls of accountability beyond design. *Journal of European Public Policy*, 19(5), 719-736.
- Coen, D. (2007). Empirical and theoretical studies in EU lobbying. *Journal of European Public Policy*, 14(3), 333-345.
- Commission, E. (2007). 50 years of food safety in the European Union.
- Commission, E. (2014). Food Safety in the EU. Retrieved 24 November, 2014, from http://europa.eu/pol/food/index_en.htm
- Commission, E. U. (2007). 50 years of food safety in the European Union. (pp. 50). Luxembourg : Office for Official Publications of the European Communities, 2007.
- Craig, P., & De Búrca, G. (2011). *EU law: text, cases, and materials*: Oxford University Press.
- Creswell, J. W. (2013). *Research design: Qualitative, quantitative, and mixed methods approaches*: Sage.
- Curtin, D., & Nollkaemper, A. (2005). Conceptualizing accountability in international and European Law. *Netherlands yearbook of international law*, 36(01), 3-20.
- Damro, C. (2012). Market power europe. *Journal of European Public Policy*, 19(5), 682-699.
- De Vaus, D. A., & de Vaus, D. (2001). *Research design in social research*: Sage.
- Deckwirth, C. (2005). *The EU Corporate Trade Agenda: The Role and the Interests of Corporations and their Lobby Groups in Trade Policy-Making in the European Union*: Seattle to Brussels Network.

- Dunlop, C. A. (2010). Epistemic communities and two goals of delegation: hormone growth promoters in the European Union. *Science and Public Policy*, 37(3), 205-217.
- EC. (2015a). GFL: Regulation 178/2002. *Official Journal of the European Communities*, L 31/1, 24.
- EC. (2015g). Regulations: 852/853/854/2004 Food Hygiene - Basic Legislation. Retrieved 26 January, 2015, from http://ec.europa.eu/food/food/biosafety/hygienelegislation/comm_rules_en.htm
- EFSA. (2014). about EFSA. Retrieved 5 January 2014, 2014, from <http://www.efsa.europa.eu/en/aboutefsa.htm>
- EFSA. (2015). European Food Safety Authority. Retrieved 5 January, 2015, from <http://www.efsa.europa.eu/en/aboutefsa.htm>
- Egeberg, M. (2006). *Multilevel union administration: the transformation of executive politics in Europe*: Palgrave Macmillan Basingstoke.
- Engel, K. H., Vogel, R. F., Knorr, D., Habermeyer, M., Kochte-Clemens, B., & Eisenbrand, G. (2011). The role of the concept of "history of safe use" in the safety assessment of novel foods and novel food ingredients. Opinion of the Senate Commission on Food Safety (SKLM) of the German Research Foundation (DFG). *Molecular nutrition & food research*, 55(6), 957-963.
- Europa.eu. (2013). FOOD SAFETY STRATEGY. Retrieved 6 march, 2014, from <http://europa.eu/pol/food/>
- Exworthy, M., & Powell, M. (2012). Case studies in health policy: An introduction. *Shaping health policy: Case study methods and analysis*, 3-20.
- FNV, A. (2013). Medewerkers Voedsel- en Warenautoriteit bezorgd over voedselveiligheid. Retrieved 22 December, 2013, from <http://www.abvakabofnv.nl/over-ons/nieuws/nieuwsoverzicht/2013/09/560621-voedselveiligheid-in-gevaar-door-hogewerkdruk-voedsel-en-warenautoriteit/>
- Follesdal, A., & Hix, S. (2006). Why there is a democratic deficit in the EU: A response to Majone and Moravcsik. *JCMS: Journal of Common Market Studies*, 44(3), 533-562.
- Force, B. R. T. (1998). *Principles of good regulation*.
- Gerring, J. (2004). What is a case study and what is it good for? *American political science review*, 98(02), 341-354.
- Gerring, J. (2007). Case study research. *Principles and Practices*. Cambridge.
- Gerring, J. (2011). *Social science methodology: A unified framework*: Cambridge University Press.
- GFL. (2013). Regulation 178/2002. Retrieved 1 June, 2014, from http://ec.europa.eu/food/food/foodlaw/index_en.htm
- Golafshani, N. (2003). Understanding reliability and validity in qualitative research. *The qualitative report*, 8(4), 597-607.
- Goldacre, B. (2010). *Bad science: quacks, hacks, and big pharma flacks*: McClelland & Stewart.
- Goldacre, B. (2014). *Bad Pharma: How drug companies mislead doctors and harm patients*: Macmillan.
- Grant, R. W., & Keohane, R. O. (2005). Accountability and abuses of power in world politics. *American political science review*, 99(01), 29-43.
- Grunert, K. G. (2005). Food quality and safety: consumer perception and demand. *European Review of Agricultural Economics*, 32(3), 369-391.
- Guba, E. G., & Lincoln, Y. S. (1994). Competing paradigms in qualitative research. *Handbook of qualitative research*, 2, 163-194.
- Hansen, M. E. (2006). Risk Assessment-The Role of Combined Environmental and Toxic Stress.
- Hartlapp, M. (2007). On Enforcement, Management and Persuasion: Different Logics of Implementation Policy in the EU and the ILO*. *JCMS: Journal of Common Market Studies*, 45(3), 653-674.
- Hathcock, J. N. (2001). The precautionary principle-an impossible burden of proof for new products.
- Hey, C., Jacob, K., & Volkery, A. (2007). Better regulation by new governance hybrids? Governance models and the reform of European chemicals policy. *Journal of cleaner Production*, 15(18), 1859-1874.

- Holland, N., Robinson, C., & Harbinson, R. Conflicts on the menu: A decade of industry influence at the European Food Safety Authority (EFSA). Brussels, Belgium. Corporate Europe Observatory and Earth Open Source. February 2012.
- Holland, N., Robinson, C., & Harbinson, R. (2012). Conflicts on the menu: A decade of industry influence at the European Food Safety Authority (EFSA). Brussels, Belgium. Corporate Europe Observatory and Earth Open Source. February 2012.
- Holm, L., & Halkier, B. (2009). EU food safety policy: localising contested governance. *European Societies*, 11(4), 473-493.
- Höreth, M. (2001). The European Commission's White Paper Governance: A 'Tool-Kit' for closing the legitimacy gap of EU policymaking? ZEI Discussion Papers: 2001, C 94.
- Houghton, J. R., Rowe, G., Frewer, L., Van Kleef, E., Chrysoschoidis, G., Kehagia, O., . . . Strada, A. (2008). The quality of food risk management in Europe: Perspectives and priorities. *Food policy*, 33(1), 13-26.
- Howlett, M., & Cashore, B. (2014). Conceptualizing Public Policy. *Comparative Policy Studies: Conceptual and Methodological Challenges*, 17.
- Ingenbleek, P., Immink, V. M., Spoolder, H. A., Bokma, M. H., & Keeling, L. J. (2012). EU animal welfare policy: Developing a comprehensive policy framework. *Food policy*, 37(6), 690-699.
- Jacxsens, L., Luning, P., Marcelis, W., Van Boekel, T., Rovira, J., Osés, S., . . . Uyttendaele, M. (2011). Tools for the performance assessment and improvement of food safety management systems. *Trends in Food Science & Technology*, 22, S80-S89.
- Jann, W., & Wegrich, K. (2007). 4 Theories of the Policy Cycle. *Handbook of public policy analysis*, 43.
- Jarman, H. (2014). Public health and the Transatlantic trade and investment partnership. *The European Journal of Public Health*, 24(2), 181-181.
- Jordana, J., & Levi-Faur, D. (2004). *The politics of regulation: institutions and regulatory reforms for the age of governance*: Edward Elgar Publishing.
- Kerry, J. P., & Kerry, J. F. (2011). *Processed meats: Improving safety, nutrition and quality*: Elsevier.
- Koedijk, K., Kremers, J., David, P., & Röller, L.-H. (1996). Market opening, regulation and growth in Europe. *Economic Policy*, 445-467.
- Leibovitch, E. H. (2007). Food safety regulation in the European Union: Toward an unavoidable centralization of regulatory powers. *Tex. Int'l LJ*, 43, 429.
- Lelieveld, H., Holah, J., & Napper, D. (2014). *Hygiene in food processing: principles and practice*: Elsevier.
- Levi-Faur, D. (2011). Regulatory networks and regulatory agencification: towards a Single European Regulatory Space. *Journal of European Public Policy*, 18(6), 810-829.
- Lin, C.-F. (2010). Global food safety: Exploring key elements for an international regulatory strategy. *Va. J. Int'l L.*, 51, 637.
- Lo, B., Wolf, L. E., & Berkeley, A. (2000). Conflict-of-interest policies for investigators in clinical trials. *New England Journal of Medicine*, 343(22), 1616-1620.
- Lodge, M. (2004). *Accountability and transparency in regulation: critiques, doctrines and instruments*: Edward Elgar Publishing.
- Louis Hancisse, A. M., Mark Perera, Ronny Patz. (2014). The European Union Integrity System (1st. ed., pp. 248): The Transparency International European Union Liaison Office
- Mahoney, C. (2007). Lobbying success in the United States and the European Union. *Journal of Public Policy*, 27(01), 35-56.
- Malyshev, N. (2006). Regulatory policy: OECD experience and evidence. *Oxford Review of Economic Policy*, 22(2), 274-299.
- Mattli, W., & Woods, N. (2009a). In whose benefit? Explaining regulatory change in global politics. *The politics of global regulation*, 1-43.
- Mattli, W., & Woods, N. (2009j). *The politics of global regulation*: Princeton University Press.
- Mayring, P. (2004). Qualitative content analysis. *A companion to qualitative research*, 266-269.

- Michener, G., & Bersch, K. (2011). *Conceptualizing the quality of transparency*. Paper presented at the paper apresentado na 1ª Conferência Global sobre Transparência, ocorrida na Rutgers University, Newark, em maio de.
- Millstone, E., & Van Zwanenberg, P. (2002). The Evolution of Food Safety Policy-making Institutions in the UK, EU and Codex Alimentarius. *Social Policy & Administration*, 36(6), 593-609.
- Moravcsik, A. (2008). The myth of Europe's democratic deficit. *Intereconomics*, 43(6), 331-340.
- Munro, I., Renwick, A., & Danielewska-Nikiel, B. (2008). The threshold of toxicological concern (TTC) in risk assessment. *Toxicology letters*, 180(2), 151-156.
- Nestle, M. (2013). *Food politics: How the food industry influences nutrition and health* (Vol. 3): Univ of California Press.
- Nicolaides, A., & Kearney, J. Promoting awareness of legal requirements and liabilities in food and beverage operations.
- Observatory, C. E. (2013). Unhappy Meal: The European Food Safety Authority Independence Problem (pp. 39): Corporate Europe Observatory.
- Patton, M. Q. (2005). *Qualitative research*: Wiley Online Library.
- Paul, K. T., & Garnet, E. (2008). *Thought for Food (Safety) in the EU: A discourse-analytical approach*: University of Warwick, Centre for the Study of Globalisation and Regionalisation.
- Perlis, R. H., Perlis, C. S., Wu, Y., Hwang, C., Joseph, M., & Nierenberg, A. A. (2014). Industry sponsorship and financial conflict of interest in the reporting of clinical trials in psychiatry.
- Pisanello, D. (2010). SHORTCOMINGS IN ENFORCING EU FOOD LAW. WHAT DOES EU FOOD LAW STAND FOR? (pp. 42): Lex Alimentaria Food Law Office.
- Primova, R. Assessing Social Accountability in the EU Multi-level Governance System. The Case of EU Energy Policy-Making.
- Quittkat, C., & Finke, B. (2008). The EU Commission consultation regime. *Opening EU-Governance to Civil Society*, 183.
- Rademakers, M. F. (2000). Agents of trust: business associations in agri-food supply systems. *The International Food and Agribusiness Management Review*, 3(2), 139-153.
- Reale, A. (2003). *Representation of interests, participatory democracy and lawmaking in the European Union: which role and which rules for the social partners?* : New York University School of Law.
- Regulation, C. (2002). No 178/2002 of the European Parliament and of the Council of 28 January 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. *Official Journal of the European Communities*.
- Regulation, E. (2004a). REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004: on the hygiene of foodstuffs *Official Journal of the European Communities*.
- Regulation, E. (2004s). REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004: laying down specific hygiene rules for on the hygiene of foodstuffs *Official Journal of the European Communities*.
- Regulation, E. (2004af). REGULATION (EC) No 854/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004: laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. *Official Journal of the European Communities*.
- Ridker, P. M., & Torres, J. (2006). Reported outcomes in major cardiovascular clinical trials funded by for-profit and not-for-profit organizations: 2000-2005. *JAMA*, 295(19), 2270-2274.
- Řiháčková, V. (2007). Making the European Commission more accountable? Enhancing input legitimacy and its possible impact.
- Robinson, C., Holland, N., Leloup, D., & Muilerman, H. (2013). Conflicts of interest at the European Food Safety Authority erode public confidence. *Journal of epidemiology and community health*, jech-2012-202185.
- Sabatier, P. A. (2007). *Theories of the policy process* (Vol. 2): Westview Press Boulder.

- Sacks, G., Swinburn, B., Kraak, V., Downs, S., Walker, C., Barquera, S., . . . Kumanyika, S. (2013). A proposed approach to monitor private-sector policies and practices related to food environments, obesity and non-communicable disease prevention. *Obesity Reviews*, 14(S1), 38-48.
- SANCO, D. (2014). General Food Law- Principles. Retrieved 20 November, 2014, from http://ec.europa.eu/food/food/foodlaw/principles/index_en.htm
- Schedler, A., & Plattner, M. F. (1999). *The self-restraining state: power and accountability in new democracies*: Lynne Rienner Publishers.
- Séralini, G.-E., Clair, E., Mesnage, R., Gress, S., Defarge, N., Malatesta, M., . . . De Vendômois, J. S. (2012). RETRACTED: Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. *Food and chemical toxicology*, 50(11), 4221-4231.
- Simpson, C. (2005). The precautionary principle in European community food law. *Steptoe & Johnson—EU Regulatory Practice* (<http://tinyurl.com/bpgk8>).
- Spadaro, R. (2003). *European Union citizens and sources of information about health*: European Union Research Group.
- Stern, J., & Holder, S. (1999). Regulatory governance: criteria for assessing the performance of regulatory systems: an application to infrastructure industries in the developing countries of Asia. *Utilities Policy*, 8(1), 33-50.
- Stiglitz, J. (2002). Transparency in government. *The right to tell: The role of mass media in economic development*, 27-44.
- Thomas, G. (2011). A typology for the case study in social science following a review of definition, discourse, and structure. *Qualitative Inquiry*, 17(6), 511-521.
- Traill, W. B., & Koenig, A. (2010). Economic assessment of food safety standards: Costs and benefits of alternative approaches. *Food Control*, 21(12), 1611-1619.
- Trochim, P. D. W. M. (2003). *Research methods*: Dreamtech Press.
- van der Meulen, B. M. (2009). System of Food Law in the European Union, The. *Deakin L. Rev.*, 14, 305.
- van der Meulen, B. M. (2013). The Structure of European Food Law. *Laws*, 2(2), 69-98.
- Van der Muelen, B. M., & Freriks, A. A. (2006). Millefeuille-The Emergence of a Multi-Layered Controls System in the European Food Sector. *Utrecht L. Rev.*, 2, 156.
- Van Gerven, W. (2005). Which form of accountable government for the European Union? *Netherlands yearbook of international law*, 36(01), 227-258.
- Veiligheid, S. M. e. (2013). Voedselveiligheid in gevaar door verzwakte inspectiedienst. Retrieved December 22, 2013, from <http://www.maatschappijveiligheid.nl/kennisbank/>
- Verschuren, P., Doorewaard, H., & Mellion, M. (2010). *Designing a research project*: Eleven International Publishing.
- Vos, E. (2000a). EU food safety regulation in the aftermath of the BSE crisis. *Journal of Consumer Policy*, 23(3), 227-255.
- Vos, E. (2000c). Reforming the European Commission: what role to play for EU agencies? *Common Market Law Review*, 37(5), 1113-1134.
- Wang, X. (2002). Assessing Administrative Accountability Results from a National Survey. *The American Review of Public Administration*, 32(3), 350-370.
- Whaley, P. (2012). Thresholds of toxicological concern: evaluating an initiative to reduce animal testing (part 1). *Health & Environment Online*, 23.
- Yin, R. K. (2014). *Case study research: Design and methods*: Sage publications.
- Young, A. R. (2014). Europe as a global regulator? The limits of EU influence in international food safety standards. *Journal of European Public Policy*, 21(6), 904-922.
- ZEMBLA. (2013). Sjoemelen met vlees. Retrieved 22 December, 2013, from <http://zembla.incontxt.nl/seizoenen/2013/afleveringen/05-09-2013>
- Žurek, K. (2011). *European food regulation after enlargement: facing the challenges of diversity*: Martinus Nijhoff Publishers.

Appendixes

I: EU Secondary Law

The following table below summarises the secondary laws used at EU level:

(1) Regulations are laws which are the foremost centralised mode of regulating used in the EU, because they are utilised to guarantee uniformity. In the EU, a regulation has a general application and are direct applicable (Baldwin et al., 2012). In addition a regulation in the EU, goes into effect after an specified date (as stated or 20 days after the publication in the Official Journal, see Article 297 TFEU) and are thus by design incorporated into the national legal order of the Member States (Baldwin et al., 2012, p. 390). As a result, there is no transposition necessary, albeit in some cases national implementing measures are needed (Baldwin et al., 2012);

(2) Directives are laws which are binding with regard to the results that need to be achieved (Baldwin et al., 2012). Moreover, this mode of regulating leaves the Member States a certain degree of discretion regarding the form and methods to transpose its obligation (Baldwin et al., 2012). Likewise, directives have a set deadline for transposition and can concern one or more Member States, or the EU as a whole obligation (Baldwin et al., 2012) and

(3) Decisions are laws relating to specific cases, they are fully binding to those to which it is addressed obligation (Baldwin et al., 2012). Likewise, decisions may be addressed to a Member State(s) or to individuals (Baldwin et al., 2012). Decisions also requires the addressee to be notified of any decision taken (Baldwin et al., 2012, p. 390). In general decisions are addressed to Member States instead of private parties' (Baldwin et al., 2012).

Table 15: Overview of EU Regulations, Directives and Decisions

II: EU Consultation Process

The following figure below borrowed from lobbyplanet.eu illustrates in a simplified manner the EU consultation process¹⁷⁰:

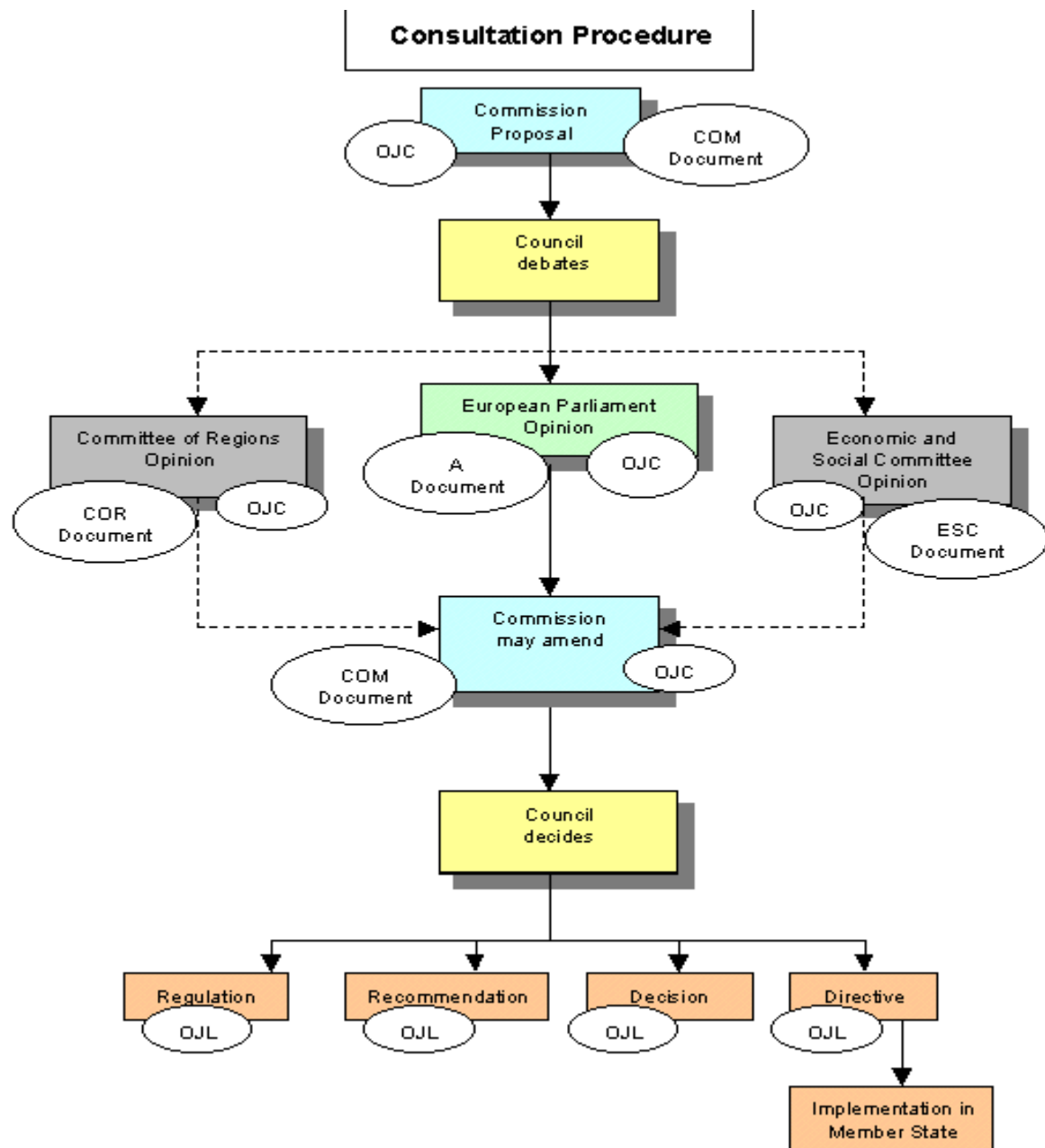


Figure 11: EU legislative process example

¹⁷⁰ <http://www.lobbyplanet.eu/wiki/when/legislative-procedures/draft/>

III: List of Food Safety Crises in the EU from 2002 till 2013

The following table below illustrates an example of the numerous food safety crises that have occurred in the EU:

<p>2002 – In Northern Ireland, nitrofurans were detected in 5 (of 45) samples of chicken imported from Thailand and Brazil. The product was withdrawn and destroyed.</p>
<p>2002 – In the UK, nitrofurans were detected in 16 (of 77) samples of prawns and shrimps imported from SE Asia. Affected batches were withdrawn and destroyed.</p>
<p>2003 – The banned veterinary antibiotic nitrofurans were found in chicken from Portugal. Poultry from 43 farms was destroyed. Nitrofurans are banned from food because of concerns including a possible increased risk of cancer in humans through long-term consumption.</p>
<p>2004 – Organic free-range chicken was found to contain traces of the banned veterinary drug, nitrofurantoin. Up to 23 tonnes of affected chicken, originating from a farm in Northern Ireland, was distributed to supermarkets across the UK resulting in a voluntary product recall and consumer warnings.</p>
<p>2008 – Irish pork crisis of 2008: Irish pork and pork products exported to 23 countries was traced and much was recalled when animal feed was contaminated with dioxins in the feed drying process. The cost of cattle and pig culling exceeded €4M, compensation for lost revenue was estimated to be €200M.</p>
<p>2008 – It was discovered that additives included substances like sulfuric acid and hydrochloric acid had been used to dilute wines in Italy.</p>
<p>2011 – German E. coli O104:H4 outbreak was caused by EHEC O104:H4 contaminated fenugreek seeds imported from Egypt in 2009 and 2010, from which sprouts were grown in Germany.</p>
<p>2011 – Meat, eggs and egg products in Germany contaminated from animal feed containing fat contaminated with dioxins. 4,700 German farms affected. 8,000 hens and hundreds of pigs were culled. Imports from Germany to China were banned.</p>
<p>2012 – More than a quarter of a million chicken eggs are being recalled in Germany after in-house testing discovered "excessive levels" of the poisonous chemical, dioxin.</p>
<p>2012 – Around 1 million pots of herbs had to be destroyed in North Rhine-Westphalia after treatment with an apparently organic plant growth strengthener was found to contain DDAC (didecyl dimethyl ammonium chloride) which resulted in contamination levels above the EU MRL of 0.01 mg/kg. This has resulted in significant additional costs to member states across the EU who put in place a monitoring programme until February 2013 for DDAC and other quaternary ammonium compounds across a wide range of commodity groups.</p>
<p>2013 – It was disclosed that horse meat contaminated beef burgers had been on sale in Britain and Ireland. Two companies, ABP Food Group and Liffey Meats, had supplied various supermarkets with contaminated own brand burgers from their meat factories in the U.K. and Ireland.</p>
<p>2013 – In Germany 200 farms are suspected of selling eggs as "organic" but not adhering to the conditions required for the label.</p>
<p>2013 – A vegetable seller in western Germany, Rhine Main, realized that the lettuce he had been selling throughout the day contained rat poison. The poison appears as small blue kernels.</p>
<p>2013 – Contamination with aflatoxins results in a milk recall in Europe and a dog food recall in the United States. See 2013 aflatoxin contamination for further details.</p>
<p>2013 – Halal Lamb Burgers contained samples of Pork DNA, affected schools 19 schools in Leicester, UK.</p>

Table 16: Overview of food safety crises in Europe