How do food businesses organize their food regulatory affairs activities?

An explorative study on the organization of food regulatory affairs activities at food businesses

Master Thesis

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Preface

This thesis report is conducted as part of my study Master Food Safety. During the first year of my master I had my first course in food law. I experienced this area of food-related sciences as very interesting and wanted to know more about it. Therefore I decided to do my thesis at the Law and Governance Group. I heard about the topic food regulatory affairs and found out that there was almost no data available concerning this topic. So my research became explorative. In this thesis report I will describe how food businesses organize their food regulatory affairs activities. Some parts of the research are not revealed due to confidentiality, like the names of the interviewed persons and companies. The main focus of my research was on the empirical research, because there was a lack of literature concerning this new area in food. It has been a long process and not always easy, but I learned a lot from it.

I want to thank my supervisors at the Law and Governance group Harry Bremmers and Bernd van der Meulen, for their help and feedback. I want to thank Bernadette van Leeuwen for her help and her network with contact persons for interviews. I want to thank the respondents from the interviewed companies for their time and their interesting information. I also want to thank all those other persons that helped me find respondents for the interviews.

Frederike Koster

Wageningen, February 2013

Abstract

Purpose– This master thesis aims to gain insight in the organization of food regulatory affairs activities at food businesses. The word ''organization'', includes both the content and the technical organization (position within the company, the level of integration and the in-house performance or outsourcing) of the food regulatory affairs activities. With the level of integration is meant: the official existence of the job within the company. The scope of this thesis research is investigating the organization of food regulatory affairs activities (dependent factors) in food companies of different size and/or type (independent factors).

Design/methodology/approach– The independent and dependent factors are both unknown, so a direct survey research on the impact of the independent variables on the structuring of regulatory affairs is not possible. Therefore a choice has been made to carry out an explorative research using a grounded theory approach. In this approach, the empirical results deliver the theoretical underpinning for further empirical data gathering. The research starts with a theoretical framework. Next, explorative empirical research is executed by performing first an initial interview and subsequently sequential interviews.

Findings– In total 15 interviews were performed. The responsibility of the person that performs food regulatory affairs activities is to assure that the products and processes of the company are compliant with current food legislation. This is achieved by executing four main activities: gathering knowledge about present and new food legislation, lobbying on behalf of the food company with the authorities when new or changes in present food legislation occur, implementation/compliance with food legislation and informing internally and externally about food legislation. Food regulatory affairs is often positioned high in hierarchy within the R&D department of the company. It appeared that most companies have an integrated food regulatory affairs profession. Most of the food companies hire a food regulatory affairs consultant, even if they have an integrated food regulatory affairs profession.

Practical implications– The findings of this report will help to decrease the knowledge gap about the organization of food regulatory affairs activities in the food sector.

Summary

Despite the growing interests of food businesses in food regulatory affairs, only a handful of literature is available concerning this profession (job) in the food sector. Also, no empirical research about the organization of this profession in food businesses has been carried out so far. So there exists a lack of knowledge concerning the organization of the food regulatory affairs profession. Some food companies do not even have this profession within their company. Therefore an explorative empirical research about the organization of the food regulatory affairs activities within food companies is needed to fill up the knowledge gap. The objective of this research is to describe how food businesses organize their food regulatory affairs activities. The word ''organize'', includes both the content and the technical organization (position within the company, the level of integration and the in-house performance or outsourcing) of the food regulatory affairs activities. With the level of integration is meant: the official existence of the job within the company. The scope of this thesis research is investigating the organization of food regulatory affairs activities (dependent factors) in food companies of different size and/or type (independent factors). The independent and dependent factors are both unknown, so a direct survey research on the impact of the independent variables on the structuring of regulatory affairs is not possible. Therefore a choice has been made to carry out an explorative research using a grounded theory approach. In this approach, the empirical results deliver the theoretical underpinning for further empirical data gathering. The educational objective of this research is that the information obtained from this thesis research can be used to better prepare graduates of the new master specialisation Food Safety Law at Wageningen University for the responsibilities in food regulatory affairs functions.

In the research two methods will be applied to obtain information about the organization of the food regulatory affairs activities in food companies, namely a theoretical framework and an empirical research. The theoretical framework will include the topics: the European food and drink sector, food law and regulatory affairs in companies. Next, empirical research will be executed. The empirical research consists of two parts, namely an initial interview and sequential interviews (where every next interview takes into account the results from the previous one). The results from the theoretical framework and the empirical research will be combined in order to answer the research sub questions (number 1 till 5 at the section below) and the main research question, namely: ''How do food businesses organize their food regulatory affairs activities?''. The sub-questions and the results thereon are described in the section below.

1) What are the similarities and differences of the regulatory affairs activities between the food and the pharmaceutical sector?

Due to the lack of literature concerning regulatory affairs in the food sector, it was searched for literature concerning regulatory affairs in the pharmaceutical sector. More literature is present on regulatory affairs in the pharmaceutical sector, because the profession exists already for a longer period of time in this sector. The pharmaceutical regulatory affairs main activities are similar to the food regulatory affairs main activities. A difference between food and pharmaceutical regulatory affairs is that different legislation is used, in which the medicine legislation is stricter (less flexibility in compliance). Another difference is that the fines of non compliance with medicine legislation are higher compared to food legislation.

2) What factors determine to maintain an integrated (existence of the job within the company) or not- integrated (not existence of the job within the company) food regulatory affairs profession within the business?

- Size

An integrated food regulatory affairs profession is more often present at large and medium-sized food companies than at small food companies.

- Type of products

Food companies that produce genetically modified foods and novel foods have an integrated food regulatory affairs profession more often, to deal with the extra food legislation activities, even if it is a small food company.

- Type of company

An integrated food regulatory affairs profession is more often present at business to consumer food companies than at business to business food companies.

3) What factors determine to keep the food regulatory affairs activities in-house of the food business or to apply (partially) outsourcing of these activities?

90% (N=10) of the large sized food companies hires consultants on occasions, therefore it cannot be concluded that small food companies outsource food regulatory affairs activities more easily. Determining factors are:

- Specific knowledge
- Second opinion
- Time
- Money
- Frequency of food regulatory affairs activities

4) How do food businesses organize their food regulatory affairs activities?

- **When an integrated profession/department exist within the company**
- **When the activities are performed in house or when they are partially outsourced**

At 87% (N=15) of the interviewed food companies an integrated food regulatory affairs profession is present. Their responsibility is that the products and processes of the company are compliant to the current food legislation. The four main food regulatory affairs activities are: gathering knowledge about present and new food legislation, lobbying on behalf of the food company with the authorities when new or changes in food legislation occur, implementation/compliance with food legislation and informing internally and externally about food legislation. Respondents that work at business to consumer companies spend most of their time on product presentation topics; secondly on raw material/ingredient/product topics and least of their time on other topics. Respondents working at business-to-business food companies spend most of their time on raw material/ingredient/product topics; secondly on product presentation topics and least of their time on other topics. The results concerning the position (hierarchy) of food regulatory affairs in the company differ much. The main reason for this is that the respondents answered in different contexts and therefore the results are not very reliable. It is not possible to draw a general conclusion concerning the position of food regulatory affairs in companies. Still it is observed that food regulatory affairs is often positioned within the R&D department of the company. Most (87%; N=15) of the food companies hire a food regulatory affairs consultant, even if they have an integrated food regulatory affairs profession.

5) How do food businesses organize their food regulatory affairs activities?

- **When an integrated profession/department does not exist within the company**
- **When the activities are performed in house or when they are (partially) outsourced**

At 13% (N=15) of all the interviewed food companies no integrated food regulatory affairs profession is present. One of these companies is a small and the other one is a large food company. So a large food company can lack an integrated food regulatory affairs profession, while it was expected that this would not be the case. These two food companies organize their food regulatory affairs activities in different ways (this can be found in appendices 8 and 13).

How can graduates of the new master specialisation Food Safety Law be better prepared for responsibilities in food regulatory affairs?

To better prepare graduates of the new master specialisation Food Safety Law for responsibilities in food regulatory affairs the following is important. Graduates should preferably have a master degree in a technical field (this includes technological studies), because such background knowledge is necessary to perform activities to comply with technical standards. The interviewed persons that perform food regulatory affairs activities mostly have a master degree (53%; N=17) in a technical field (88%; N=17). Most (77%; N=17) of the respondents have working experience in a technical job before starting in food regulatory affairs. The major part of the respondents has working experience in product development and food quality assurance at a food company. Most (29%; N=48) of the food law knowledge from the respondents is gathered from learning on the job. Competences that are important for a person that performs food regulatory affairs activities are: background in food science and knowledge about food legislation. The total amount of results (N) is sometimes higher or lower than 15, because at some interviews more or less persons answered the question or persons gave the same answer.

Finally the main research question of this thesis needs to be answered: ‘’**How do food businesses organize their food regulatory affairs activities?**’’ The theoretical framework and empirical research showed that all food companies have to deal with food legislation. Some organize it in a way that no integrated food regulatory affairs profession is needed in the company, but most companies have an integrated food regulatory affairs profession. Most of the food companies hire a food regulatory affairs consultant, even if they have an integrated food regulatory affairs profession. The profession becomes increasingly important in companies. Consequently more jobs and studies in this area are made available. The pharmaceutical regulatory affairs activities that already exist for a longer period of time are similar to the food regulatory affairs main activities. Factors that determine to maintain an integrated or not integrated food regulatory affairs profession within the business are size, type of products and the type of company. Factors that determine to keep the food regulatory affairs activities in-house or to (partially) outsource these activities are: specific knowledge, second opinion, time, money and frequency of food regulatory affairs activities. The responsibility of the person that performs food regulatory affairs activities is that the products and processes of the company are compliant with the current food legislation. This is achieved by four main activities, namely: gathering knowledge about present and new food legislation, lobbying on behalf of the food company with the authorities when new or changes in present food legislation occur, implementation/compliance-oriented activities with food legislation and informing internally and externally on food legislation. Food regulatory affairs is often positioned high in hierarchy within the R&D department of the company. Recommendations for further research are: perform a quantitative research on food regulatory affairs, continue the investigation of the influence of independent

factors on the organisation of regulatory affairs activities and perform food regulatory affairs studies outside the Netherlands.

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1. Introduction

Presently there exists a growing demand of food businesses in persons with knowledge on the technical aspects of food and on food law. Consequently more studies and courses emerge in this domain. In September 2012 the Master Food Safety at Wageningen University started with the new specialisation ''Food Safety Law''. This specialisation focuses on the legal aspects of food safety and introduces the different forces that are active in the field of food law. Students will participate in courses in food law and in courses in natural sciences (Wageningen University, 2011).

Nowadays the food sector is in size the first production sector in the European Union (Van der Meulen & Van der Velde, 2008 P:41). To avoid possible problems, it is necessary for governments to regulate this area well. Van der Meulen and Van der Velde (2008 P:41) report that the food sector is after automobiles and chemicals, the most regulated market in the European Union. Previously the food sector was only regulated to create a level of playing field for a well functioning internal market, but presently the aim is also to protect consumers' health and other interests. The legislation for food companies in Europe has mainly been laid down at the European level in regulations and directives (van der Meulen & van der Velde, 2008 P:146). These European regulations and directives are only valid in the European Union. Regulations have direct effect in all the European Union member states. Directives set end results that must be adopted in the Member State(s). Directives may concern all the Member States, or only some. Each directive has a date at which the national laws must be adapted. National authorities should change their laws to meet the goals, but they are free to decide how they will do this. Due to this approach the directives give national authorities space within the deadlines to take account of differing national situations (European Commission, 2012 a). Food companies have the obligation to comply with the European Food Law. Due to the large number of food companies and a continuous change of food law, growing interests exist by food businesses in persons with knowledge on the technical aspects of food and on food law

People with knowledge about the technical part of food and of food law have career possibilities in food regulatory affairs in companies, governmental organizations and in academic research (Wageningen University, 2011). This thesis research will focus on food regulatory affairs in food companies. Food regulatory affairs activities are mostly the domain of a food regulatory affairs professional. Regulatory affairs professionals in companies have the responsibility to ensure that their company complies with the law, to advise the company about regulatory issues and to work together with governmental agencies on specific topics which are affecting their business. Most of the regulatory affairs departments are found in the pharmaceutical sector. More recently they also have been installed in the food sector (Keramidas, 2003).

Despite the growing interests of food businesses in food regulatory affairs professionals, only a handful of literature is available concerning this profession (job) in the food sector. A bigger stock of literature concerning regulatory affairs is available in the pharmaceutical sector. As there is a well-developed regulatory affairs profession in the pharmaceutical sector, literature in this sector can be studied as a starting point to get insight in similar activities in the food industry. Also, no empirical research about this profession in food businesses has been carried out as yet. So there exists a lack of knowledge concerning the organization of the food regulatory affairs profession, especially with respect to the level of integration (official existence of the job within the company), in-house

performance or outsourcing of the activities and the job activities. Some food companies do not even have this profession within their company. Therefore an explorative empirical research about the organization of the food regulatory affairs activities within food companies is needed to fill up the knowledge gap.

1.1 Problem statement

European food businesses have to comply with the continuously changing European food law. Presently most of these food regulatory activities are the work of the food regulatory affairs professional. As described in the section above there exists a lack of knowledge about the organization of this profession in the food sector, some food companies do not even have this profession within their company. Therefore the problem statement of this thesis is: How do food businesses organize their food regulatory affairs activities? The word ''organize'', includes both the content and the technical organization (position within the company, the level of integration and the in-house performance or outsourcing) of the food regulatory affairs activities. With the level of integration is meant: official existence of the job within the company.

1.2 Research objective

The scientific objective of this research is to describe how food businesses organize their food regulatory affairs activities. The word ''organize'', includes both the content and the technical organization (position within the company, the level of integration and the in-house performance or outsourcing) of the food regulatory affairs activities. With the level of integration is meant: the officially existence of the job within the company.

The educational objective of this research is that the information obtained can be used to better prepare graduates of the new master specialisation Food Safety Law at Wageningen University for responsibilities in food regulatory affairs positions.

1.3 Research questions

As described above, the main question of the thesis research is: How do food businesses organize their food regulatory affairs activities?

To answer the main research question, the research is divided in sub questions and sub-sub questions. These are schematically represented in figure 1.1. In figure 1.1 the sub questions are presented in blue and the sub-sub questions are presented in lighter blue.

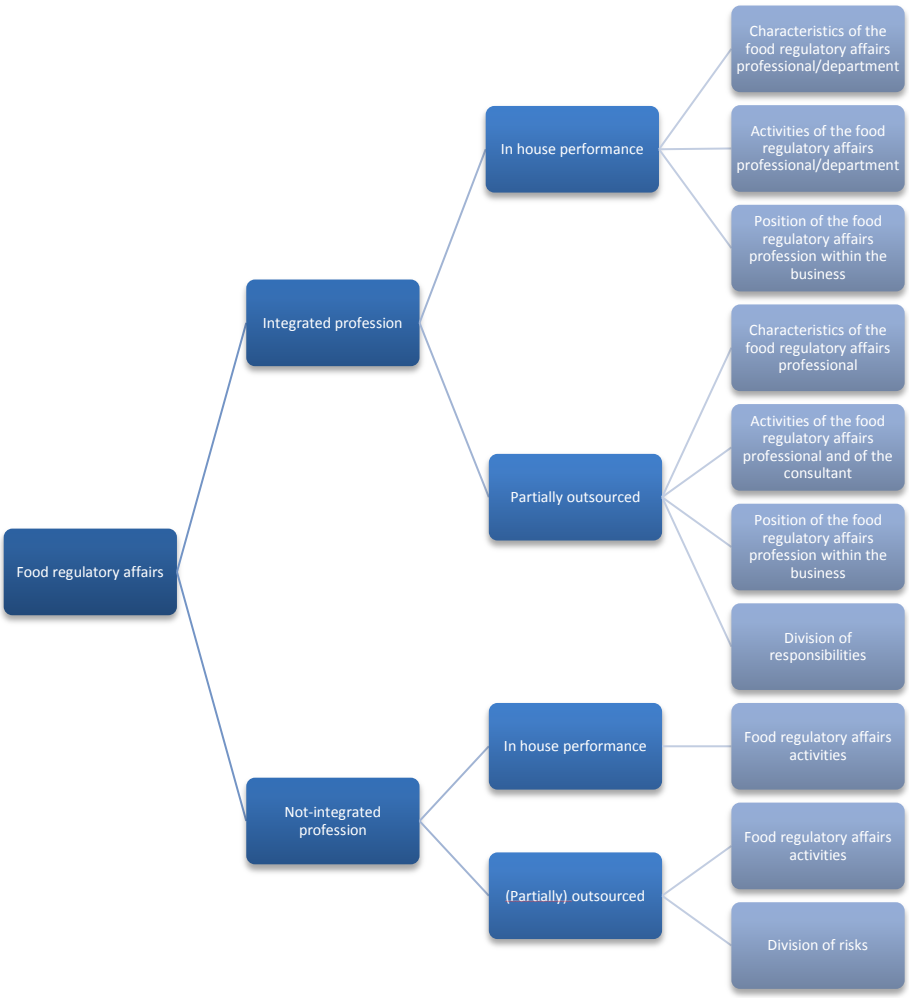

Figure 1.1: Schematically representation of the sub and the sub-sub research questions

1.3.1 Research sub questions:

1. What are the similarities and differences of the regulatory affairs activities between the food and the pharmaceutical sector?

2. What factors determine to maintain an integrated or not integrated food regulatory affairs profession within the business?

3. What factors determine to keep the food regulatory affairs activities in-house of the food business or to apply (partially) outsourcing of these activities?

4. How do food businesses organize their food regulatory affairs activities?
   - When an integrated profession/department exist within the company
   - When the activities are performed in house or when they are partially outsourced

5. How do food businesses organize their food regulatory affairs activities?
   - When an integrated profession/department does not exist within the company
   - When the activities are performed in house or when they are (partially) outsourced

1.4 Demarcation of the study

The scope of this thesis research is investigating the organization of food regulatory affairs activities (dependent factors) in food companies of different size and/or type (independent factors). The independent and dependent factors were both unknown, so a direct survey research on the impact of the independent variables on the structuring of regulatory affairs was not possible. Therefore a choice has been made to carry out an explorative research using a grounded theory approach. In this approach, the empirical results deliver the theoretical underpinning for further empirical data gathering. Independent and dependent factors that will be investigated in this thesis research are schematically represented in figure 1.2.

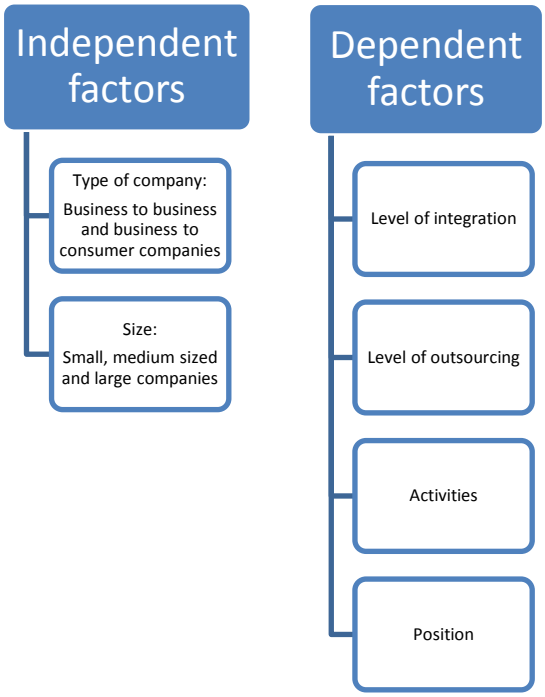

Figure 1.2: Research scope

1.5 Research methods

In the research two methods were applied to obtain information about the organization of the food regulatory affairs activities in food companies, namely a theoretical framework and an empirical research (figure 1.3).

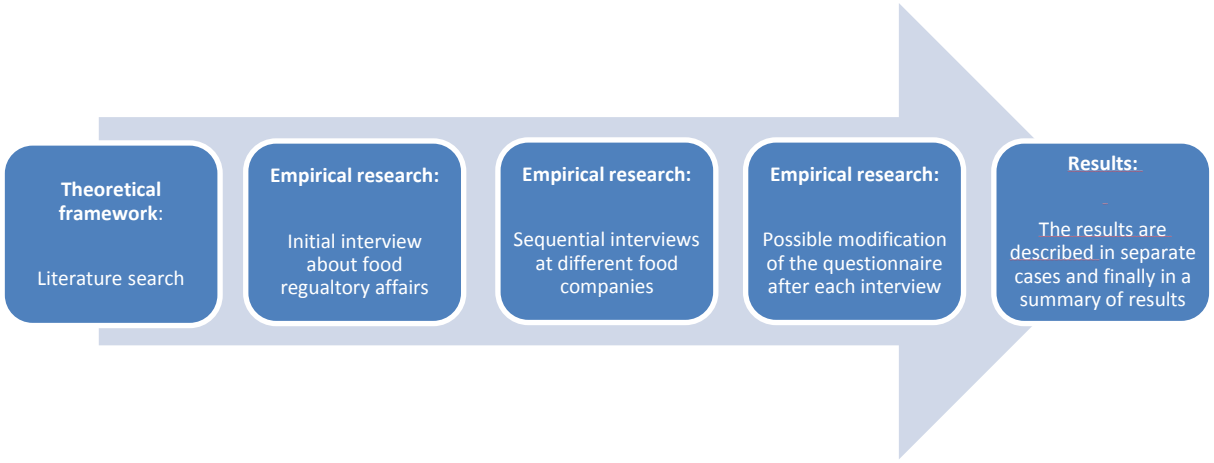

Figure 1.3: Research methods

1.5.1 Theoretical framework

The research starts with a theoretical framework. This theoretical framework includes a literature search. The theoretical framework includes the topics: the European food and drink sector, food law and regulatory affairs in companies. There exists a shortage in literature concerning the regulatory affairs profession in food businesses. A bigger stock of literature concerning regulatory affairs is available in the pharmaceutical sector compared to the food sector. As there is a well-developed regulatory affairs profession in the medical/pharmaceutical sector, literature in this sector was studied as a starting point to get insight in the organization of the regulatory affairs profession.

1.5.2 Empirical research

Next, empirical research was executed. The empirical research consists of two parts, namely an initial interview and sequential interviews.

The empirical research started with performing one initial interview with a food regulatory affairs professional. This initial interview was used as starting point for subsequent interviews. With the information from the initial interview, a questionnaire targeted at the organization of food regulatory affairs activities in food businesses was designed that was used in further empirical research.

After performing the initial interview, sequential interviews were carried out at different food companies in the Netherlands and Germany. Respondents were selected using own contacts, via others and by asking for cards during a food law academy held in Oosterbeek (The Netherlands). The interviews were executed by visiting the company or via the telephone. Persons were interviewed that perform food regulatory affairs activities at small, medium sized and large food companies. The questionnaire used for the interviews contained more open than closed questions, to prevent that the response is influenced on beforehand. Another reason is that there is almost no information about food regulatory affairs. Therefore it is difficult to design closed questions. Due to the fact that after the different interviews new information was available, the questionnaire for the next interviews was adapted to the gained insight after every series of interviews (so the interviews are sequentially organised). This sequential interview process is schematically represented in figure 1.4. The names of the interviewed persons and food companies are kept anonymous. Only the size of the location of the company where the interview was held is mentioned. A division was made between small, medium-sized and large food companies. Definitions of small, medium sized and large enterprises are: small = 10 to 49 employees; medium sized = 50 to 249 employees; large = more than

249 employees (Food Drink Europe, 2012 c). The answers of the interviews were included in a written file by the student during the interview. The results of the interviews are described in different cases (appendices 3-17), because every company has a different interpretation of the content of the profession. Finally the results were summarized in the summary of results (section 5.3).

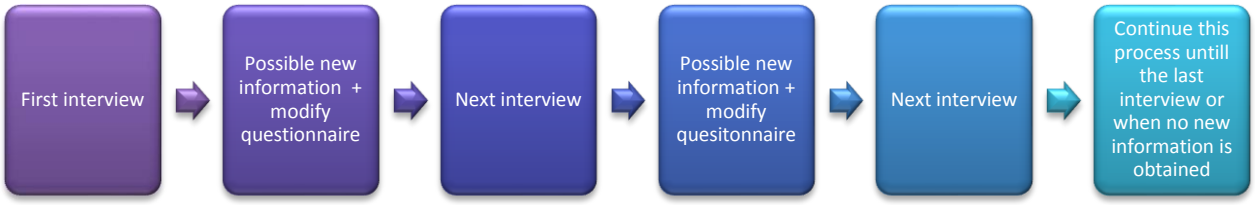

Figure 1.4: Sequential interviews

2. Theoretical framework

The theoretical framework is divided in three parts. The first part contains information about the European food and drink sector. The second part contains information about food law. The last part contains information about regulatory affairs in companies.

2.1 The European food and drink sector

In this part of the theoretical framework, information about the European food and drink sector is gathered. This next section contains information on the activities and roles of the main stakeholders (industry, consumer and government) in the food and drink sector.

2.1.1 Main stakeholders in the food and drink sector

The main stakeholders in the food and drink sector are the industry, the consumers and the government (Food Chain Strategy Division Food Standards Agency, 2012). The different stakeholders all have different goals.

2.1.1.1 Food and drink industry

The goal of the (food) industry is to make profit by providing safe food to the market. The food and drink industry is the producer, processor and/or seller of food and drink products. The European food and drink industry is an important pillar of the European Union (EU) economy. According to the 2011 annual report on data and trends of the European food and drink industry, the food and drink industry is the largest manufacturing sector in the EU in terms of turnover, value added and employment (Food Drink Europe, 2012 a). In terms of the number of companies in the EU, the food and drink industry is listed on the second place (Food Drink Europe, 2012 a). The ranking of global and European agri-food companies by food and drink sales from 2010-2011 can be observed in figure 2.1. Contradictory results can be seen between the World and European ranking of sales of the food companies. A contradictory example is that, in the world ranking of sales Heineken is ranked below Unilever. In the European ranking Heineken it is ranked above Unilever. The reason is probably that Heineken sells most of its products in Europe and Unilever also a lot outside Europe. The 2011 annual report contains information about the European food and drink industry in the year 2010. Facts about the European food and drink sector in 2010 are: turnover of 956.2 billion euro, value added of 2%, employment of 4.1 million direct jobs and many more indirect jobs; the industry consists of 274000 companies of which 99% are small or medium-sized. European countries that are the largest food and drink producers in 2010 are Germany, France, Italy, United Kingdom and Spain. The EU is also the largest food and drink exporter of the world with a value of 65.3 billion euro in 2010. The European Union market share of global exports of food and drink products has declined over the last years (from 20% in 2001 to 18% in 2010). This is beneficial for the upcoming food industries in Brazil, China, Thailand and Argentina. In terms of consumer expenditure, the first place is reserved for housing, water and energy with 23% in 2010. Food and non-alcoholic drinks are positioned on the second place with 13% in 2010. (Food Drink Europe, 2012 a).

Ranking of World Agri-food companies by Food and Drink sales

Name	Head-quarter	Fiscal year end	Sales in € billion	Net growth to previous year (%)	Employees (x1000)	Main sectors
Cargill	US	May11	88.8	18.0	130	*multi-product*
Nestlé	CH	Dec11	67.8	7.5	328	*multi-product*
Archer Daniels Midland	US	Jun11	60.2	24.0	31	*cereal processing*
PepsiCo Inc.	US	Dec11	47.8	15.0	285	*beverages, snacks*
Kraft Foods Inc.	US	Dec11	39.1[1]	6.6	127	*dairy, snacks, beverages*
The Coca-Cola Company	US	Dec11	33.4		146	*beverages*
Anheuser-Busch InBev	BE	Dec11	28.6	4.6	114	*beer*
Tyson Foods Inc.	US	Oct11	23.2	13.6	115	*meat*
Unilever Plc/Unilever NV**	NL/UK	Dec11	22.8	6.5	171	*multi-product*
Mars Inc.	US	Dec11	21.6		65	*prepared foods, confectionery*
SABMiller Plc	UK	Mar11	20.3	7.4	70	*beer*
Kirin Brewery Company Ltd	JP	Dec10	18.7	4.9	32	*beer, alcoholic beverages*
Heineken N.V.	NL	Dec11	17.1	6.1	64	*beer*
Groupe Danone	FR	Dec10	17.0	6.9	81	*dairy, waters, baby & med. nutrition*
Suntory Ltd.	JP	Dec10	15.0	12.4	25	*alcoholic beverages*
Lactalis	FR	Dec10	14.7		52	*dairy products*
Asahi Breweries Ltd.	JP	Dec10	13.4	1.2	17	*beer, alcoholic beverages*
Associated British Food	UK	Sep11	12.8	9.0	102	*sugar, starch, prepared foods*
Diageo Plc	UK	Jun11	11.4	3.0	24	*alcoholic beverages*
Fonterra	NZL	Jul11	11.3	19.0	17	*dairy products*
General Mills Inc.	US	May11	10.7	2.0	35	*prepared foods*
Kellogg Company	US	Dec11	9.5	6.5	31	*breakfast cereals, convenience food*
FrieslandCampina NV	NL	Dec10	9.0	10.0	19	*dairy products*
Vion	NL	Dec10	8.9	-2.0	27	*multi-products, ingredients*
ConAgra Foods Inc.	US	May11	8.8	1.8	23	*prepared foods*
Smithfield Foods Inc.	US	Apr11	8.8		46	*meat, processed foods*
Dean Foods Company	US	Dec10	8.7	3.3	26	*dairy products*
HJ Heinz Company	US	Apr11	8.1	2.8	35	*prepared foods*
Ferrero	IT	Aug11	7.2	9.1	22	*confectionery*
Sara Lee Corporation	US	Jun11	6.5	4.1	21	*prepared foods*

Ranking of European Agri-food companies by European Food and Drink sales

Name	Head-quarter	Fiscal year end	Sales in € billion	Net growth to previous year (%)	Employees (x1000)	Main sectors
Nestlé	CH	Dec11	12.4	4.0	95	*multi-product*
Heineken N.V.	NL	Dec11	11.0	0.0	36	*beer*
Lactalis	FR	Dec10	9.4		31	*dairy products*
Groupe Danone	FR	Dec10	9.4	1.9	46	*dairy, waters, baby & med. nutrition*
Associated British Food	UK	Sep11	8.7	10.1		*sugar, starch, prepared foods*
Unilever Plc/Unilever NV	NL/UK	Dec11	8.2	0.0	29	*multi-product*
Vion	NL	Dec10	8.0	-2.0		*multi-products, ingredients*
Carlsberg	DK	Dec10	7.6		14	*beer*
Danish Crown	DK	Oct11	7.0	14.0	24	*meat products*
Südzucker	DE	Feb11	6.2	8.0	18	*sugar, multi-product*
FrieslandCampina	NL	Dec10	5.9	3.5	13	*dairy products*
Oetker Group	DE	Dec10	5.8	13.7	26	*multi-product*
Nutreco	NL	Dec11	4.7		5	*meat products*
Anheuser-Busch InBev	BE	Dec11	4.1	4.6		*beer*
Barilla	IT	Dec10	3.9		14	*beverages, confectionery*
SABMiller Plc	UK	Mar11	3.5		14	*beer*
Diageo Plc	UK	Jun11	3.1	3.0	3	*alcoholic beverages*
Kerry Group	IR	Dec10	3.0	9.7	23	*multi-product*
Pernod Ricard	FR	Jun11	2.9	2.0	3	*alcoholic beverages*
Bongrain	FR	Dec10	2.8	8.9	14	*dairy products*
Barry Callebaut	CH	Aug11	1.8	-5.3	3	*confectionery*
Parmalat	IT	Dec11	1.2	4.4	2	*milk, fruit-based drink*
Ebro Foods	ES	Dec10	1.0	3.6		*rice, sugar, dairy*
Tate&Lyle	UK	Mar11	0.6[1]		2	*ingredients, prepared foods*

Figure 2.1: World and European agri-food companies by food and drink sales from 2010-2011 (Food Drink Europe, 2012 a)

During the recent economic crisis, the European food and drink industry remained stable. This can be derived from the following data. The output of the EU manufacturing industry decreased overall with 7.9%, while the output of food businesses increased with 1.3% from the first quarter of 2008 until the third quarter of 2011. The number of employees in the food and drink industry also decreased less compared to other manufacturing sectors (Food Drink Europe, 2012 a).

2.1.1.2 Consumer

The consumer is a person or group of people that are the final users of a product and/or services. Consumers play an important role in the economic system of a country. In the absence of their demand, the producers would lack a key motivation to produce. Nowadays the consumer wants to buy food products that are safe, convenient and have a high consistent quality in broad assortments during the whole year. They also want that the products have competitive prices (Trienekens & Van der Vorst, 2006). The consumer is increasingly concerned about the safety of food products, animal friendly husbandry and the natural environment. Even though food products are safer than ever before, the safety perception of consumers has decreased significantly (Trienekens & Van der Vorst, 2006).

2.1.1.3 Government

Concerning the food and drink sector, the government wants to protect consumer health and interests while guaranteeing the smooth operation of the single market. To obtain this objective, the government ensures that control standards are established and adhered to as regards food and food product hygiene, animal health and welfare, plant health and the prevention of the risk of contamination from external substances (Europa, 2012).

2.2 Food law

This part of the theoretical framework will start with information concerning foodborne diseases. The second part contains information about food law. The third part contains information on the compliance process of food businesses on food legislation. Finally information about the current main food regulatory issues at European food companies is provided.

2.2.1 Food borne diseases

Foodborne diseases are diseases obtained from the ingestion of unsafe food. Foodborne diseases are a worldwide growing public health problem, even in the most developed countries (World Health Organization, 2012). These diseases can range from diarrhoea to various forms of cancer and even death (World Health Organization, 2012). In some countries of the European Union, food borne diseases have reached epidemic proportions. At least 45000 illnesses and 32 deaths resulted from 5332 outbreaks of contaminated food in 2008 in the European Union (Food Safety News, 2010).

As already mentioned earlier in this theoretical framework, the food and drink sector is the largest manufacturing sector in the European Union in turnover, value added and employment. The food sector is rapidly internationalized. Nowadays retailers and food industries sell their products all over the world and buy their materials globally. This resulted in a growth of product assortment in the supermarkets. A large Western supermarket in the early 1990s has an assortment of on average 10000 products; in 2008 it had more than 30000 products. National and international governments responded by introducing new and more food legislation to ensure safe and animal friendly production, restricted pollution and to economize on the use of resources (Trienekens & Zuurbier, 2008).

2.2.2 Food law

To protect public health, to protect misleading of consumers and to obtain fair trade, food law has been introduced (Lugt et al, 2003 P:17). Van der Meulen and Van der Velde (2008 P:41) reported that the food sector is after automobiles and chemicals, the most regulated market in the European Union. Food law consists of administrative law and private law. Food law can be administrative law, because the rules focus on the relationships between public authorities and private persons. Authorities apply public power to limit or enable certain actions by private persons. Food law can also be private law, because food producers apply self regulation in which they use private law contracts or private law legal persons in addition to action by public authorities (Van der Meulen & Van der Velde, 2008 P:75). Food law is made at national, European and global level. The Warenwet is an example of a national general framework in the Netherlands with a large number of legislations, including legislation concerning food**.** A general framework for both national and community food and feed law in the European Union can be found in the General Food Law. A general framework for global legislation is a standard or advisory provision in The Codex Alimentarius (Lugt et al, 2003 P:37).

2.2.2.1 European Union food law

In the European Union, more than 4000 food laws exist (EU Food Comply, 2012). Both horizontal and vertical laws have been installed. Horizontal laws are laws which apply to a group of foods. Vertical laws apply to an individual food (EU Food Comply, 2012). European Union food law is supranational law. This means that if a new law is implemented in the European Union, the member states should apply the European food law within their national laws (Van der Meulen & Van der Velde, 2008 P:131). The legislation in the European Union has mainly been laid down at European level in

regulations and directives (Van der Meulen & Van der Velde, 2008 P:146). These European regulations and directives are only valid in the European Union. Regulations have direct effect in all the European Union member states. Directives set end results that must be adopted in the Member State(s). Directives may concern all the Member States or only some. Each directive has a date at which the national laws must be adapted. National authorities should change their laws to meet the goals, but they are free to decide how they will do this. Due to this approach the directives give national authorities space within the deadlines to take account of differing national situations (European Commission, 2012 a).

To protect public health, food safety is a minimum requirement of authorities for foods and is therefore not negotiable. The General Food Law states that food shall not be placed on the market if it is unsafe (Article 14, Regulation (EC) No 178/2002 of the European Parliament and the Council). This Regulation applies to all stages of production, processing and distribution of food and feed. It does not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption (Article 1 Regulation (EC) No 178/2002 of the European Parliament and the Council). Unsafe food is food that is injurious to health or unfit for human consumption, taking into account its purpose and the manner of its consumption (Regulation (EC) No 178/2002 art. 14).

2.2.3 The compliance of food companies

In the European Union, food companies have the obligation to comply with European Food Law. Compliance means that an organization operates in accordance with current laws. The European Union market consists of 27 member states and 6 countries that applied for a European Union membership (Europa, 2012). As national legislation may be different, compliance assurance is very complex for food companies (EU Food Comply, 2012). Experts say that the complexity and quantity of European Union food legislation has become such that it is next to impossible to obtain understanding without focussed education (Van der Meulen, 2009 P:31).

2.2.3.1 Difference in the response of firms to food safety legislation and other legislation

The response of firms on food safety legislation is different compared to the response of firms on legislation in general. One reason is that food safety is an issue of concern for consumers. Therefore the (strategic) response of food companies on new legislation is rapid. Legislation relating to food scares is implemented more quickly compared to legislation related to other areas (Loader & Hobbs, 1999). Another reason why the response of food companies on food safety legislation is different compared to other legislation is that the cost of food safety incidents can be huge, but the advantages arising from successful food safety may be relatively small. Consumers do not want to pay any extra for safe food (Loader & Hobbs, 1999). They expect the food to be safe. On the contrary, consumers are willing to pay more for positive food quality characteristics (Loader & Hobbs, 1999).

2.2.3.2 The compliance process of food companies on food safety regulation

The compliance process of food companies consists of several steps (Loader & Hobbs, 1999). These steps will be described in the sections below. Figure 2.2 schematically represents the steps.

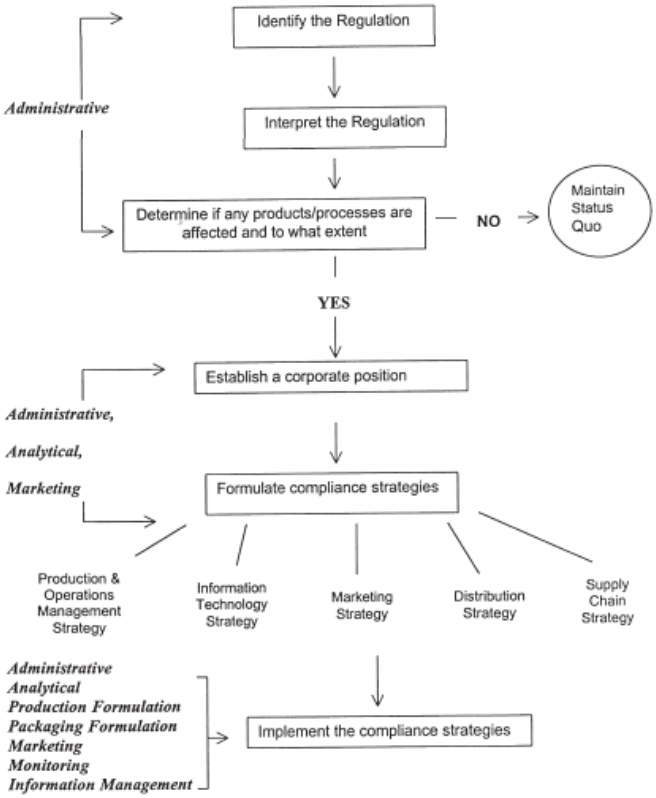

Figure 2.2: Strategic compliance process of food companies on new or a change in legislation (Loader & Hobbs, 1999)

2.2.3.2.1 Identification of the new or changed legislation

The compliance process starts when the firm becomes aware of new or changed legislation. Large firms often contain a department that is monitoring governmental regulations. Smaller firms often have one person for performing this monitoring activity (Henson & Heasman, 1998).

2.2.3.2.2 Interpreting of the new or changed legislation

The interpreting is done to establish whether any of the products and/or processes of the company are affected by new or changed legislation and to what extent this is the case (Loader & Hobbs, 1999).

2.2.3.2.3 Establish a corporate position

If interpreting shows that the food company is affected, it might establish a corporate position to support or oppose the proposed new or changed legislation. If the food company is against the new/change in legislation, it can try to lobby to have the legislation changed or removed. Lobbying is performed between the companies and authorities (Loader & Hobbs, 1999). Especially large sized food companies perform lobbying.

2.2.3.2.4 Formulate a compliance strategy

If lobbying does not work, a compliance strategy will be chosen. The method of compliance depends on the nature of the legislation (Loader & Hobbs, 1999).

2.2.3.2.5 Implement compliance strategy

Finally the new or changed legislation will be implemented in the food company.

Marcus (1984) reported that the company's response to new or changed legislation is different between companies. It can be divided in three main strategic choices:

- Stonewalling. This response includes that the firm ignores the problems created by the regulation.
- Opportunity seeking. This response includes that the food company sees the regulation as an opportunity to obtain competitive and other advantages.
- A mixed strategy. This response includes that a food company might be characterised by new product development and marketing.

Henson & Heasman (1998) reported that a company has different choices when a change in present food legislation or new food legislation occurs. Figure 2.3 represents a compliance decision tree including the choices available to firms when faced with changed or new food legislation.

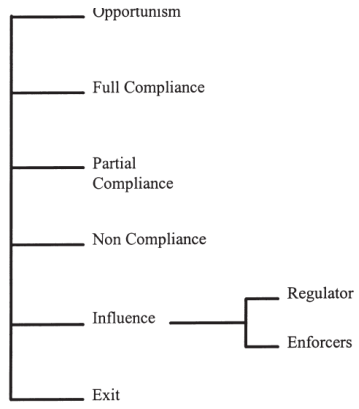

Figure 2.3: Compliance decision tree (Henson & Heasman, 1998)

Henson & Heasman, 1998 reported that a key factor that explains the difference in how food companies comply to new/change in legislation is firm size.

Informedness varies with business size. Large food companies often have a department or person responsible for food regulatory affairs. When regulatory affairs is part of the responsibilities of the quality assurance manager (mostly occurring in smaller companies), the level of knowledge seems adequate for compliance but not sufficient for proactive strategies (Van der Meulen, 2009 P:31).

There are significant differences in the compliance process between small-, medium sized and large food companies. Small and medium sized firms generally implement regulations at a later stage in the compliance process and are more likely to choose partial or non-compliance compared to large firms. Compliance with food safety legislation may also introduce larger costs for small companies compared to large companies, because small companies lack the economies of scale-advantage. Economies of scale is the increase in efficiency as the number of produced products increases (and thus the size of the firm is bigger). Further, large firms are generally more able to comply with regulations due to better resources. This may result in a competitive advantage (Henson & Heasman, 1998).

Yapp & Fairman investigated in 2006 the compliance of small and medium sized companies (SMEs) in Europe by means of empirical research undertaken within the area of food safety. The main barriers

to regulatory compliance to food safety regulations within SMEs are schematically represented in figure 2.4. The factors that motivate SME's to comply with food safety regulations are schematically represented in table 2.1.

The main barriers that prevent regulatory compliance within SMEs are (Yapp & Fairman, 2006):

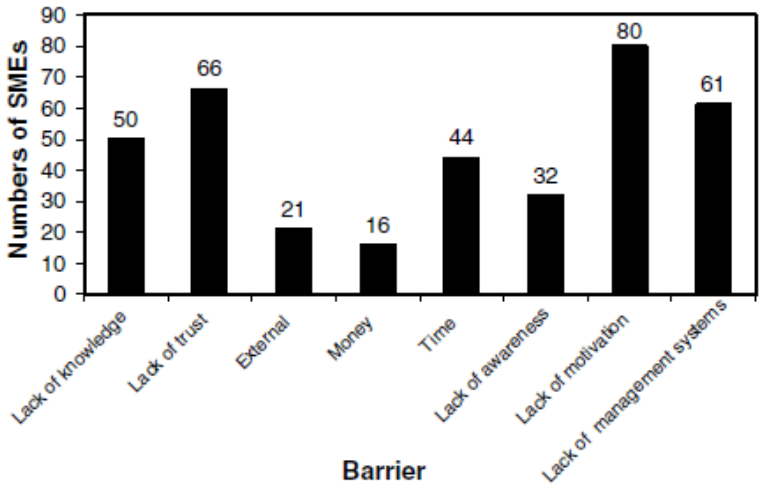

Figure 2.4: Barriers to compliance of SMEs in Europe (Yapp & Fairman, 2006)

The factors that motivate SMEs to be compliant to food safety regulations are schematically represented in table 2.1 (Yapp & Fairman, 2006).

Table 2.1: Factors that motivate SME's to comply with food safety regulations (Yapp & Fairman, 2006)

Drivers to environmental performance	
Issue of importance to UK SMEs	% considering this an issue
Legislative requirement	55
Industrial standards compliance	48
Environmental protection	39
Insurance requirements	30
Customer pressure	29
Improve business efficiency	27
Employee pressure	22
Investor pressure	3

It can be observed that lack of motivation is the biggest barrier for SMEs to comply with food law. It can also be observed that the biggest motivator for SMEs to comply with food law is the legislative requirement.

2.2.3.3 Multi-annual control plan of the Dutch new food and Consumer Product Safety Authority

In the Netherlands, the Dutch Food and Consumer Product Safety Authority (NVWA) uses a multi-annual control plan to check on and improve the compliance of food companies. The program is soft where possible and tough were necessary (figure 2.5) (Jeuring, 2012). The program includes:

- Industry's own responsibility to comply
- Risk based approach

- More compliance assistance
- More based on confidence
- Bonus/penalty principle
- More transparency

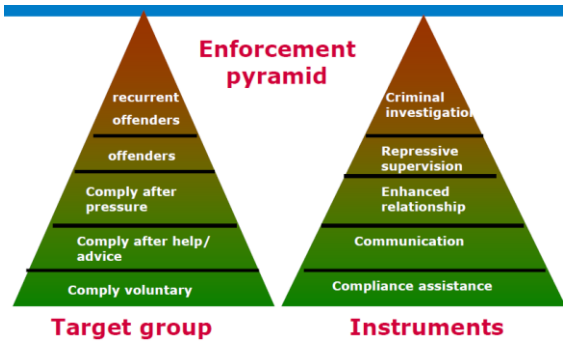

Figure 2.5: Enforcement pyramid (Jeuring, 2012).

The Dutch Food and Consumer Product Safety Authority reported that nowadays in the Netherlands an improvement of compliance of food companies is present (figure 2.6).

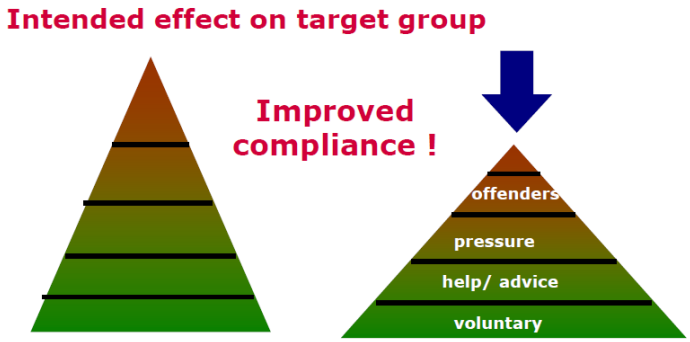

Figure 2.6: Improved compliance of food companies (Jeuring, 2012)

2.2.4 The current main food regulatory issues at European food companies

The food regulatory issues that are present in food companies depend on the structure of the food company itself. Factors that contribute to a difference in food regulatory issues in companies are: its production sector, its availability of money, its size, its national or international behaviour and its conservative or pro-active attitude. The (as a starting point) observed food regulatory issues within European food companies were obtained from an initial interview (2012) that was performed with an anonymous food regulatory affairs manager working at a large food company, supplemented by literature (Van der Meulen & Van der Velde, 2008 P:251). Based here on, the main food regulatory issues can be divided into two classes, namely product/ingredient and product presentation. Table 2.2 represents the main food regulatory issues in European food companies. The food regulatory issues will further be discussed in this the next section.

Table 2.2: Main food regulatory issues in European food companies (Anonymous, 2012)

Categories	Main food regulatory issues
Product/ingredient:	Food additives
	Food enzymes
	Flavourings
	Vitamins and minerals
	Novel ingredient/food
	Microbiological safety
	Nano technology
	Genetically modified food
Product presentation:	Nutrition and health claims
	Ingredient and nutrition labelling
	Food contact materials

2.2.4.1 Food additives

The food industry needs food additives for technological purposes. Some examples of the use of additives for technological purposes are: enhance appearance, preserve flavour and maintain quality and shelf-life of the food. Currently consumers wish food that encompasses all these properties. Food additives will be active in the food during manufacture, processing, preparation, treatment, packaging, transport or storage of the food. Examples of food additives are:

- Antioxidants
- Colours
- Emulsifiers
- Preservatives
- Stabilisers
- Sweeteners

Food additives are regulated in regulation EC 1333/2008. This regulation sets rules on: definitions, conditions of use, labelling and procedures (European Commission 2012 b).

2.2.4.2 Food enzymes

Food enzymes are products obtained from plants, animals or micro-organisms. The food industry needs food enzymes (including enzymes used as processing aids) for technological purposes. Regulations concerning food enzymes are as follows. Regulation (EC) 1332/2008 on food enzymes harmonises rules in the European Union. Regulation EC 1331/2008 establishes the common authorisation procedure for food additives, food enzymes and food flavourings. Regulation EU 234/2011 as amended by Commission Implementing regulation (EU) No 562/2012 implements the common authorisation procedure and applies from 11 September 2011 onwards (European Commission, 2012 b).

2.2.4.3 Flavourings

The food industry uses flavourings, to give and/or change the odour or taste of a product. Currently consumers prefer food with continuously changing flavours. Flavourings and certain food ingredients with flavouring properties for use in and on foods are regulated in regulation (EC) No 1334/2008 (European Commission, 2012 b).

2.2.4.4 Vitamins and minerals

Nowadays the consumer demands the availability of healthy products. Vitamins include organic substances made by plants or animals. Minerals are inorganic elements that come from the soil and water. The human body needs vitamins and minerals to grow and stay healthy. Vitamins and minerals can be divided in two groups: vitamins and minerals added to foods and food supplements.

Regulation 1925/2006 harmonises the provisions laid down in Member States which relate to the addition of vitamins and minerals and of certain other substances to foods. Annex I of the regulation is a list of vitamins and minerals which may be added to foods. Annex II is a list of the sources of vitamins and minerals which may be added to foods. Annex I and Annex II have been amended by Commission regulation (EC) 1170/2009 and by Commission regulation (EU) No 1161/2011 to include additional substances. Annex III includes a list of substances whose use in foods is prohibited, restricted or under Community scrutiny. Only vitamins and/or minerals listed in Annex I, in the forms listed in Annex II, may be added to foods (European Commission, 2012 b).

Food supplements are concentrated sources of nutrients or other substances with a nutritional or physiological effect whose purpose is to supplement the normal diet. They are marketed as pills, tablets, capsules, liquids in measured doses. Annex II of Directive 2002/46/EC is a list of permitted vitamin or mineral preparations that may be added for specific nutritional purposes in food supplements. It has been amended by Commission Directive 2006/37/EC, Commission Regulation (EC) 1170/2009 and Commission Regulation (EU) No 1161/2011 to include additional substances. The trade of products containing vitamins and minerals not listed in Annex II has been prohibited from the 1st of August 2005 (European Commission, 2012 b).

2.2.4.5 Novel food/ingredient

Foods and food ingredients that have not been used for human consumption in the European Union before 15 May 1997 are called novel foods and novel food ingredients. They must be safe for consumers and properly labelled to not mislead consumers. This category is of interest to the food industry, because consumer demand for innovative products with respect to health benefits is increasing. Novel foods and novel ingredients are regulated in regulation (EC) 258/97 (European Commission, 2012 b).

2.2.4.6 Microbiological safety

Pathogenic bacteria, parasites, viruses and prions are biological hazards. These hazards may introduce serious risks to public health. Therefore exposure of humans through food should be prevented. To regulate the biological safety of foods regulations and directives exist. The hygiene rules were adopted in April 2004 by the European Parliament and the Council. They became applicable on 1 January 2006. They are provided for in the following key acts (hygiene package):

- Regulation (EC) No 852/2004: Hygiene of foodstuffs
- Regulation (EC) No 853/2004: Specific hygiene rules for food of animal origin
- Regulation (EC) No 854/2004: Official controls on products of animal origin
- Directive 2004/41/EC: repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC, 21 April 2004 (European Commission, 2012 b).

2.2.4.7 Nano technology

Nanotechnology is a technology that manipulates materials at molecular level. A nanometer is equal to one billionth of a meter (1×10^{-9} m). Due to this technology, materials obtain new properties. The first applications of nano materials are in packaging materials of food products, like plastic bottles. Another example of nanotechnology in the food industry is nanostructures like nano emulsions in mayonnaise or margarine. It is demonstrated that nano materials do not migrate from plastic into the food (Rijksinstituut voor Volksgezondheid en Milieu, 2012). Currently, there are several pieces of EU legislation and technical guidance supporting the implementation of legislation with specific references to nano materials. To ensure conformity across legislative areas, where often the same materials are used in different contexts, the European Commission adopted the Recommendation on the definition of a nano material on 18 October 2011. The Commission intends to use the overarching definition outlined in the Recommendation as a basis to amend the current definition in the Regulation on Food Information to Consumers (Food Drink Europe, 2012 b)

2.2.4.8 Genetically modified food

With genetically modified organisms (GMOs) and genetic modification techniques the characteristics of an organism are modified to give it a new property. Genetically modified (GM) food is food that contains or consists of GMOs, or is produced from GMOs. GM foods are sold, because this is advantageous for the producer (higher returns) or consumer (better food properties). The food product can be sold with a lower price, can have a greater value (with respect to nutrition or durability) or can have both. GM food has been regulated in (EC) 1829/2003. The regulation is supplemented by regulation (EC) 1830/2003 which ensures traceability and labelling of GMOs and products produced with a GMO that is placed on the market. Directive 2001/18/EC on the deliberate release of GMOs into the environment outlines the principles for, and regulates, experimental releases and the placing on the market of GMOs in the European Union (European Commission, 2012 b).

2.2.4.9 Nutrition and health claims

A statement about a relationship between food and health is called a health claim. A nutrition claim is a claim which reports that a food has beneficial nutritional properties. This category is of interest to the food industry, because consumer demand for products with health benefits grows. Nutrition and health claims have been regulated in (EC) No 1924/2006 (European Commission, 2012 b).

2.2.4.10 Food information to consumers

Food information to consumers rules are made to enable European consumers to obtain an informed choice on food products. In 2011 a new regulation concerning food information to consumers ((EU) 1169/2011) was accepted. The rules of this new regulation will apply from 13 December 2014. The obligation to provide nutrition information will apply from 13 December 2016 onwards. Nowadays food producers have to change all information on the food products according to this new regulation. Therefore this is probably the most urgent regulatory issue of food companies. The new regulation (EU) 1169/2011 on the provision of food information to consumers changes existing legislation on food labelling including:

- Obligatory nutrition information on processed foods
- Origin labelling of fresh meat from pigs, sheep, goats and poultry
- Highlighting allergens e.g. peanuts or milk in the list of ingredients

- Better legibility i.e. minimum size of text
- Requirements on information on allergens also cover non pre-packed foods including those sold in restaurants and cafés (European Commission, 2012 b)

2.2.4.11 Food contact materials

Materials that are intended to come into contact with foods are food contact materials. Examples of food contact materials are:

- Packaging materials
- Cutlery and dishes
- Processing machines
- Containers
- Materials and articles in contact with water for human consumption

Food contact materials are regulated by:

- Framework regulation EC 1935/2004 - general requirements for all food contact materials Legislation on specific materials - groups of materials and articles listed in the Framework Regulation
- Directives on individual substances or groups of substances used in the manufacture of materials and articles intended for food contact
- National legislation covering groups of materials and articles for which European Union legislation is not yet in place (European Commission, 2012 b)

2.3 Regulatory affairs in companies

This part of the theoretical framework will start with information concerning the rise of the regulatory affairs profession in companies. Then information regarding regulatory affairs organization in pharmaceutical companies will be given. Due to a lack of literature concerning regulatory affairs in food companies, almost no information about this profession in the food industry is available. Therefore it was looked for information about regulatory affairs in pharmaceutical companies, as the organisation regarding pharmaceuticals may be similar to food.

2.3.1 The rise of the regulatory affairs profession in companies

After the First World War (started 28 July 1914 and lasted until 11 November 1918), the first legal departments arose at large companies like Unilever, Shell and Philips. Hereafter the number of legal departments increased continuously (Van Leeuwen et al., 2009 P:15). The legal department is a part of the company where the legal work for the company itself will be performed by company lawyers. A company lawyer is a person that has a degree in law and who applies it in a company (Nationale Beroepengids, 2012). Legal departments were mostly found in for-profit organizations, but nowadays an increasing number is also employed in non-profit organizations (Van Leeuwen et al., 2009 P:15). Subsequently, in 1970 the first health related regulatory affairs profession/department was established in the United States. In the late 1980s the demand for regulatory affairs professionals increased and the profession was recognized internationally (Keramidas, 2003). In 1991 the Regulatory Affairs Certification (RAC) was introduced. The RAC offers examinations for United States and European regulatory processes. In 2003, worldwide more than 3000 professionals had a RAC certificate (Keramidas, 2003). According to a pilot study of Coen en Willman (1998) that was performed in English water, rail and electricity companies, the evolution of the regulatory affairs department within businesses follows four stages. These four stages are represented in figure 2.7 (Coen & Willman, 1998). The pilot study of Coen en Willman (1998) involved interviews with

members of regulatory departments in three companies within each of the three sectors mentioned above. In this pilot study Coen en Willman (1998) researched how firms deal with regulators, how regulatory affairs departments operate, where the regulatory affairs departments are located and what the best practice is when dealing with regulators. The results of the pilot study of Coen & Willman (1998) are described below.

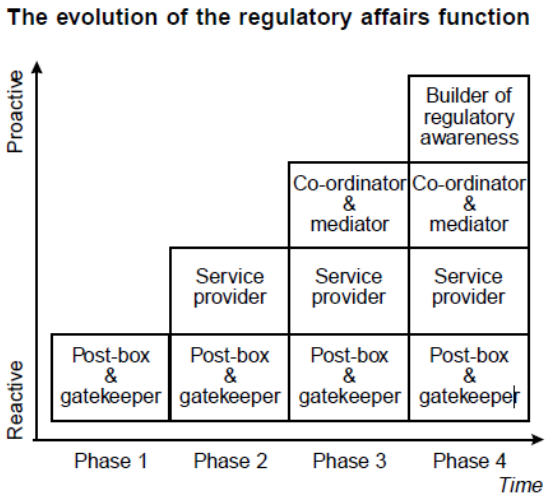

Figure 2.7: The evolution of the regulatory affairs function (Coen & Willman, 1998)

Coen & Willman (1998) reported that the first stage of the evolution of the regulatory affairs profession within businesses can be called the 'ad hoc period'. In this stage the firm was reactive towards regulatory issues. No regulatory profession was present within businesses and therefore regulation was a shared responsibility. Consequently there was no clear regulatory hierarchy and no regulatory point of contact present in the business. Due to the lack of regulatory accountability within firms an atmosphere of mistrust developed between the regulator and businesses (Coen & Willman, 1998).

The second phase is the period characterised by 'the emergence of a regulatory profession within the organization' (Coen & Willman, 1998). In this phase the regulatory affairs profession arises. The new profession was reactive in its cooperation with the regulator. High levels of tension between regulatory affairs managers and strategic affairs managers were present, because regulatory affairs managers wanted to block or discourage strategic initiatives which resulted in a regulatory risk. The regulatory affairs manager did also not recognise the benefits of having close contact with the regulators. Consequently firms failed to get regulatory opportunities that will arise from maintaining close informal relationships with the regulator (Coen & Willman, 1998).

The third phase is called 'strategic regulation' (Coen & Willman, 1998). In this phase firms realise that they could obtain benefits from having good contact and close working conditions with the regulator. The attitude emerged to not only respond effectively to the regulator, but also to influence (by means of lobbying) the adoption of new legislation. The regulatory affairs profession consequently became proactive (Coen & Willman, 1998).

Coen & Willman (1998) reported that nowadays we are probably in the phase of 'regulatory awareness within the whole company'. In this phase the regulatory affairs behaviour is proactive

(oriented towards avoidance of problems). Businesses that have a regulatory affairs profession have fewer regulatory conflicts (Coen & Willman, 1998).

2.3.2 Regulatory affairs in pharmaceutical companies

Due to the lack of literature concerning regulatory affairs in food companies, almost no information about this profession in food can be found in literature. Therefore this section focuses on regulatory affairs in pharmaceutical companies.

2.3.2.1 The activities of regulatory affairs in pharmaceutical companies

Regulatory affairs professionals are active in industry, governmental organizations and in academic research (Keramidas, 2003). Most of the regulatory affairs professionals are employed in the medical and pharmaceutical sector (Topra, 2011) & (Nationale Beroepengids, 2012). The goal of pharmaceutical regulatory affairs professionals in companies is to protect human health, to ensure safety, efficacy and quality of medicines and to ensure appropriateness and accuracy of product information (Regulatory One 2012). In the section below the three main activities of the regulatory affairs professional in pharmaceutical companies are pointed out.

1) Regulatory affairs professionals have the responsibility to ensure that products made by their company comply with the current legislation. They have to keep track of the continuously changing legislation affecting their business (Topra, 2011).
2) Regulatory affairs professionals give the appropriate regulatory advice to the company (Topra, 2011).
3) Regulatory affairs professionals communicate with regulatory agencies regarding product information or issues on specific topics that are affecting their business. This is done to lobby, to obtain better relations and avoid conflicts between the company and governmental agencies (Onetonline, 2011) & (Ehow, 2012).

Regulatory affairs professionals should avoid regulatory problems within the company. The regulatory affairs professional is central to the company and could closely work together with a broad variety of specialties (Topra, 2011). Examples of pharmaceutical regulatory affairs activities will be described in the following sections.

Regulatory affairs professionals are mainly involved in the process of research and development and medicine approval. They give advice and support in the stages of design, monitoring of clinical studies, marketing (approve packaging), advertising, communication and medicine approval (Keramidas, 2003). To avoid problems of internationally sold medicines, regulatory affairs professionals should also be aware of the international legislation (Topra, 2011).

Regulatory affairs activities are of economic importance for the company, because they play an important role in the reduction of time of a new product to reach the market. In the competitive environment of today this is critical for the product and the businesses' success. Inadequate information provision on a new product by marketing should be noticed by the regulatory affairs professional, because this can result in a delay of bringing the product on the market. This delay will possibly cause big financial losses. Another example is that of a product sold with an incorrect label. Regulatory affairs should advise the marketing department to change the label to obtain compliance with the current legislation. Otherwise this can result in a recall which can cost several millions of

units of sales and the trust of the customers. Therefore, a good regulatory affairs professional will have a 'first time right approach' (Topra, 2011).

The differences between food and pharmaceutical regulatory affairs in The Netherlands are:

- Different legislation is used. Medicine legislation is stricter and more detailed. There are more controls of compliance with medicine legislation. The authorisation procedures of new medicines are stricter (Geneesmiddelenwet, 2007).
- The fines connected to non-compliance with the medicine law are higher compared to the food law. Standard fines per violation at food legislation in the Netherlands vary from €525,00 till €2.100,00 (depends on the size of the company). Standard fines per violation at medicine legislation vary from €450,00 till €450.000,00 (Nederlandse Voedsel -en Waren Autoriteit, 2012).

2.3.2.2 The characteristics of the regulatory affairs professional in pharmaceutical companies

The regulatory affairs professional should contain knowledge about law and science. The Regulatory Affairs Professionals Society (RAPS) (2011) reports that most of the regulatory affairs professionals have a technical bachelor degree. Contradicting results about the study degree can be found in other literature sources. Keramidas (2003) reported that at least 60 percent of the regulatory affairs professionals have a master degree and almost 20 percent a PhD degree. Over 85 percent of the regulatory affairs professionals have a degree in life sciences, clinical sciences or technical sciences.

Regulatory affairs is an attractive profession, because of the diversity of the job, its central role and the opportunity for professional growth (Keramidas, 2003). Regulatory affairs professionals usually have already experience in other jobs before starting in regulatory affairs (Regulatory Affairs Professionals Society, 2011). Often, in companies, employees get additional training to grow in a regulatory affairs profession (iseek, 2012). Job experience is a key advantage to become a regulatory affairs professional.

Personal characteristics that are important to become a regulatory affairs processional are: communication skills, understanding legal and scientific matters, attention for detail, analytical frame of mind, high degree of sensitivity, the ability to spread trust and confidence and project management skills (Topra, 2011).

In the Netherlands, the salary of a regulatory affairs manager is between 65000 and 80000 euro per year (Expat jobs, 2012). A survey by CenterWatch on employment trends in the clinical trials industry shows that the regulatory affairs professional is the position with highest demand and with the fastest growth rate (Gundersen, 2002). The reasons for this are the lack of candidates, increased number of companies and increased turnover. Those interested in entering the regulatory affairs field should search for the proper training in order to come up to the demand for qualified regulatory affairs professionals. Recently, graduate programs in regulatory affairs have been established (Gundersen, 2002). A growth of regulatory affairs managers can be observed in the United States of America (table 2.3).

Table 2.3: Employment outlook for regulatory affairs managers in the USA (Expat jobs, 2012)

Employment Outlook for regulatory affairs managers				
	Employment		Employment Change	
	2010	2020	Number	Percent
U S A	828.100	893.500	65.400	7,9%

2.3.2.3 Become a successful regulatory affairs professional

In this section of the theoretical framework, Gundersen's (2002) opinion is described concerning how to become a successful regulatory affairs professional.

Grow and keep learning. Gundersen (2002) states that in order to become a successful regulatory affairs professional, knowledge about the current regulation affecting the business is crucial. This can be achieved in different ways. Nowadays internet is a very good source for regulatory literature. Also regulatory journals contain a lot of useful information. Subscribe for a journal that seems helpful and consider the impact of every new regulation on the business. Another way to keep up to date with the current legislation is to subscribe for courses or regulatory meetings (Gundersen, 2002). This can be done at universities or private businesses.

Teamwork. Gundersen (2002) states that teamwork of the whole company is needed to successfully develop a new pharmaceutical product that is in compliance with the current legislation. Therefore the regulatory affairs professional should be a team player who has strong personal relations. To obtain strong relations with everybody in the team, personal interest and knowledge about every personal team member is needed. He should show interest in their work and also explain to them what the responsibilities of the regulatory affairs professional are (Gundersen, 2002).

Share regulatory knowledge. Gundersen (2002) also mentioned that to obtain better results it is better to share knowledge with the team members. If team members understand the importance of regulatory issues, it will encourage them to apply this in their jobs. Consequently better results will be obtained already early in the process. Ways to share regulatory information are providing copies of new regulations or organise an informative lunch (Gundersen, 2002).

Networking. Gundersen (2002) also states that networking is important for a regulatory affairs professional. Discussion groups, branch organizations and other organizations can be attended for informal networking. Information on experiences of regulatory affairs professionals at other companies can help solving regulatory issues in the own company. A balance should be struck between sharing enough information and the confidentiality of this information (Gundersen, 2002).

Staff development. Finally, Gundersen (2002) suggests that the best regulatory affairs department is a department in which all the staff members are regulatory experts that are working together. Regulatory affairs experts should be sent to meetings and courses. Often department meetings should be organised, not only to discuss regular business and scheduling, but also to share the regulatory information within the whole department. Every employee who attended a course should be asked to write a report and share this new information with the whole department (Gundersen, 2002).

3. Initial interview

3.1 Regulatory affairs in food companies

In order to provide for a starting point on regulatory affairs in the food sector, an initial interview about food regulatory affairs was performed with a food regulatory affairs manager working at a large food company. The results of this interview are described in this chapter. The results are used to have some fundamental knowledge with respect to food regulatory affairs and next to design the first questionnaire.

3.1.1 The regulatory affairs activities in a food company

The interviewed food regulatory affairs manager said that in his company the food regulatory affairs professional only deals with food and food quality related legislation. With food quality legislation is meant for example HACCP, ISO, GMP etc. The three main activities of this food regulatory affairs professional are: knowledge gathering with respect to food law, informing internally about food law and creating a fit of the goals of the company and public authorities. These main activities are schematically represented in figure 3.1 and will be further described in the next sections.

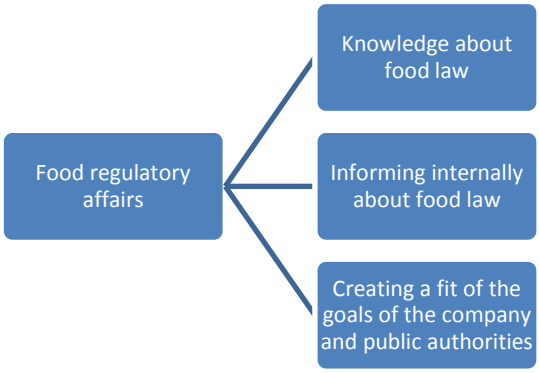

Figure 3.1: Main activities of an interviewed food regulatory affairs manager (Anonymous, 2012)

3.1.1.1 Knowledge about food law

National food law should comply with European food law. The interviewed food regulatory affairs manager said that therefore especially knowledge about European food law is needed. According to the interviewed food regulatory affairs manager, also some knowledge on global rules like in the SPS Agreement and Codex Alimentarius are needed. Another important issue for the regulatory affairs professional in his company is to have knowledge about the attitude towards food legislation of different European Union member states. France and Germany are examples of member states that rely more on national than international rules, compared to for example the Netherlands. Less national rules leave more space for the interpretation of food companies (Anonymous, 2012).The interviewed food regulatory affairs manager said that the food regulatory affairs professional in his company should keep knowledge about current legislation up-to-date. In his company, the regulatory affairs professional acquires knowledge especially by attending courses and organizations. From attended courses new knowledge about food legislation can be obtained. Joining clubs/organizations is beneficial for the network of the food regulatory affairs professional. At meetings in organizations food regulatory affairs professionals from different food companies inform and advise each other on regulatory issues affecting their businesses (Anonymous, 2012).

3.1.1.2 Informing internally about food law

The interviewed food regulatory affairs manager interprets the legislation and consequently advises internally about what regulatory actions and regulatory risks can be taken. Food legislation can be interpreted in different ways and this leaves space for own interpretation. The interviewed regulatory affairs manager is inclined to take minor regulatory risks, because otherwise the company cannot make a profit anymore. Often large companies do not want to take risks, because it can spoil their image. If an incident occurs, they will experience losses on their profit and image. If a change in legislation occurs that affects the company, a meeting will be organised to inform the personnel. The regulatory affairs manager will consequently inform and advice the affected department on how to comply with the new legislation (Anonymous, 2012).

3.1.1.3 Creating a fit of the goals of the company and public authorities

The interviewed food regulatory affairs manager is the link between the government and the company with respect to food regulatory affairs (figure 3.2). His aim is to find a balance between the governmental wishes and the company desires. Finding this balance often results in internal and external discussions, tensions and conflicts. Companies have other goals than public authorities. If companies comply in everything to the law and do not take any risk, it is difficult for a company to make a profit (Anonymous, 2012). Companies wish to make a profit and therefore risks have to be taken. It is impossible for authorities to regulate everything. So there still exists a margin of freedom for interpretations of food law. The interviewed food regulatory affairs manager said that his responsibility is to make the products of the company compliant to the current food legislation, but with an interpretation that is still positive for the company (Anonymous, 2012).

Figure 3.2: The position of the food regulatory affairs professional (Anonymous, 2012)

3.1.2 Demarcation of the food regulatory affairs profession

The interviewed food regulatory affairs manager said that probably most of the small food companies will not maintain a separate food regulatory affairs profession. A small company has a limited amount of food regulatory affairs activities and also a lack of money to pay the food regulatory affairs professional. Consequently, often the quality manager includes the food regulatory affairs activities in his/her work (Anonymous, 2012). As described above, the interviewed food regulatory affairs manager only deals with food and quality related legislation. Therefore for example environmental, quality and legal issues are dealt with in different departments within his company. In the company of the interviewed food regulatory affairs manager, a difference exists between legal and regulatory affairs. In his company the legal department deals with problems that are not only food-related. Some examples of issues dealt with by the legal department are: contracts for employees, trade contracts and licenses, product liability and insurances. Almost all the employees at the legal department have a degree in law. Most of the food regulatory affairs employees in his

company have a technical background. The quality department only deals with legislation concerning quality. The interviewed food regulatory affairs manager handles all the food legislation concerning the company, including quality legislation. The quality department in his company has an executive task. The interviewed food regulatory affairs manager informs the quality department if a big change in legislation occurs and the quality department has to implement it. The same is true for the other departments in the research and development process within the company (Anonymous, 2012).

3.1.3 The characteristics of the regulatory affairs professional in food companies

The interviewed food regulatory affairs manager said that almost all the food regulatory affairs professionals in his company have a technical background in food science. He said that he started working in quality assurance. Consequently he continued his career in the field of food regulatory affairs (Anonymous, 2012). The interviewed food regulatory affairs manager said that the most important personal characteristics that are needed to become a food regulatory affairs professional in his company are flexibility, convincing power and demarcation of own boundaries. With the personal characteristic demarcation of own boundaries is meant that the food regulatory affairs professional should prevent from getting overruled by others that have a different opinion. Being flexible is important, because the daily work is never the same. A regulatory issue can become manifest at any time, which may have a bigger importance than the current work (Anonymous, 2012).

3.1.4 First conclusion about food regulatory affairs

As already said at the beginning of this chapter, the results from this initial interview are used to have some starting level on food regulatory affairs and on that basis to design the first questionnaire. In this section a first conclusion about the content of the food regulatory affairs profession will be drawn, using the answers of the interviewed regulatory affairs manager. This first conclusion will be described in the next section.

Food regulatory affairs deals with food and quality related legislation. The legal, quality and food regulatory affairs professions all deal with legislation, but differences exist. The legal department deals with legislation that is not only food related. The quality department only deals with legislation concerning quality. The quality department has an executive task concerning quality legislation. Food regulatory affairs regards all the food legislation within the company, including quality legislation. The main activities of the food regulatory affairs professional are knowledge about food law, informing internally about food law and creating a fit of the goals of the company and public authorities. Almost all food regulatory affairs professionals have a technical background. The most important personal characteristics that are needed to become a food regulatory affairs professional are flexibility, convincing power and demarcation of own boundaries.

4. Construction of the questionnaire

4.1 The questionnaire

By making use of the information obtained from the theoretical framework and from the initial interview, a first questionnaire concerning the organization of the food regulatory affairs activities within food businesses was constructed. The questionnaire is included in appendix 1. The questionnaire is split up in three parts.

The first part contains questions about the characteristics of the person who performs the food regulatory affairs activities within the food company. These questions are asked to obtain information about the career path of that person. The questions are about his/her education, about how the respondent obtained his/her knowledge with respect to food law, how he/she keeps up to date with the current legislation and what personal characteristics are important to perform the food regulatory affairs activities.

The second part of the questionnaire especially contains questions about the activities of the person who performs the food regulatory affairs activities within the food company.

The final part includes questions on the organizational position of the person who performs the food regulatory affairs activities in the food company. In this part questions about the organizational structure (hierarchy), the amount and the background of the employees that perform food regulatory affairs activities will be asked.

An explanation about the selection of questions for the questionnaire can be found in following sections.

4.2 Explanation about the selection of questions

4. 2.1 Characteristics of the person who performs the food regulatory affairs activities within the food company

The goal of the first two questions is to obtain information about the career path of the persons who perform food regulatory affairs activities in food companies. The regulatory affairs manager in the initial interview (Anonymous, 2012) said that most of the regulatory affairs persons in his company have a technical background. At the end of the interviews it can be concluded if indeed the major part of food regulatory affairs professionals has a technical background. Also information will be obtained about how he/she got the information to perform food regulatory affairs activities. Persons that perform regulatory affairs activities usually have experience in other professions before starting in regulatory affairs (Regulatory Affairs Professionals Society, 2011).

With question three it will be tested whether working experience is needed to perform food regulatory affairs activities. With this information it can be researched whether recently graduated persons can directly start in food regulatory affairs.

Question four will ask information about the personal characteristics and competences that are necessary to perform food regulatory affairs activities. With this question information is obtained about how the new master in food regulatory affairs should train its students.

4. 2.2 The food regulatory affairs activities within the food company

In the initial interview information about the main food regulatory affairs activities was obtained. Due to this information a framework categorizing the main food regulatory affairs activities was designed. The framework is included in the questionnaire. Question five will check what the (main) food regulatory affairs activities, powers, responsibilities and communication patterns are in the different food companies.

Question six is asked to obtain information about how the time is split up over the different activities listed in question five. Consequently, insight is obtained in the division of time between the different main food regulatory affairs activities in food companies.

With the initial interview information about the food regulatory topics/issues was obtained. Using this information a table about the food regulatory topics/issues was made. The figure is added in the questionnaire. Question seven will check what the main food regulatory affairs topics/issues are in the food companies.

There exists no information about the exact demarcation of the food regulatory affairs activities compared to other professions within food businesses. Therefore question eight is asked.

Coen & Willman (1998) reported that earlier no regulatory awareness existed in companies. They also reported that nowadays companies are in a phase of regulatory awareness. To test if this is correct for food companies, question nine is asked.

It is a challenge for the food regulatory affairs professional to find a balance between the needs of the company and of the government (Anonymous, 2012). With question ten, information will be obtained how this balance is created by the person(s) who perform food regulatory affairs activities.

Question eleven and twelve are asked to get more information about the food regulatory affairs activities within food companies. These questions ask how the person who performs food regulatory affairs activities would react on specific situations.

To find out what the difference is in activities between food regulatory affairs managers and food regulatory affairs officers, question thirteen is asked.

Coen & Willman (1998) reported that in the past the attitude of the regulatory affairs department was reactive. Nowadays the behaviour changed towards proactive. To test if this is indeed the case in food companies, question fourteen is asked.

Food regulatory affairs activities can be outsourced to consultants. To investigate what kind of food companies use outsourcing (small, medium or large), the reason, what activities are outsourced and how the communication and risks are divided question fifteen is asked.

4.2.3 Position of food regulatory affairs within the food company

To obtain information about the position of the person that performs food regulatory affairs activities within a food company, questions sixteen and eighteen are asked.

Question seventeen is asked to understand how the food regulatory affairs department (if present) divides the food regulatory affairs activities.

Regulatory affairs within the biomedical/health products sector is a relatively young profession (Keramidas, 2003). To test this for the regulatory affairs profession in the food sector, question nineteen is asked.

The Regulatory Affairs Professionals Society (Regulatory Affairs Professionals Society, 2011) reported that most of the regulatory affairs professionals have a bachelor degree, commonly in a technical field. Keramidas (2003) gave contradicting information and reported at least 60 percent of the regulatory affairs professionals have a master degree and almost 20 percent a PhD degree. Question twenty will investigate which information is correct for the persons that perform food regulatory affairs activities in food companies.

5. Results

In this chapter the results of the interviews about the organization of food regulatory affairs activities at food companies will be described. The results of each interview will be described in a separate case. The results are described in the order of the interviews. Each interview starts with a small introduction. The results of the empirical research (15 interviews) take too many pages to include in this chapter. Therefore the results are added in appendices 3-17. The characteristics of the interviewed food companies can be found in table 5.1.

Table 5.1: Overview of the characteristics of the interviewed food companies

	Size of the company	Business to consumer or business to business company	Integrated food regulatory affairs profession?
1)	Medium sized	Business to consumer company	Yes
2)	Large	Business to consumer company	Yes
3)	Large	Business to business company	Yes
4)	Large	Business to consumer company	Yes
5)	Large	Business to business company	Yes, but the respondent also works on quality assurance and safety activities
6)	Large	Business to consumer company	No, the food regulatory affairs activities are divided over employees in the company
7)	Medium sized	Business to consumer company	Yes, but the respondent also works on quality assurance activities
8)	Large	Business to consumer company	Yes
9)	Large	Business to consumer company	Yes
10)	Medium sized	Business to business company	Yes
11)	Small	Business to business company	No, the food regulatory affairs activities are performed by the food quality manager
12)	Small	Business to business and business to consumer company	Yes
13)	Large	Business to business and business to consumer company	Yes
14)	Large	Business to consumer company	Yes
15)	Large	Business to business company	Yes

5.1 Intermediate summary of results

After nine interviews at medium and large sized food companies information is presented about the organization of the food regulatory affairs activities. At this point an intermediate summary of results is drawn up. It includes findings and general conclusions that are valid to state at this phase of the research.

5.1.1 Food regulatory affairs

At this phase it is observed that food regulatory affairs at medium sized and large food companies deals with legislation concerning foods. Other legislation is dealt with by other professions, especially by legal persons within the company. Most, namely 89% (N=9) of the interviewed medium sized and large food companies have an integrated food regulatory affairs profession at the interviewed location, or at another location of the company. At 11% of the interviewed medium and large sized food companies an integrated food regulatory affairs profession does not exist. The food regulatory affairs activities are included in other jobs.

5.1.1.1 Characteristics of the food regulatory affairs professional

After nine interviews it is observed that 91% (N=11) of the respondents have a technical background and 9% of the respondents have a background in law. Food regulatory affairs is a discipline that is

especially learned on the job. Food regulatory affairs activities are getting more important in food companies, due to the increase of food legislation. The first source of the respondents to keep up to date with the current food legislation is national and European branch organizations. Branch organizations are commonly the first ones that know if a new or change in food legislation is made. Various answers are given by the respondents about the needed personal characteristics to perform food regulatory affairs activities (see appendices 3-17 for more information).

The total amount of results (N) at this interview question is 11, because at some interviews more persons answered the question or gave the same answer. The N will differ at the interview questions, because at some interviews the question was not asked, there was not enough time to ask the question, or the answer was not usable.

5.1.1.2 Activities of the food regulatory affairs professional

At this point the respondents agreed that there are four main food regulatory affairs activities. The four main food regulatory affairs activities are: knowledge gathering about food legislation, lobbying, implementation/compliance assurance of food legislation and informing internally and externally about food legislation. In some of the companies these activities are not all executed by one person. The activities can be divided between the different persons on the food regulatory affairs department, between different departments (when an integrated food regulatory affairs profession does not exist) and between different locations or teams (central team) of the food company. Figure 5.1 schematically represents the main food regulatory affairs activities at medium and large food companies.

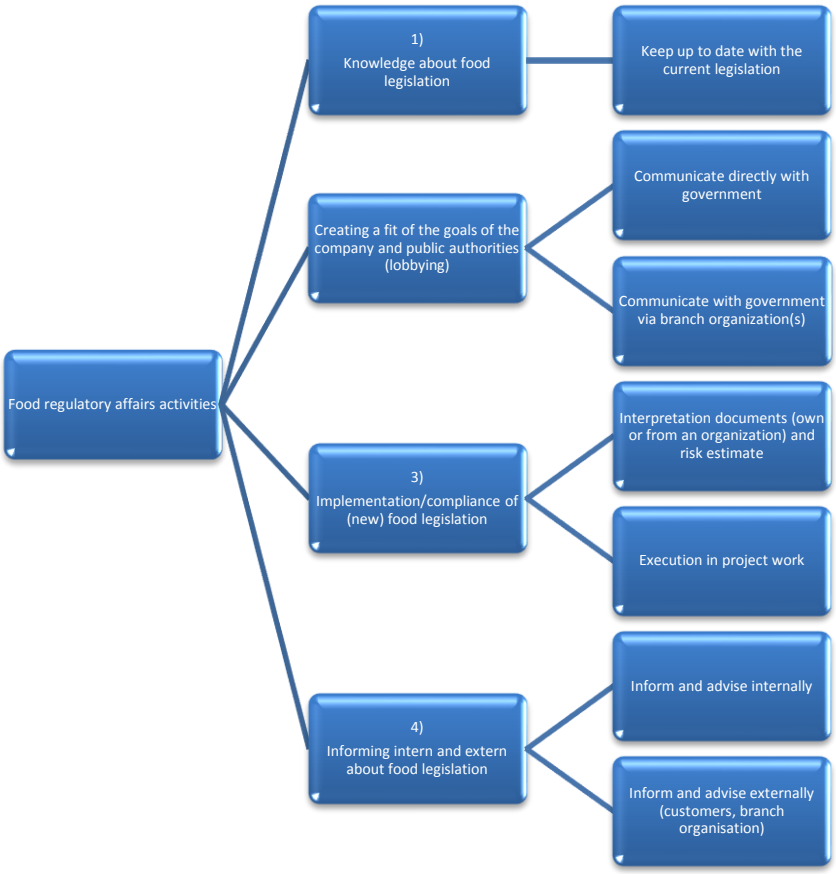

Figure 5.1: Main food regulatory affairs activities at medium and large sized food companies

Table 5.2 includes food regulatory affairs topics that were mentioned. Not all the food regulatory topics were present at all the interviewed food companies. Table 5.2 mentions all discerned activities by the respondents

Table 5.2: Food regulatory issues/topics present at food companies

Categories	Food regulatory issues/topics
Raw material/ingredient/product:	Food additives
	Food enzymes
	Flavourings
	Vitamins and minerals
	Novel ingredient/food
	Functional foods
	Microbiological safety (hygiene, microbiological criteria)
	Nano technology
	Genetically modified food
	Contaminants
	Quality
	Cloning
	Specific foods
	Food contact materials
Product presentation:	Ingredient and nutrition labelling
	Nutrition and health claims
Other:	Food law at national, European and global level
	Product liability

It can be concluded that there are clear differences between food regulatory affairs, legal affairs and food quality topics. The major difference between these three professions is that food regulatory affairs deals with legislation concerning food. Legal affairs deals with all kind of legislation, except food legislation. Food quality deals with legislation concerning food quality (examples: HACCP, ISO, GMP). At 38% (N=8) of the companies, the quality department itself has to monitor for changes in food quality legislation. Food regulatory affairs is not doing this for the quality department. At 38% of the companies, the quality department does not have to monitor changes in food quality legislation itself. This is taken care of by food regulatory affairs. At 24% of the companies, food quality and food regulatory affairs activities are performed integrated in one profession.

It can be concluded that regulatory awareness exists in all the interviewed food companies. This was expected, because otherwise they probably would not participate in the interview. In all the interviewed food companies this awareness is also growing. The regulatory awareness within the hierarchical levels of the company is very different between the food companies. At 56% (N=9) of the food companies, the regulatory awareness is the highest at top level. At 11% of the food companies, the regulatory awareness is the highest at medium level. At 11% of the food companies, the regulatory awareness is the highest at professions positioned close to food regulatory affairs. At 11% of the food companies, the regulatory awareness is the same at all the levels of the company. Finally at 11% of the food companies the regulatory awareness within the different levels of the company depends on the food regulatory subject.

The goal of all the interviewed food companies is to work proactively with respect to food legislation. The food companies wish to avoid food regulatory problems. At 75% (N=8) of interviewed food

companies, this attitude evolved towards a more proactive approach. At 25% of the interviewed food companies this attitude stayed the same.

5.1.1.3 Position of the food regulatory affairs profession/department

The results concerning the position in the company of the person(s) who perform(s) food regulatory affairs activities differ(s) a lot between the food companies. More empirical data is needed to draw a valid conclusion.

5.1.2 Hypotheses

On the basis of the obtained results after nine interviews, hypotheses can be stated. These hypotheses will be tested by using the results of the next round of interviews.

1. The most important source of food regulatory affairs knowledge of the persons that perform food regulatory affairs activities is learning on the job.

2. Persons that perform food regulatory affairs activities have a technical background.

3. The size of the company is one factor that determines whether an integrated food regulatory affairs profession exists within the food company. The larger the food company, the more often an integrated food regulatory affairs profession is observed.

4. The size of the company is one factor that determines if the food regulatory affairs activities are kept in-house or if the food business has to (partially) outsource activities. Smaller food companies will outsource food regulatory affairs activities more frequently than large companies.

5. Business to business companies spend less time on product presentation issues/topics compared to business to consumer companies.

At this point the questionnaire will be modified from general questions to more specific questions in order to obtain detailed information about food regulatory affairs. The detailed questionnaire will be used during the next round of interviews. With the results on the detailed questionnaire the hypotheses can be tested.

5.2 Constructing a more detailed questionnaire

To obtain detailed information about the organization of food regulatory affairs activities within food companies, the questionnaire will be largely modified from general questions to specific questions. This modified questionnaire with detailed questions will be used in the next round of interviews. The large modification of the questionnaire is done after nine interviews, because at this point enough general information is obtained to draw primary conclusions and more detailed information is required next. The new modified questionnaire is included in appendix 2. During the first nine interviews the questionnaire was modified after every interview. However, these were minor modifications. In the following sections it will be explained what questions are modified and the reasons why.

The first question in the new questionnaire is kept the same, but a sub question is added. The added sub question is: is earlier technical working experience in a food company making it easier to start working in food regulatory affairs? This sub question is added, because in earlier interviews respondents said that it was helpful to already have working experience before starting in food regulatory affairs. By means of this sub question it will be confirmed whether this is also correct in the next interviews.

To make the modified questionnaire clearer, question two is divided into two separate parts. Question two is asking how the knowledge about food law was obtained that is used to perform food regulatory affairs activities. Also a sub question is added to question two. The added sub question asks which part of the respondent's food law knowledge comes from the job, study, courses and/or colleagues. This is done to obtain detailed information about where food law knowledge comes from. This is interesting to know, because earlier no studies in Europe existed that prepared graduated students for working in food regulatory affairs positions.

To question three (in the previous questionnaire question two) also an extra sub question is added. The added sub question asks if the respondent to rank according to importance how up to date knowledge of current food legislation is acquired. This sub question is added to obtain insight in the most important source(s) that keep(s) the respondent up to date with current food legislation.

Question four (in the previous questionnaire this is question three) is asking about the needed competences, instead of the needed personal characteristics and competences. In the earlier interviews enough information is obtained about the personal characteristics that are needed to perform food regulatory affairs activities. Less information is obtained about the needed competences to perform food regulatory affairs activities. Information concerning the competences is necessary to achieve the educational objective of this thesis research. The educational objective is: to better prepare graduates of the new master specialisation Food Safety Law at Wageningen University for responsibilities in food regulatory affairs positions.

Question five (in the previous questionnaire question four) addresses the main question: do you perform the same food regulatory affairs activities as in figure 1 in the questionnaire. Also two sub questions were added. One of the sub questions was question five in the previous questionnaire. Also a new sub question is added, namely: can you describe the minor food regulatory affairs activities. This sub question is added to obtain detailed information about the minor food regulatory affairs activities.

Question six, seven and nine were in the previous questionnaire included in question four. In the new questionnaire they are separated to make the questions clearer.

Question six (in the previous questionnaire question four) is made more detailed. Also a sub question is added. The added sub question is: what is the procedure if somebody in the company does not agree with your advice/obligation? This question is made more detailed to obtain more information about the authority of the person who performs food regulatory affairs activities. Also information will be obtained about how an internal conflict between the person that performs food regulatory affairs activities and an employee at another department will be resolved.

Question seven (in the previous questionnaire question four) is kept the same. It is kept the same, because this question will be asked to all the companies in the same way.

Question eight is a new question. The respondents said that within their food regulatory affairs activities, they try to interpret food legislation in a positive way for the company. Question eight will check if this is also the case for more companies. The sub question of question eight asks the respondent to give an example about a positive interpretation for the company of food legislation.

Question nine (in the previous questionnaire question four) is made more detailed by adding sub questions. The first sub question is: do you spend more time on internal or more time on external communication. Another sub question is: how much time do you use for communication with each of the persons/departments internally and externally? This question is made more detailed to obtain more information about the communication process of the person who performs food regulatory affairs activities.

Question ten is new. It is added to test if the conclusion made so far about food regulatory affairs is correct. The sub questions of question ten were already present in the previous questionnaire (question six).

Question eleven (in the previous questionnaire question ten) is kept the same. This question was already detailed.

Question twelve (in the previous questionnaire question eleven) is modified to make the question more understandable. Also a sub question is added. This sub question is added to obtain detailed information about the organisational position of food regulatory affairs in the company. It will be asked if food regulatory affairs is a line or a staff function.

Question thirteen includes question twelve and thirteen of the previous questionnaire. These questions are similar and therefore question thirteen is added as a sub question to question twelve (now question thirteen).

Question fourteen is kept the same. The question stays in the questionnaire, to test if the food regulatory affairs profession is a relatively young profession.

The questions about the difference between legal, quality and regulatory affairs, about regulatory awareness and about the proactive or reactive attitude are removed from the questionnaire. These questions are removed from the questionnaire, because enough information is obtained to draw a conclusion about these topics.

5.2.1 Questions asked during the interviews

The questions that are asked at each interview are schematically represented in table 5.3.

Table 5.3: questions asked during the interviews

Questions	Interview number
Characteristics of the food regulatory affairs professional	
Can you describe your career path (studies, previous jobs and years of working experience)?	1, 2, 3, 4, 5, 6, 7, 8, 9
How did you acquire your knowledge about food law and how do you keep up to date with the continuously changing legislation?	1, 2, 3, 4, 5, 6, 7, 8, 9
Is working experience needed to perform a food regulatory affairs profession?	1, 2
What personal characteristics and competences are important for a food regulatory affairs professional? Can you rank them according to importance?	1, 2, 3, 4, 5, 6, 7, 8, 9 1, 2, 3, 4
Activities of the food regulatory affairs professional	
Can you describe in detail the food regulatory affairs profession (tasks/activities, powers, responsibilities and communication)? Do you perform the same activities as in the figure below and can you elucidate this?	1, 2, 3, 4, 5, 6, 7, 8, 9 1, 2, 3, 4, 5, 6, 7, 8, 9
How is your time divided between the different food regulatory affairs activities?	1, 2, 3, 4, 5, 6, 7, 8
What food regulatory affairs topics occur in the company? The table below shows some examples of food regulatory affairs topics that are found in literature. Can you rank the topics within the different legislation groups according to the time allocation?	1, 2, 3, 4, 5, 6, 7, 8, 9 1, 2, 3, 4, 5, 6, 7, 8, 9
By what activities does the food regulatory affairs professional distinct him/herself from other professions, for example legal and quality?	1, 2, 3, 4, 5, 6, 7, 8, 9
Does regulatory awareness exist within the whole company? How is the regulatory awareness within the different levels of the company (low, medium, high)?	1, 2, 3, 4, 5, 6, 7, 8, 9 1, 2, 3, 4, 5, 6, 7, 8, 9
How do you manage to find the balance between the needs of the company and public authorities?	1, 2, 3, 4
How do you act if a change in food legislation occurs?	1, 2, 3, 4
Did you have a food regulatory conflict and how did you resolve this?	1, 2
What is the difference in activities between the food regulatory affairs manager and the food regulatory affairs officer?	1, 2, 3, 4, 5
Do you work proactive (try to avoid problems) or reactive (problem solving) Did this attitude evolve over time?	1, 2, 3, 4, 5, 6, 7, 8, 9 1, 2, 3, 4, 5, 6, 7, 8, 9
Is external help of consultants needed on specific food regulatory affairs topics? Why? What are the outsourced activities? How is the communication arranged? How is the division of risks arranged?	1, 2, 3, 4, 5, 6, 7, 8, 9 1, 2, 3, 4, 5, 6, 7, 8, 9 1, 2, 3, 4, 5, 6, 7, 8, 9 1, 2, 3, 4, 5, 6, 7, 8, 9 1, 2, 3, 4, 5, 6, 7, 8, 9
Position and general information about the food regulatory affairs profession/department	
How does the organisational structure (hierarchy) look like within the food regulatory affairs department and within the business?	1, 2, 3, 4, 5, 6, 7, 8, 9
How many people work at the food regulatory affairs department and how are the activities divided between these people?	1, 2, 3, 4, 5, 6, 7, 8, 9
Are the food regulatory affairs professionals positioned central (the food regulatory affairs professionals are placed in one office) or decentral (the food regulatory affairs professionals are placed in different offices)?	1, 2, 3, 4, 5, 6, 7, 8, 9
How long does the food regulatory affairs profession exist within your company?	1, 2, 3, 4, 5, 6, 7, 8, 9
What is the background of the employees at the food regulatory affairs department?	1, 2, 3, 4, 5, 6, 7, 8, 9

Modified questionnaire after 9 interviews	
Characteristics of the food regulatory affairs professional	
Can you describe your career path (studies, previous jobs and years of working experience)?	10, 11, 12, 13, 14, 15
Is earlier technical working experience in a food company making it easier to start working in food regulatory affairs?	10, 11, 12, 13, 14, 15
How did you acquire your knowledge about food law?	10, 11, 12, 13, 14, 15
Which part of your knowledge comes from your study?	10, 11, 12, 13, 14, 15
Which part of your knowledge comes from colleagues?	10, 11, 12, 13, 14, 15
Which part of your knowledge comes from training on the job?	10, 11, 12, 13, 14, 15
Which part of your knowledge comes from courses?	10, 11, 12, 13, 14, 15
Which part of your knowledge comes from ....?	10, 11, 12, 13, 14, 15
How do you keep up to date with the continuously changing legislation?	10, 11, 12, 13, 14, 15
Can you rank your answer according to importance?	10, 11, 12, 13, 14, 15
What competences are important for a person who performs food regulatory affairs activities?	10, 11, 12, 13, 14, 15
Activities of the food regulatory affairs professional	
Do you perform the same main food regulatory affairs activities as in figure 1 and can you elucidate this?	10, 11, 12, 13, 14, 15
How is your time divided between the main food regulatory affairs activities?	10, 11, 12, 13, 14, 15
Can you describe also the minor food regulatory affairs activities?	10, 11, 12, 13, 14, 15
How far goes your power, is it only giving advice or do you also have the power to obligate?	10, 11, 12, 13, 14, 15
What is the procedure if somebody in the company does not agree with your advice/obligation?	10, 11, 12, 13, 14, 15
What are the responsibilities of a person who performs food regulatory affairs activities?	10, 11, 12, 13, 14, 15
Do you try to be compliant to the law and to interpret it positive for the company?	10, 11, 12, 13, 14, 15
Can you give an example of a positive interpretation for the company?	10, 11, 12, 13, 14, 15
With whom do you communicate internally and externally?	10, 11, 12, 13, 14, 15
Do you spend more time on internal or on external communication?	10, 11, 12, 13, 14, 15
How much time do you use for communication with each of the persons/departments internally and externally?	10, 11, 12, 13, 14, 15
Is it correct that the persons who perform food regulatory affairs activities deal with all the legislation concerning foods that are present in the business?	10, 11, 12, 13, 14, 15
Which of food regulatory affairs issues/topics represented in table 1 are dealt by people who perform food regulatory affairs activities?	10, 11, 12, 13, 14, 15
Can you rank the three categories according to the time allocation?	10, 11, 12, 13, 14, 15
Is external help of consultants needed on specific food regulatory affairs topics?	10, 11, 12, 13, 14, 15
Why?	10, 11, 12, 13, 14, 15
What are the outsourced activities?	10, 11, 12, 13, 14, 15
How is the communication arranged?	10, 11, 12, 13, 14, 15
How is the division of risks arranged?	10, 11, 12, 13, 14, 15
Position and general information about the food regulatory affairs profession/department	
What is the position of food regulatory affairs within the business?	10, 11, 12, 13, 14, 15
Is regulatory affairs a line or a staff function?	10, 11, 12, 13, 14, 15
How many people work at the food regulatory affairs department/on regulatory affairs activities?	10, 11, 12, 13, 14, 15
How are the regulatory activities divided between the people?	10, 11, 12, 13, 14, 15
Are the food regulatory affairs professionals positioned central or decentral?	10, 11, 12, 13, 14, 15
How long does the food regulatory affairs profession exists within your company?	10, 11, 12, 13, 14, 15

5.3 Summary of the results

In this part of the thesis research, the results of the fifteen interviews are summarized according to the order of the questions asked in the questionnaires. The interviews were conducted at 10 large food companies, 3 medium sized food companies and 2 small food companies. Respondents were interviewed at 8 business to consumer companies, 5 business to business companies and 2 companies that are both business to business and business to consumer. Detailed information about each interview can be found in appendices 3-17.

5.3.1 General results

Table 5.4 is added in this section to give a schematic overview that can be used in the sections below. As already explained in the introduction, with an integrated profession is meant that one or more persons in the company officially perform a food regulatory affairs job. Regulatory affairs is part of their job name.

Table 5.4: Overview of the characteristics of the interviewed food companies

Size of the company	Business to consumer or business to business company	Integrated food regulatory affairs profession?
1) Medium sized	Business to consumer company	Yes
2) Large	Business to consumer company	Yes
3) Large	Business to business company	Yes
4) Large	Business to consumer company	Yes
5) Large	Business to business company	Yes, but the respondent also works on quality assurance and safety activities
6) Large	Business to consumer company	No, the food regulatory affairs activities are divided over employees in the company
7) Medium sized	Business to consumer company	Yes, but the respondent also works on quality assurance activities
8) Large	Business to consumer company	Yes
9) Large	Business to consumer company	Yes
10) Medium sized	Business to business company	Yes
11) Small	Business to business company	No, the food regulatory affairs activities are performed by the food quality manager
12) Small	Business to business and business to consumer company	Yes
13) Large	Business to business and business to consumer company	Yes
14) Large	Business to consumer company	Yes
15) Large	Business to business company	Yes

Company size and the presence of an integrated food regulatory affairs profession

90% (N=10) of the large food companies have an integrated food regulatory affairs profession. 100% (N=3) of the medium sized food companies have an integrated food regulatory affairs profession. 50% (N=2) of the small food companies have an integrated food regulatory affairs profession. At 13% (N=15) of all the interviewed food companies no integrated food regulatory affairs profession is present. One of these companies is a small food company and the other is a large food company (table 5.4). So a large food company can lack an integrated food regulatory affairs profession as well. At the other 87% of all the interviewed food companies an integrated food regulatory affairs profession is present at the interviewed location, or at another location of the company. It can be summarized that most of the interviewed food companies have an integrated food regulatory affairs profession. It appears that an integrated food regulatory affairs profession is more often present at large and medium sized food companies than at small food companies.

Hypothesis 3 is partly confirmed. It is not confirmed that the larger the food company the more often an integrated food regulatory affairs profession is present. A food regulatory affairs profession is 100% present at medium sized food companies and not always in small and large food companies. Still an integrated food regulatory affairs profession is more often present at large and medium sized food companies than in small food companies.

Hypothesis 3: The size of the company is one factor that determines whether an integrated food regulatory affairs profession exists within the food company. The larger the food company, the more often an integrated food regulatory affairs profession is observed.

Type of company (business to consumer or business to business) and the presence an integrated food regulatory affairs profession

88% (N=8) of the business to consumer companies have an integrated food regulatory affairs profession. 80% (N=5) of the business to business companies have an integrated food regulatory affairs profession. It can be summarized that an integrated food regulatory affairs profession is more often present at business to consumer food companies (table 5.4).

5.3.2 Characteristics of the food regulatory affairs professional

Please describe your career path (studies, previous jobs and years of working experience)?

Job name

The word ''food'' is not present in the job name of the respondents. The most (24%; N=17) used job name for the respondents who perform food regulatory affairs activities is: Regulatory affairs manager. It can be observed that the person that performs food regulatory affairs activities is often called manager.

The total amount of results (N) at this interview question is 17, because 14 interviews were held with 1 person answering this question and 1 interview was held with 3 persons answering this question. The N will differ at the following interview questions, because at some interviews the question was not asked, there was not enough time to ask the question, or the answer was not usable.

Study

Most (53%; N=17) of the respondents have a Master degree. The other 47% of the respondents have a Bachelor degree. Most (88%; N=17) of the respondents have a technical background. It can be concluded that in this study Keramidas (2003) was correct about the fact that most of the regulatory affairs professionals have a master degree in a technical field. The other 12% of the respondents have a background in law. It can be concluded that hypothesis 2 is partly confirmed. The major part of respondents has a technical background, but a minor part of the respondents has a non-technical background.

Hypothesis 2: Persons that perform food regulatory affairs activities have a technical background.

It can be observed that none of the respondents has a degree lower than a HBO Bachelor. According to these results, it can be summarized that a person should minimally have a bachelor degree, preferably in a technical field, when starting in a food regulatory affairs profession.

The major part (50%) of the respondents with a bachelor degree studied food technology (figure 5.2). The major part (22%) of the respondents with a master degree study food technology, food safety or laws (figure 5.3).

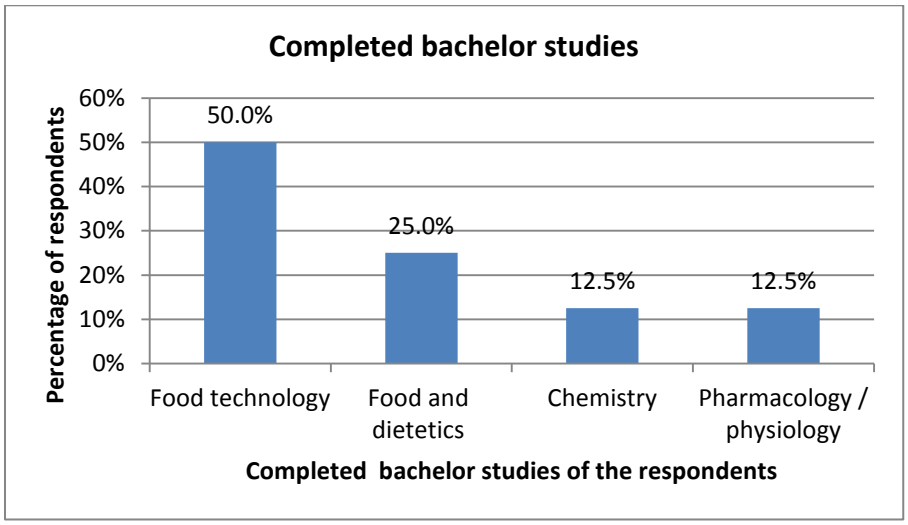

Figure 5.2: Completed bachelor studies of the respondents (N = 8)

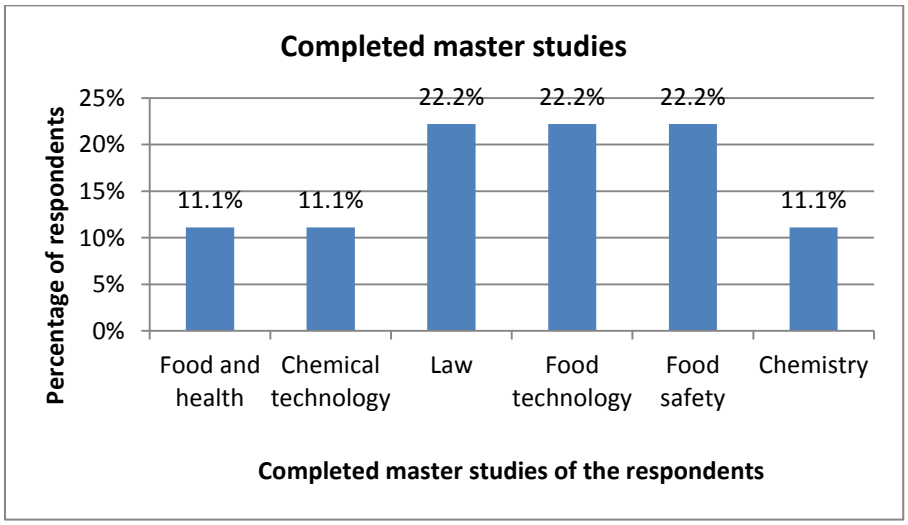

Figure 5.3: Completed master studies of the respondents (N = 9)

Growing importance of food regulatory affairs in food companies

Food regulatory affairs becomes more and more important in food companies. When looking at the results of this thesis research it is observed that integrated food regulatory affairs professions are created. Food regulatory affairs was in previous days a minor part of the daily job at all the different sized food enterprises. Currently it is observed that food regulatory affairs becomes a full job content in food companies.

Does earlier technical working experience in a food company make it easier to start working in food regulatory affairs?

Most (77%; N=17) of the respondents have working experience before starting in food regulatory affairs. A smaller part (23%) of the respondents directly started in food regulatory affairs after they obtained their diploma. So it can be concluded that the Regulatory Affairs Professionals Society was correct concerning the fact that persons that perform regulatory affairs activities usually have experience in other professions before starting in regulatory affairs. In the past, food regulatory affairs was a final stage in the career. Nowadays this is different; persons will directly start in food regulatory affairs after their education. Still the respondents said that it is important to have working experience before starting in food regulatory affairs. The reason is that then the company, its products and its processes are easier understood.

Before the respondents started working in food regulatory affairs they had working experience in:

- Product development at a food company
- Food quality at a food company or hospital
- Food safety at a food company
- Health education to industry
- Food research at a research institute
- Commerce at a food company
- Inspecting incoming foods at a food company
- Emergency response service at a research institute
- General secretary at a food company
- Application technologist at a food company

It can be concluded that most of the respondents have working experience in a technical field. The major part of the respondents has working experience in product development and food quality assurance at a food company.

How did you acquire your knowledge of food law?

Most (29%; N=48) of the food law knowledge of the respondents comes from learning on the job (figure 5.4). It can be concluded that hypothesis 1 is confirmed. No education existed in food regulatory affairs. Currently education exists that prepare students on food regulatory affairs functions, for example the Master specialisation food safety law at Wageningen University.

Hypothesis 1: The most important source of food regulatory affairs knowledge of the persons that perform food regulatory affairs activities is learning on the job.

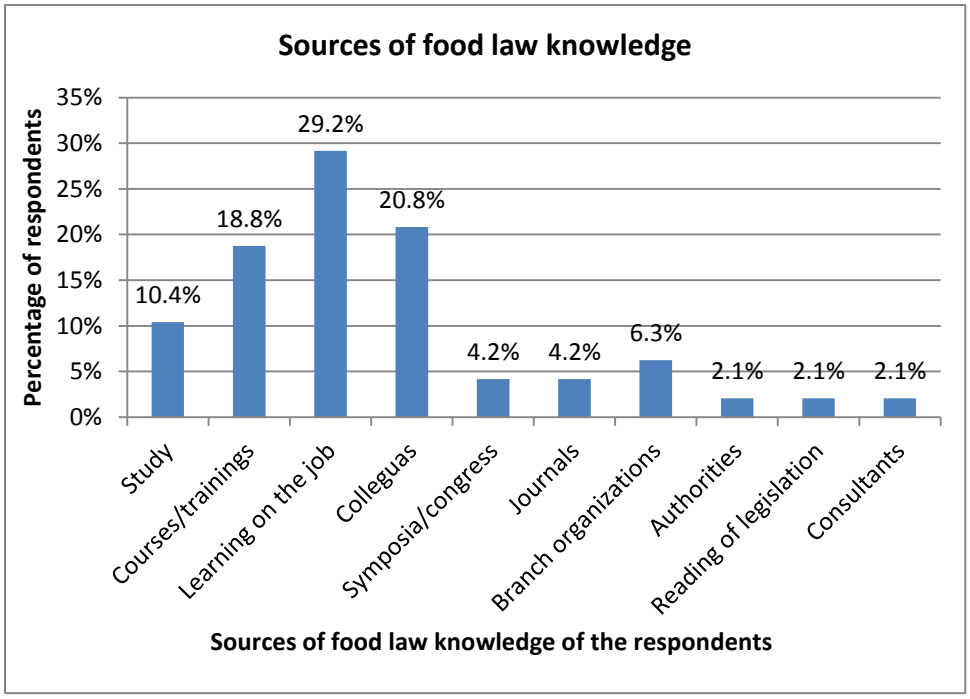

Figure 5.4: Sources of food law knowledge of the respondents

Which part of your knowledge originates from your education?

10% (N=48; figure 5.4) of the food law knowledge comes from their education. Respondents that studied at Wageningen University followed the course European Food Law. This course is very helpful to obtain knowledge about the basics of European food law.

Which part of your knowledge comes from colleagues?

21% (figure 5.4) of the food law knowledge comes from colleagues. Food law concerns the products and processes of the business. Colleagues that work or worked in food regulatory affairs can explain how and which food legislation is relevant for the company.

Which part of your knowledge comes from ''learning on the job''?

As already noted, most (29%; figure 5.4) of the food law knowledge from the respondents is obtained by ''learning on the job''.

Which part of your knowledge comes from courses?

19% (figure 5.4) of the food law knowledge is acquired via courses. General and specific food law knowledge is obtained from internal and external courses. Examples are courses on additives and packaging.

Which part of your knowledge comes from authorities?

2% (figure 5.4) of the food law knowledge comes from authorities. The authorities explain the respondent the different steps that a company has to take when applying for example for authorisation of a novel food.

Which part of your knowledge comes from consultants and branch organizations?

6% (figure 5.4) of the food law knowledge comes from consultants and 2% from branch organizations. Consultants and branch organizations help the respondents with questions concerning food legislation in other countries in and outside the European Union. Due to their answers, more food law knowledge about food legislation in other countries is obtained by the respondents.

How do you keep up to date with the continuously changing food legislation?

The most important source (39%; N=36) of the respondents to keep up to date their knowledge on current food legislation is national and European branch organizations (figure 5.5). Respondents state that branch organizations are the first ones that have information about the development of new or changes in existing food legislation. The branch organizations inform the respondents in meetings, courses, emails, by means of journals and internet sites.

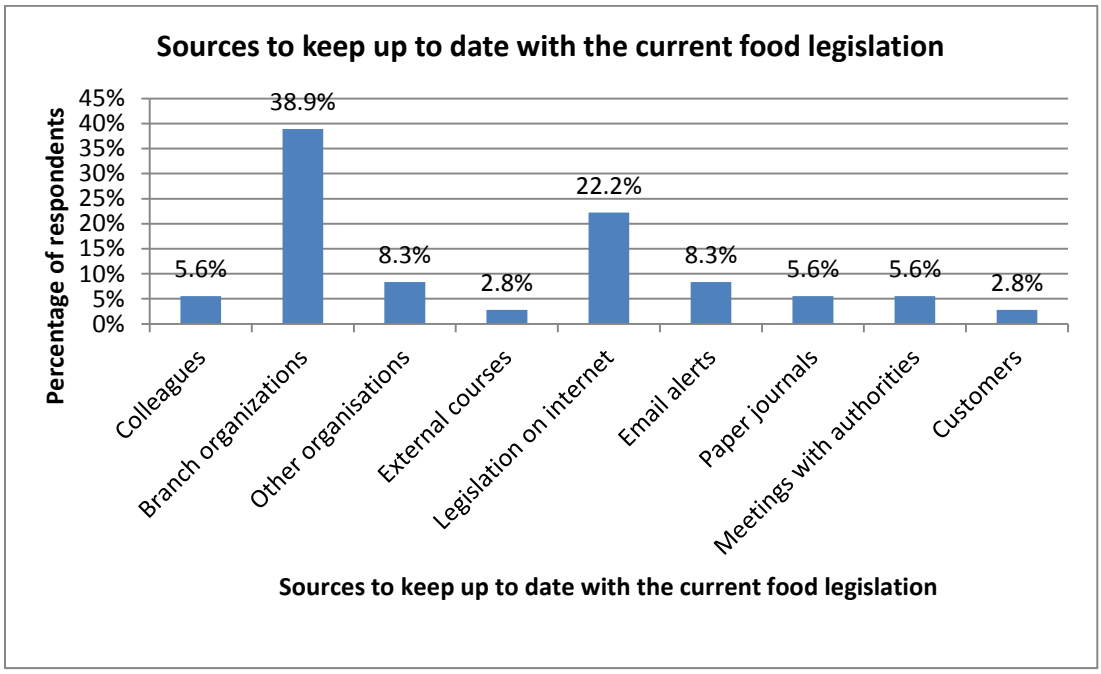

Figure 5.5: Sources to keep up to date with the current food legislation

What personal characteristics are important for a food regulatory affairs professional?

Different answers are given by the respondents such as accurate, communication skills, broad oriented, creative, taking decisions, convincing, strong, reliable, analytical and independent (see appendices 3-17 for more information).

What competences are important for a person who performs food regulatory affairs activities?

Competences that are important for a person who performs food regulatory affairs activities are:

- Background in food science. To understand specific food parts in the food legislation.
- Knowledge about food legislation.

5.3.3 Activities of the food regulatory affairs professional

Do you perform food regulatory affairs activities as in figure 5.6?

As already mentioned in the intermediate summary of results, the four main food regulatory affairs activities are: gathering knowledge about present and new food legislation, lobbying on behalf of the food company with the authorities when new or changes in food legislation occur, implementation/compliance with food legislation and informing internally and externally about food legislation. Figure 5.6 schematically represents the main food regulatory affairs activities at food companies.

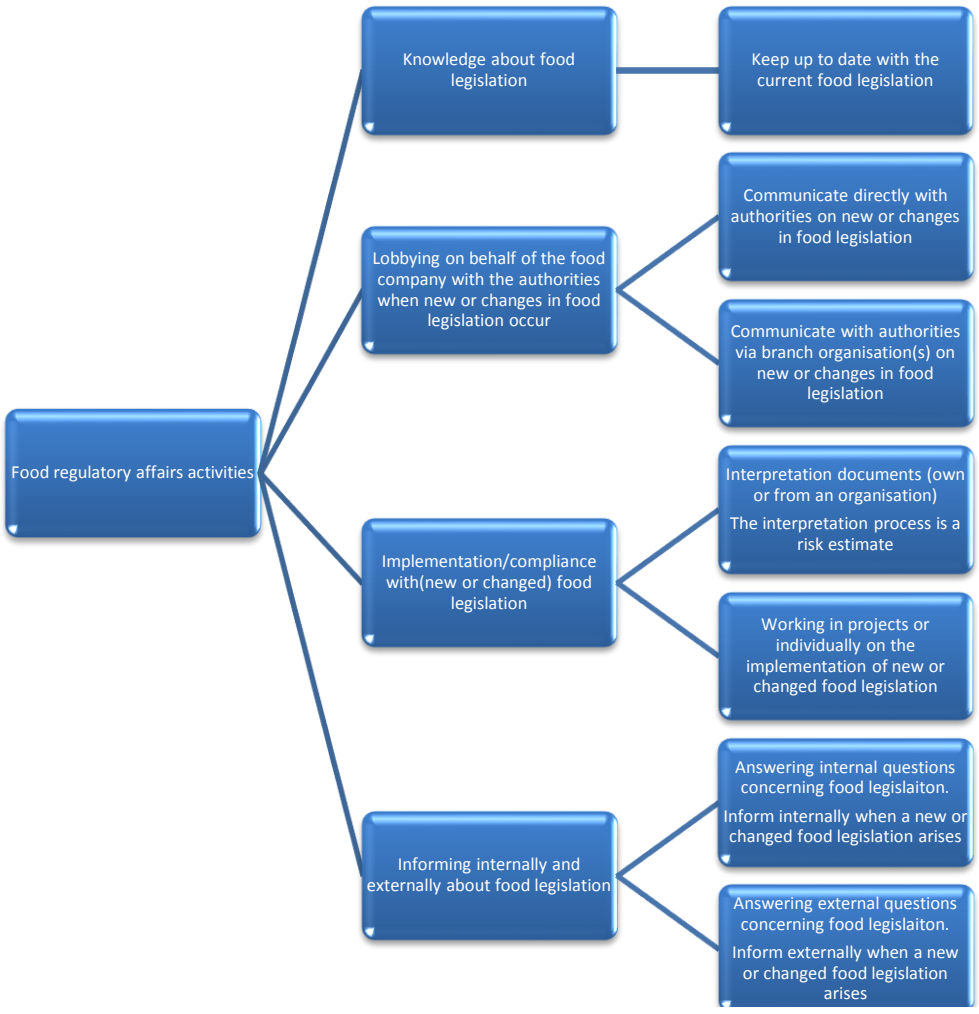

Figure 5.6: Main food regulatory affairs activities at food companies

The activities described in figure 5.6 can be performed by 1 person, divided over different employees at the food regulatory affairs department, divided between different departments (when an integrated food regulatory affairs profession does not exist) and divided between different locations or teams (like a central team) of the food company. Some respondents implemented the changed or new food legislation themselves. Others only gave an advice or information to the relevant department that has to implement the new or changed food legislation.

How is your time divided between the food regulatory affairs activities?

It is observed that least time of the respondents is spent on the lobbying activity at all the different sizes of food companies (figure 5.7, 5.8 and 5.9). It is observed that large companies spend more time on the lobbying activity compared to small and medium sized companies. It can be observed that in large food companies almost no differences exist with respect to the time spend by the respondent on the 4 activities (figure 5.9). At the medium sized and small food companies, bigger differences are observed in the distribution of working time (figure 5.7 and 5.8).

Small food companies:

The calculated average results of the respondents working at small food companies concerning their time spent on the food regulatory affairs activities are schematically represented in figure 5.7.

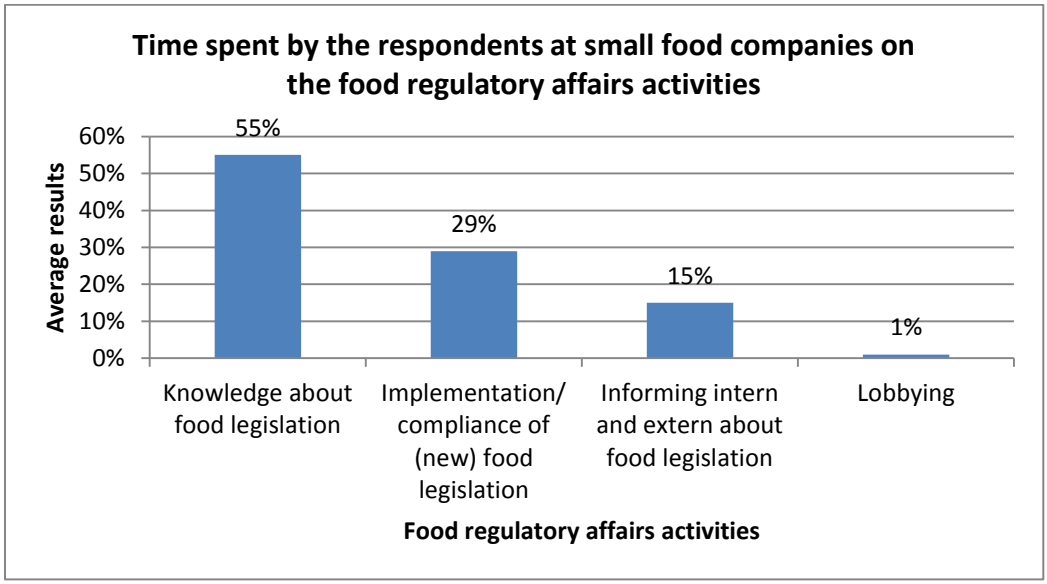

Figure 5.7: Time spent by the respondents at small food companies on the food regulatory affairs activities (N=2)

Medium sized food companies:

The average results of the respondents working at medium sized food companies concerning their time spent on the food regulatory affairs activities are schematically represented in figure 5.8.

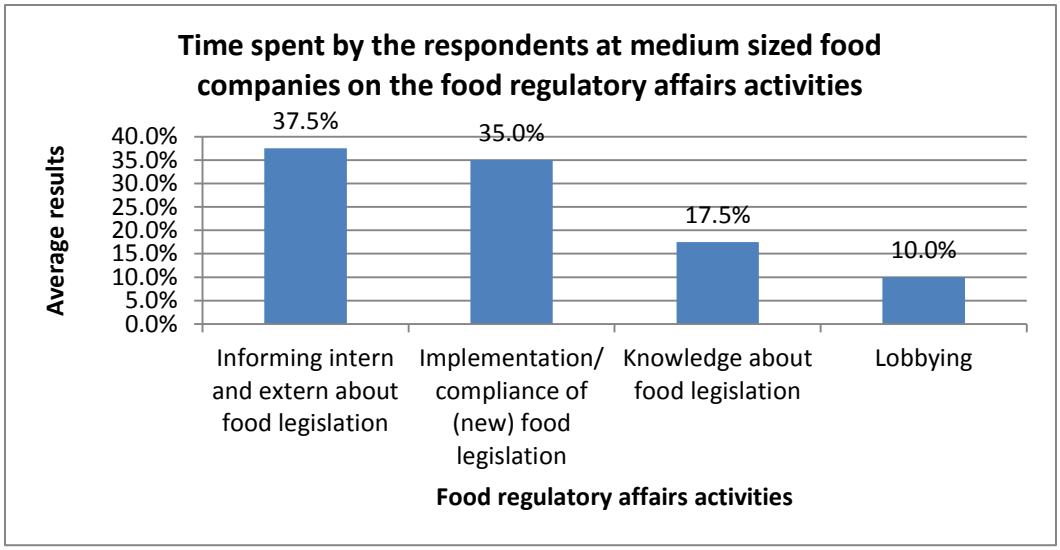

Figure 5.8: Time spent by the respondents at medium sized food companies on the food regulatory affairs activities (N=2)

Large food companies:

The average results of the respondents working at large food companies concerning their time spent on the food regulatory affairs activities are schematically represented in figure 5.9.

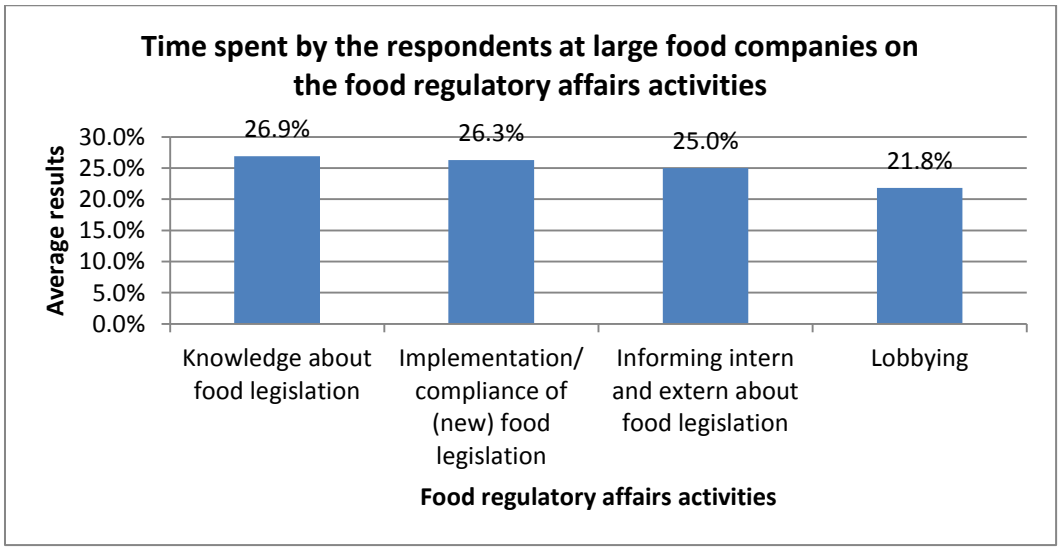

Figure 5.9: Time spent by the respondents at large food companies on the food regulatory affairs activities (N=8)

Can you describe the minor food regulatory affairs activities?

The minor food regulatory affairs activities mentioned by the respondents are:

- Customers education
- Learning about new food and feed regulatory affairs areas
- Apply for intellectual property rights. Food law is concerned with intellectual property rights when patents or trademarks are used in the production or sale of feed or food (Van der Meulen & Van der Velde, 2008 P: 75)

- Participate in food regulatory affairs conferences
- Give internal trainings about food regulatory affairs

How much authority in enforcing decisions do you have?

Most (60%; N=15) of all the respondents have the authority to issue an order. 40% of all the respondents have the authority to issue an advice.

The authority at the different sizes of food companies is as follows:

Small food companies

100% (N=2) of the small food companies have the authority to issue an order.

Medium sized food companies

33% (N=3) of the medium sized food companies have the authority to issue an order.

Large food companies

60% (N=10) of the large food companies have the authority to issue an order.

It is observed that the respondents working at small food companies have the authority to issue an order. Respondents working at small food companies are positioned in or close to the management team. Therefore they have more power. Respondents working at medium sized and large food companies are often not positioned in the management team. Probably therefore they have less often the authority to issue an order compared to small food companies.

What is the consequence if somebody in the company does not agree with you?

In case an employee does not listen to the advice or order of the respondents concerning food regulatory affairs, usually the case will be resolved at a higher level.

What is the main responsibility of a person who performs food regulatory affairs activities?

The main responsibility of the respondents is that the products and processes of the company are compliant to the current food legislation.

Do you try to interpret food legislation in an advantageous way for the company?

Most (83%; N=6) of the respondents try to interpret food legislation in a positive/advantageous way (according to the company goals) for the company. The food regulatory affairs professional is searching for the limits in the interpretation in which they are compliant, but that it is also advantageous to the company. The other 17 % of the respondents does not try to interpret food legislation in an advantageous way. This 17% does not want to take any risk that something goes wrong.

This question was added to the modified questionnaire after 9 interviews. Therefore only the answers of the 10^{th} until the 15^{th} interview are used to summarize this question.

Can you give an example of a positive interpretation for the company?

Respondents said that some parts in food legislation leave space for own interpretation, for example food legislation concerning labelling. For more examples see appendices 3-17.

With whom do you communicate internally and externally?

Various answers are given by the respondents. See appendices 3-17 for more information.

Do you spend more of your time (more than 50%) on internal or on external communication?

100% (N=5) of the respondents said that they spend more time on internal communication.

How much time do you use for communication with each of the persons/departments internally and externally?

Appendices 3-17 should be checked for the results of this question.

Can you give a detailed definition of food regulatory affairs?

The respondents gave different definitions about food regulatory affairs, but results had one common part. The common part is: Food regulatory affairs should continuously assure the company's compliance with food legislation.

Is it correct that the persons who perform food regulatory affairs activities deal with the legislation concerning foods that is applicable in the business?

The statement is confirmed for the respondents that perform food regulatory affairs activities.

Which of food regulatory affairs issues/topics represented in table 5.5 are dealt with by persons that perform food regulatory affairs activities?

Table 5.5 includes food regulatory affairs topics on which the respondents work on. This table is different compared to the table at the intermediate summary of results, because more issues/topics are added.

Table 5.5: Food regulatory affairs issues/topics at food companies

Categories	Food regulatory issues/topics	Ranking: 1
Raw material/ingredient/product:	Food additives	
	Food enzymes	
	Flavourings	
	Vitamins and minerals	
	Novel ingredient/food	
	Functional foods	
	Microbiological safety (hygiene, microbiological criteria)	
	Nano technology	
	Genetically modified food	
	Contaminants	
	Quality	
	Cloning	
	Specific foods	
	Food contact materials	
		Ranking: 2
Product presentation:	Ingredient and nutrition labelling	
	Nutrition and health claims	
	Country of origin	
		Ranking: 3
Other:	Food law at national, European and global level	
	Product liability	
	Taxes in different countries	
	Consumer health legislation	
	Intellectual property rights	
	Processing equipment	

Can you rank the three categories according to time allocation? (1 = most, 2 = less, 3 = least)

The summarized result of the respondents about the ranking concerning food regulatory affairs issues/topics according to time allocation can be observed in table 5.5.

All the companies:

It can be observed that the respondents spend most of their time on raw material/ingredient/product topics. Secondly on product presentation topics. Respondents spend the least of their time on other topics (table 5.5). N=9.

Business to consumer companies:

The respondents spend most of their time on product presentation topics. Secondly on raw material/ingredient/product topics. Respondents spend the least of their time on other topics. N=6.

Business to business companies:

The respondents spend most of their time on raw material/ingredient/product topics. Secondly on product presentation topics. Respondents spend the least of their time on other topics. N=5.

Business to consumer companies have a different time allocation between the food regulatory affairs issues/topics compared to business to business companies. Business to consumer companies spend most of their time on product presentation topics/issues, especially now with the new food information regulation. Business to business companies spend less of their time on product presentation topics/issues. It can be concluded that hypothesis 5 is confirmed. Business to business companies do not have to label products that are sold to the consumers. Their products are sold only to other companies. This is a reason why these companies spend less time on this topic/issue.

Hypothesis 5: Business to business companies spend less time on product presentation issues/topics compared to business to consumer companies.

By what activities does the food regulatory affairs professional distinct him/herself from other professions, for example legal and quality?

As already mentioned in the intermediate summary of results, it can be concluded that there are clear differences between food regulatory affairs, legal and food quality. The major difference between these three professions is that food regulatory affairs deals with legislation concerning food. The legal department deals with all kind of legislation, except food legislation. Food quality deals with legislation concerning food quality. At 38% (N=8) of the companies, the quality department itself has to monitor for changes in food quality legislation. Food regulatory affairs is not doing this for the quality department. At 38% of the companies, the quality department does not have to monitor for changes in food quality legislation. This is performed by food regulatory affairs. At 24% of the companies, food quality and food regulatory affairs activities are performed together in one profession.

Does regulatory awareness exist within the whole company?

As already mentioned in the intermediate summary of results, regulatory awareness exists at all the interviewed food companies. At all interviewed food companies it is also of increased importance. It can be concluded that Coen & Willman (1998) were correct about the fact that nowadays companies are in a phase of regulatory awareness.

What is the level of regulatory awareness within the different levels of the company (low, medium, high)?

The regulatory awareness within the levels of the company is different between food companies. At 56% (N=9) of the food companies the regulatory awareness is highest at top level. At 11% of the food companies the regulatory awareness is the highest at medium level. At 11% of the food companies the regulatory awareness is the highest at professions positioned close to food regulatory affairs. At 11% of the food companies, the regulatory awareness is the same in all the levels of the company. Finally at 11% of the food companies the regulatory awareness within the different levels of the company depends on the food regulatory subject.

How do you handle a change in food legislation?

Below the results of one respondent are given.

1. The new or changed food legislation will be communicated by different sources to the respondent
2. The respondent will read the new or changed food legislation
3. The respondent will discuss internally and externally about the new or changed food legislation
4. Interpretation documents will be used/made
5. The new or changed food legislation will be implemented

Did you have a food regulatory conflict internally and how did you resolve this?

No internal conflict about food regulatory affairs occurred. The employees of the companies listen to the advice/obligation of the person(s) who perform(s) the food regulatory affairs activities.

What is the difference in activities between the food regulatory affairs manager and the food regulatory affairs officer?

The regulatory affairs manager will divide the different food regulatory affairs activities between the employees of the department. He is also responsible for the department and the internal and external first point of contact.

Do you work proactively (try to avoid problems) or reactively (problem solving)

Most (93%; N=15) of the respondents work proactively on food regulatory affairs. 7% of the respondents work reactively on food regulatory affairs. The food company that works reactively is most of the time a small food company. This small food company works reactively because there is not enough time available for the necessary activities.

Did this attitude evolve over time?

Food companies that work proactively wish to avoid food regulatory problems. At 75% (N=8) of interviewed food companies, this attitude evolved gradually towards a more proactive approach. At 25% of the interviewed food companies the attitude stayed the same over time. It can be concluded that Coen & Willman (1998) were correct about the fact that nowadays the attitude of companies changed towards working proactively.

Is external help of consultants needed on specific food regulatory affairs topics?

Most (87%; N=15) of the food companies hire a food regulatory affairs consultant. The rest (13%) does not hire a food regulatory affairs consultant. The 13% includes a large and a small food company. It cannot be concluded that small food companies outsource food regulatory affairs activities more frequently than large ones (hypothesis 4), because 90% of the large food companies hires a consultant for food regulatory affairs issues/topics.

Hypothesis 4: The size of the company is one factor that determines if the food regulatory affairs activities are kept in-house or if the food business has to (partially) outsource activities. Smaller food companies will outsource food regulatory affairs activities more frequently than large companies.

Why are food regulatory affairs consultants hired?

Below a summary can be found from the results obtained from the respondents.

- When specific food law knowledge is missing
- Not enough time
- Food legislation not clear
- Difficulties with interpretation of food legislation
- Not enough people
- Second opinion
- Advice used for an indication

- Not enough food regulatory affairs activities

What are the outsourced activities?

Below a summary can be found from the results obtained from the respondents.

- Food legislation concerning specific topics
- Food legislation in different countries
- Interpretation problems

How is the communication arranged?

Via email, telephone and meetings. At some food companies the consultant had a working place at the company.

How is the division of risks arranged?

The food company itself is responsible for the actions of the consultant. Commonly this is written down in the contract.

Why do some food companies not hire a food regulatory affairs consultant?

These companies have enough knowledge and time to perform all the food regulatory affairs activities themselves. Or they do not have enough money to pay for a consultant.

5.3.4 Position of the food regulatory affairs profession/department

What is the organisational position of food regulatory affairs within the business?

The results differ a lot for this question. The respondents gave answers in different contexts. Some respondents described the position of the job when looking at the R&D department (figure 5.10), some described the position of the job when looking at the whole company (figure 5.11) and some described the position of the job when looking at the whole organization (figure 5.12), including the different locations of the company. Therefore it is not possible to totally summarize the results. For more information concerning the position, appendices 3-17 should be checked. Still it is observed that food regulatory affairs is often positioned within the R&D department of the company (figure 5.10). The profession is positioned high in the hierarchy of the company, because the person that performs food regulatory affairs activities is mostly called a manager and it is mostly a line function (an explanation about a line function can be found in the next section). It is also observed that the future aim of more and more food companies is to regulate food regulatory affairs central for the whole organization.

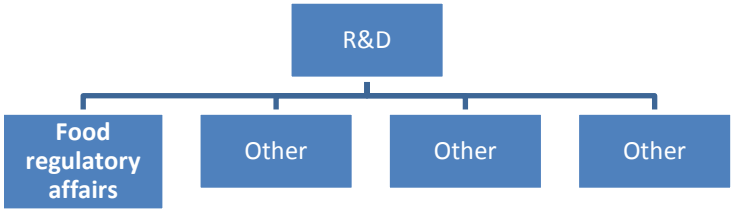

Figure 5.10: Food regulatory affairs positioned within the R&D department as a line function

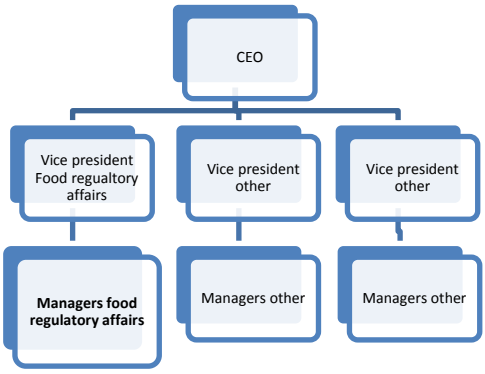

Figure 5.11: Position of the food regulatory affairs profession in the company

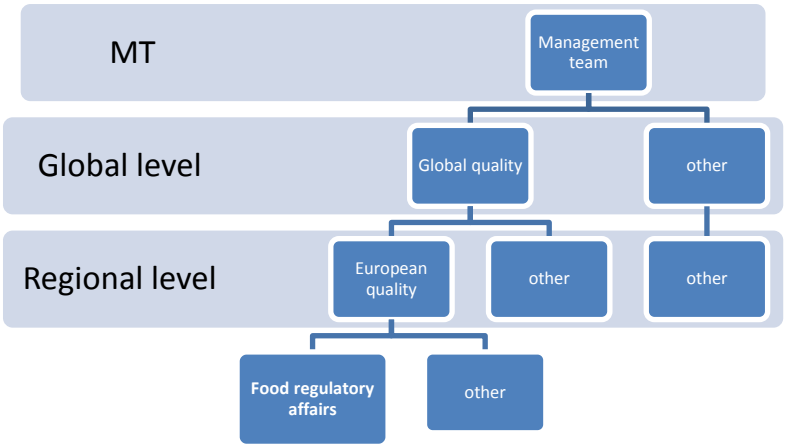

Figure 5.12: Position of food regulatory affairs in the total organization of the company

Is food regulatory affairs a line or a staff function?

In most (57%; N=14) of the companies food regulatory affairs is positioned as a line function. In 43% of the companies food regulatory affairs is positioned as a staff function. Person in a line function, have the authority to issue an order. Persons in a staff function only have the authority to issue an advice.

How many personnel work on food regulatory affairs activities at the interviewed location?

In most (36%; N=14) of the food companies, 1 person performs the food regulatory affairs activities at the interviewed location (figure 5.10).

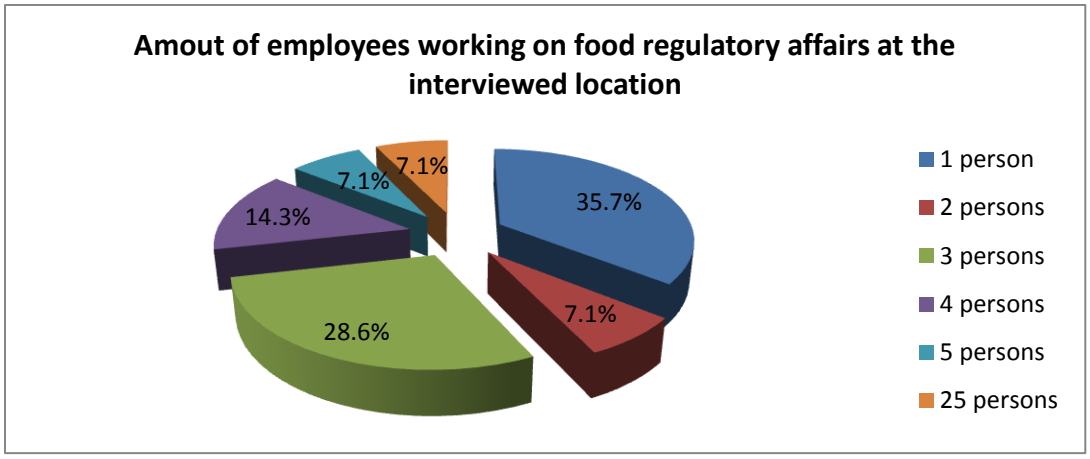

Figure 5.10: Amount of employees working on food regulatory affairs at the interviewed location

How are the food regulatory activities split up over personnel?

The respondents said that the food regulatory affairs activities are especially split up according to subject/project over the personnel that performs food regulatory affairs activities at the interviewed location.

Are the food regulatory affairs professionals positioned central or decentral?

This question cannot be summarized. The reason is that the answers of the respondents have different contexts. Some of the answers are about the total organization, so addressing all the locations of the company. Some of the answers only refer to the interviewed location. For the results of this question appendices 3-17 should be studied.

How long does the food regulatory affairs profession exist within your company?

It can be concluded that at most (30%; N=10) of the food companies the profession exists for 12 years (figure 5.11). The profession is relatively new and it is getting more important in food companies. With this result, it can be concluded that Keramidas (2003) is correct concerning the fact that (food) regulatory affairs is a relative young profession.

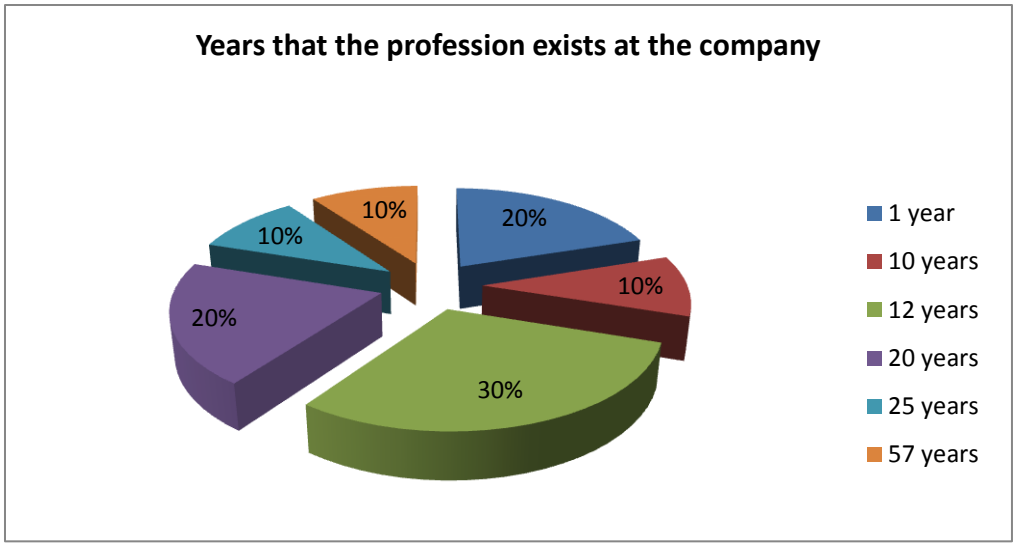

Figure 5.11: Years that the profession exists at the food companies

What is the background of the employees at the food regulatory affairs department?

Most of the employees at the food regulatory affairs department have a technical background. A minor amount has a background in law.

6. Conclusion

In this chapter the results from the theoretical framework and of the empirical research will be combined in order to answer the research sub questions and the main research question, namely ''**How do food businesses organize their food regulatory affairs activities?''** As already explained in the introduction of this report, the word ''organize'', includes both the content and the technical organization (position within the company, the level of integration and the in-house performance or outsourcing) of the food regulatory affairs activities. With integration is meant: officially existence of the job within the company.

6.1 Hypotheses

The tested hypotheses and its conclusions are schematically represented in table 6.1. More information and explanations are included in the next sections.

Table 6.1: Overview of the hypotheses and its conclusions

Number	Hypothesis	Conclusion
Hypothesis 1	The most important source of food regulatory affairs knowledge of the persons that perform food regulatory affairs activities is learning on the job.	Confirmed.
Hypothesis 2	Persons that perform food regulatory affairs activities have a technical background.	Partly confirmed. The major part of the respondents has a technical background.
Hypothesis 3	The size of the company is one factor that determines whether an integrated food regulatory affairs profession exists within the food company. The larger the food company, the more often an integrated food regulatory affairs profession is observed.	Partly confirmed. It can be concluded that a food regulatory affairs profession is 100% present at medium sized food companies and not always in small and large food companies. Still an integrated food regulatory affairs profession is more often present at large and medium sized food companies than at small food companies.
Hypothesis 4	The size of the company is one factor that determines if the food regulatory affairs activities are kept in-house or if the food business has to (partially) outsource activities. Smaller food companies will outsource food regulatory affairs activities more frequently than large companies.	Not confirmed. It cannot be concluded that small food companies outsource food regulatory affairs activities more frequently than large ones, because 90% of the large food companies hires a consultant for food regulatory affairs issues/topics. So size is not a decisive factor in this research.
Hypothesis 5	Business to business companies spend less time on product presentation issues/topics compared to business to consumer companies.	Confirmed.

6.2 What are the similarities and differences of the regulatory affairs activities between the food and the pharmaceutical sector?

This sub question has been answered by the theoretical framework on food regulatory affairs in the pharmaceutical industry and by the empirical research on food regulatory affairs in companies. It can be concluded that the pharmaceutical regulatory affairs' main activities (section 2.3.2) are similar to the food regulatory affairs' main activities (section 5.3.3). It appeared that some respondents were at the same time food and pharmaceutical regulatory affairs manager (appendices 9 and 15). A difference between food and pharmaceutical regulatory affairs in The Netherlands is that different legislation is used, in which the medicine legislation is stricter (less flexibility in compliance). Another difference is that the fines of non compliance with medicine legislation are higher compared to food legislation (section 2.3.2.1). Standard fines per violation at food legislation vary from €525,00 till €2.100,00 (depends on the size of the company). Standard fines per violation at medicine legislation vary from €450,00 till €450.000,00.

6.3 What factors determine to maintain an integrated or not- integrated food regulatory affairs profession within the business?

This sub question is answered by the use of the results of the empirical research.

- Size

One factor that determines the presence of an integrated food regulatory affairs profession is size of the food company. Hypothesis 3 is partly confirmed, because a food regulatory affairs profession is 100% present at medium sized food companies and not always in small and large food companies. Still an integrated food regulatory affairs profession is more often present at large and medium sized food companies than at small food companies (section 5.3.1). A medium sized and large food company commonly produces a wider range of food products. Subsequently the company should comply with a wider range of food legislation. Another reason is that medium and large sized food companies wish to work proactively to avoid food regulatory affairs compliance problems. Food safety problems are not good for the image of these companies and potentially can harm them financially in a substantial way. Small companies do not always want or are not able to work proactively, because they are not exposed to public scrutiny, have less time and fewer food regulatory affairs activities.

- Type of products

Another factor that determines the presence of an integrated food regulatory affairs profession is the type of products. Food companies that produce novel foods and genetically modified foods have to deal with more food legislation and have consequently more food regulatory affairs activities than companies that produce traditional food products. Food companies that produce genetically modified foods and novel foods have an integrated food regulatory affairs profession more frequently, to deal with the extra food legislation activities, even if it is a small food company.

- Type of company

The last distinguished factor that determines the presence of an integrated food regulatory affairs profession is the type of company. An integrated food regulatory affairs profession is more often present in business to consumer food companies than in business to business food companies (section 5.3.1). Business to consumer companies spend most of their time on product presentation topics/issues, especially because of the new food information regulation. Business to business companies spend less of their time on product presentation topics/issues. It can be concluded that hypothesis 5 is confirmed. The (semi) final products of business to business food companies are sold to other companies and not to the consumers. Therefore they have fewer rules to comply with and consequently fewer food regulatory affairs activities (see section 5.3.3).

6.4 What factors determine to keep the food regulatory affairs activities in-house of the food business or to outsource these activities?

This sub question is answered using the results of the empirical research. It cannot be concluded that small food companies outsource food regulatory affairs activities more frequently than large ones, because 90% of the large food companies hires a consultant for food regulatory affairs issues/topics. Therefore hypothesis 4 is not confirmed (section 5.3.3).

- Specific knowledge

If specific knowledge concerning a food regulatory affairs topic/issue is missing at the company, the specific issues or topics will be (partly) outsourced to food regulatory affairs consultants.

- Second opinion

If the food company wants to be sure about the correctness of its food regulatory affairs activities it asks a consultant for a second opinion.

- Time

If the employees do not have enough time to perform all the food regulatory affairs activities, some activities will be (partly) outsourced to food regulatory affairs consultants.

- Money

At some food companies not enough money is present to hire a new food regulatory affairs employee. At these food companies some of the food regulatory affairs are (partly) outsourced.

- Frequency of food regulatory affairs activities

If not enough food regulatory affairs activities are present to hire a new food regulatory affairs employee, some of the food regulatory affairs activities will be (partly) outsourced.

6.5 How do food businesses organize their food regulatory affairs activities?

- **When an integrated profession/department exist within the company**
- **When the activities are performed in house or when they are partially outsourced**

This sub question is answered by using the results of the empirical research. At 87% (N=15) of the interviewed food companies an integrated food regulatory affairs profession is present (section 5.3.1).

6.5.1 The food regulatory affairs activities within the food company

The persons that perform food regulatory affairs activities base their work on food legislation. Their responsibility is that the products and processes of the company are compliant to the current food legislation. The four main food regulatory affairs activities are: gathering knowledge about present and new food legislation, lobbying on behalf of the food company with the authorities when new or changes in food legislation occur, implementation/compliance with food legislation and informing internally and externally about changed food legislation. Figure 5.6 (section 5.3.3) schematically represents the main food regulatory affairs activities in the interviewed food companies. It can be concluded that least time is spent on the lobbying activity at all the different size levels of companies (section 5.3.3). Lobbying stands for working proactively. It is shown in the results from the empirical research that 75% (N=8) of the food companies made a shift from an attitude of working reactively towards an attitude of working proactively on food regulatory affairs activities (section 5.3.3). It can be concluded that large food companies spend more time on the lobbying activity compared to small and medium sized companies (section 5.3.3). The reason is that large food companies have more time, employees, knowledge and money to work proactively. Table 5.5 (section 5.3.3) includes an overview of all the food regulatory affairs topics mentioned on which the respondents work. If a distinction is made between business to consumer companies and business to business companies the following can be concluded. Respondents that work at business to consumer companies spend most of their time on product presentation topics. Secondly on raw material/ingredient/product topics. Respondents spend the least of their time on other topics. Respondents working at business to business food companies spend most of their time on raw material/ingredient/product topics. Secondly on product presentation topics. Respondents spend the least of their time on other topics. The (semi) final products of business to business food companies are sold to other companies and

not to the consumers. Therefore they have fewer food information rules to comply with and consequently these companies have to spend less time on it.

6.5.2 Position of food regulatory affairs within the food company

The results concerning the position (hierarchy) of food regulatory affairs in the company differ a lot. The main reason for the different results is that the respondents answered in different contexts. Still it is observed that food regulatory affairs is often positioned within the R&D department of the company. The profession is positioned high in the hierarchy of the company, because the person that performs food regulatory affairs activities is mostly called a manager and it is mostly a line function. It is also observed that the future aim of more and more food companies is to regulate food regulatory affairs central for the whole organization. In most (57%; N=14) of the companies food regulatory affairs is positioned as a line function. In 43% of the companies food regulatory affairs is positioned as a staff function (section 5.3.4).

6.6 How do food businesses organize their food regulatory affairs activities?

- **When an integrated profession/department does not exist within the company**
- **When the activities are performed in house or when they are (partially) outsourced**

This sub question is answered with the help of the results of the empirical research. At 13% (N = 15) of all the interviewed food companies no integrated food regulatory affairs profession is present. One of these companies is a small food company and the other is a large food company. So a large food company can also lack an integrated food regulatory affairs profession. These two food companies organize their food regulatory affairs activities both in different ways (appendices 8 and 13). Although no integrated food regulatory affairs profession is present in both companies, it can be concluded that the main food regulatory affairs activities of these two companies are the same compared to food companies that have an integrated food regulatory affairs profession.

6.7 How can graduates of the new master specialisation Food Safety Law be better prepared for responsibilities in food regulatory affairs?

This question is concluded to answer the educational objective as described in the introduction. To better prepare graduates of the new master specialisation Food Safety Law for responsibilities in food regulatory affairs positions the following is important. Food regulatory affairs becomes important in companies, more jobs in food regulatory affairs arise. This is positive for Food Safety Law graduates. Graduates should preferably have a master degree in a technical field. It has been shown that the person that performs food regulatory affairs activities mostly has a master degree (53%; N=17) in a technical field (88%; N=17). So it can be concluded that hypothesis 2 is confirmed (section 5.3.2). Most (77%; N=17) of the respondents have working experience before starting in food regulatory affairs. The major part of the respondents has working experience in product development and/or food quality assurance at a food company. Most (29%; N=48) of the food law knowledge of the respondents is derived from learning on the job. It can be concluded that hypothesis 1 is confirmed (section 5.3.2). Competences that are important for the students that in the future want to perform food regulatory affairs activities are a background in food science and knowledge of food legislation.

6.8 Overall conclusion

Finally the main research question of this thesis needs to be answered: **''How do food businesses organize their food regulatory affairs activities?**'' The theoretical framework and empirical research showed that all food companies have to deal with food legislation. Some organize it in a way that no integrated food regulatory affairs profession is needed in the company, but most companies have an integrated food regulatory affairs profession. Most of the food companies hire a food regulatory affairs consultant, even if they have an integrated food regulatory affairs profession. The profession becomes increasingly important in companies. Consequently more jobs and studies in this area are made available. The pharmaceutical regulatory affairs activities that already exist for a longer period of time are similar to the food regulatory affairs main activities. Factors that determine to maintain an integrated or not integrated food regulatory affairs profession within the business are size, type of products and the type of company. Factors that determine to keep the food regulatory affairs activities in-house or to (partially) outsource these activities are: specific knowledge, second opinion, time, money and frequency of food regulatory affairs activities. The responsibility of the person that performs food regulatory affairs activities is that the products and processes of the company are compliant with the current food legislation. This is achieved by four main activities, namely: gathering knowledge about present and new food legislation, lobbying on behalf of the food company with the authorities when new or changes in present food legislation occur, implementation/compliance-oriented activities with food legislation and informing internally and externally on food legislation. Food regulatory affairs is often positioned high in hierarchy within the R&D department of the company.

7. Discussion

In this chapter the methods and results of this thesis are discussed.

7.1 The new area of food regulatory affairs in companies

Food regulatory affairs is a new working area in food companies. Therefore at the start of this thesis research there was a lack of information concerning this profession. This made it difficult to start the research, but it was also a challenge to be one of the first persons that is carrying out empirical research in this area. The problem concerning starting the research with a lack of information was solved by performing an initial interview on food regulatory affairs. With this interview, information on food regulatory affairs was obtained and consequently this information was used to compose the first questionnaire.

7.2 High interest and collaboration of food companies

It was striking how much interest food companies had in this thesis research. All the contacted food companies wanted to participate in an interview. This shows that food regulatory affairs is an interesting field.

7.3 Need for more specific results

This thesis research contained a theoretical framework and an empirical research that were quite broad, because it was an explorative thesis research in a new area. Different questions were asked during the interviews. Almost all questions were open, to be able to obtain enough information. With different (open) questions it is difficult to gather specific results and to formulate a clear conclusion. It was attempted to obtain specific results with a questionnaire that gradually increased in level of detail. Still some of the results are general. Further research should go deeper into this topic, possibly by performing a quantitative research and using a closed question format.

7.4 Distribution of the interviewed food companies

In this thesis research the distribution of the interviews over different company size categories was not equal. More interviews were held at large food companies than at medium sized and small food companies. The reason for this was that more contact details were obtained of large food companies. Due to the unbalanced size distribution of the interviewed food companies, it was difficult to compare the results. Therefore the results are not generalizable. In further research more small and medium sized food companies should be interviewed to obtain an equal size distribution of the food companies. Subsequently a better comparison and more reliable results will be obtained. The same applies to the different types of food companies (business to business and business to consumer). More interviews at business to business companies are needed to obtain the same number of companies as the interviewed business to consumer companies, to better be able to compare.

7.5 Position of food regulatory affairs in food companies

It was not possible to draw a total conclusion concerning the position of food regulatory affairs in food companies, because the results were given in different contexts. In a further research more attention should be paid that results are obtained in the same context.

8. Recommendations

In this chapter recommendations for further research on this thesis topic will be described.

8.1 Perform a quantitative research on food regulatory affairs

This thesis research was explorative and qualitative, because there was a lack of information at the start. That is why also mainly open questions were asked during the interviews. The research should be continued by a person that performs a quantitative research. In this quantitative research closed questions should be used to enable to statistically analyze the results. Both qualitative and quantitative results can be combined to obtain more valid and reliable results.

8.2 Continue the investigation of the influence of independent factors on the organisation of regulatory affairs activities

The scope of this thesis research was investigating the organization of food regulatory affairs activities (dependent variable) in different sized food companies and different types of food companies (independent variables). Both the independent and dependent variables were still unknown when this research was started. In further research the influence of other independent factors should be investigated. The influence of the independent factor product characteristics (perishable or not perishable products) could for instance be investigated (figure 8.1).

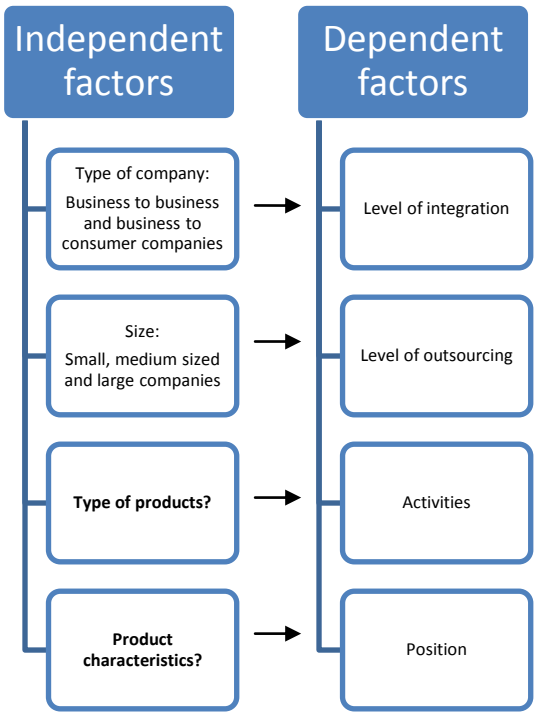

Figure 8.1: Research scope including possible new independent factors to investigate

8.3 Perform food regulatory affairs studies outside the Netherlands

This thesis research mainly focussed on the organization of food regulatory affairs in food companies in the Netherlands. For further research it is interesting to investigate if the food regulatory affairs activities are organized in the same way at in other countries.

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Appendix

See the appendix document. The appendix document is too many pages to include in this report.