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CHALLENGES IN IMPLEMENTING FOOD SAFETY LEGISLATION

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ACADEMIC DISSERTATION

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ABSTRACT

After a series of food incidents in the 1990s, the food business sector has become one of the most heavily regulated sectors in the European Union (EU), with ever-evolving regulations regarding both official food control and food business operators (FBOs). The regulatory framework is meaningless if the regulation is not implemented promptly according to transitional provisions and in a unified way by both food control officials and the FBOs. Dissenting implementation of food safety legislation may also endanger the equal treatment of FBOs and the principle of free trade of foodstuff in the EU. This research provides a new perspective on the challenges of implementing food legislation, with the phenomenon surveyed from the viewpoints of both control officials and FBOs. Resources and organization of food control affect actual control work and were thus included. Varying ways of reporting and handling food frauds on the local, national and EU levels were also investigated.

Fulfilling food control requirements set in food legislation necessitates an adequate quantity and quality of personnel, whereas organization of food control can differ between countries or areas depending on socio-economic and political factors. In some countries, the responsibility of food control is divided between state and local authorities, while in others all official food control is state-governed. In Finland, municipalities alone or as a joint control unit are responsible for local food control in their respective areas. According to the results, this may lead to varying implementation and interpretation of food legislation, endangering equal treatment of FBOs. There is an alarming shortage of food control personnel in some regions in Finland. Even when food safety is the responsibility of FBOs, scarce resources in food control result in a lower percentage of approved in-house control systems among FBOs. This research revealed a connection between the number of approved in-house control systems and the number of reported food- or waterborne outbreaks in the area, especially in regions with inadequate food control resources. EU legislation concerning quality systems, food control plans and food control fees are implemented in Finland at regionally different time points and with different contents directly influencing FBOs in regionally variable ways. Control officials support larger control units, with the rationale that they will increase equal treatment of FBOs. Intra-regional co-operation with larger control units is highly supported by control officers and is also seen to increase uniform treatment of FBOs.

Both control officials and FBOs have problems in implementation of food legislation, and FBOs are also challenged with varying interpretation of legislation and requirements of control officials. As food safety is the responsibility of the FBOs, they need to understand and carefully comply with legislation. The challenges of fish and meat FBOs in implementation of legislation were therefore evaluated. According to this study, the most common problems concerning food safety legislation are related to layout of production premises and transport routes, control fees, requirements concerning in-house control and structures and maintenance of premises. Risk evaluation is problematic for both control officers and FBOs.

Traditional food control measures are challenged, when requirements set by law are intentionally violated for financial gain by FBOs, with food deliberately placed on the market with the intention of deceiving the consumer (food fraud). Uniform methods to detect and report food fraud are needed. Hence patterns of food frauds published in the EU Rapid Alert System for Food and Feed (RASFF) in 2008–2012, recalls of notifications published by the Finnish Food Safety Authority Evira in 2008–2012 and local Finnish food fraud cases in 2003–2012 were analysed.

Challenges created by ever-evolving food frauds were investigated. Patterns of food fraud and manners of reporting frauds at the local, national and EU levels differ significantly. If the detection and reporting of frauds and the legal consequences incurred by FBOs for frauds differ among member states, it may create distortion of competition.

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TABLE OF CONTENTS

LIST OF ORIGINAL PUBLICATIONS

The thesis is based on the following original publications referred to in the text by their Roman numerals:

I Tähkäpää, S., Maijala, R., Hörman, A., Poutiainen-Lindfors, U. & Korkeala, H. 2008. Reasons behind inadequate local food control resources. Food Control 19, 403–411.

II Tähkäpää, S., Kallioniemi, M., Korkeala, H. & Maijala, R. 2009a. Food control officers' perception of the challenges in implementing new food control requirements in Finland. Food Control 20, 664–670.

III Tähkäpää, S., Nevas, M., Kallioniemi, M., Korkeala, H. & Maijala, R. 2013. Control fees and quality systems have improved food control as perceived by local food control officers in Finland. Food Control 32, 304–308.

IV Tähkäpää, S., Kaario, N., Maijala, R., Korkeala, H., Tulokas, A. & Lundén, J. 2009b. Problems for meat and fish business operators in implementing food law in Finland. Archiv für Lebensmittelhygiene 60, 172–178.

V Tähkäpää, S., Maijala, R., Korkeala, H. & Nevas, M. 2015. Patterns of food frauds reported in EU RASFF and in Finland. Food Control 47, 175–184.

In addition, some unpublished material has been presented.

ABBREVIATIONS

EC	European Commission
EFSA	European Food Safety Authority
EP	European Parliament
EU	European Union
Evira	Finnish Food Safety Authority Evira (before 1st of May 2006, National Food Authority)
FAO	Food and Agriculture Organization of the United Nations.
FBO	Food business operator
FVO	Food and Veterinary Office
GMO	Genetically modified organisms
HACCP	Hazard analysis and critical control points – a system that identifies, evaluates and controls hazards deemed significant for food safety
INTOSAI	International Organization of Supreme Audit Institutions
RASFF	Rapid Alert System for Food and Feed – a network that provides food and feed control authorities with an effective tool to exchange information about measures taken in response to serious risks detected in relation to food or feed between EU national food safety authorities, European Commission, EFSA, ESA, Norway, Liechtenstein, Iceland and Switzerland
ISO	International Organization for Standardization
ISSAI	International Standards of Supreme Audit Institutions
SPS-agreement	Agreement on the Application of Sanitary and Phytosanitary Measures entered into force in 1995 with the establishment of the WTO; concerns the application of food safety and animal and plant health regulation
WFP	World Food Programme (of the United Nations)
WHO	World Health Organization
WTO	World Trade Organization

1 INTRODUCTION

As far back as records go, people have occasionally gotten sick from eating foods. Thus, the quality of food has been supervised from the earliest societies known, and food laws are among the earliest enactments known to man (Lasztity et al. 2004). Laws were laid down by Moses to prevent the consumption of meat from unclean animals, especially animals that had died from causes other than supervised slaughter (Bible 3; Moses 11:1-47). The Egyptians had requirements for labelling on certain foods, and the Romans provided a well-organized state-controlled food control system to protect consumers from being defrauded (FAO 2000). In the Middle Ages, the trade associations had a powerful influence on the regulation of food trade and the prevention of falsification of food products (WHO/FAO 2006). Later, the initiative in food control was taken by the state, municipal or other local authorities (WHO/FAO 2006). Official food control has always had its foundation in law. Without the legal framework of the government, there is no credibility for official activities or for those who carry them out (FAO 2000). Where there have been food regulations, there have also been endeavours to harmonize the regulations (Lasztity et al. 2004). In the European Union (EU), all member states must comply with EU food safety regulations.

In Europe, the Treaty of Rome, signed in 1957 and establishing the European Economic Community, is considered the fundamental treaty of the EU. It did not provide any guidance for food regulation because a major objective was freedom of movement of foodstuffs (EU 2014). In the 1950s, food producers were primarily concerned with the quantity of goods they needed to supply in order to overcome post-war scarcity, but with the shortage of food the prices rose and markets became more lucrative for food frauds. There were no standard food safety measures in place across Europe at that time. Instead, national governments introduced and enforced their own rules (EC 2007). Since the 1960s, the EU has laid down rules to protect animals against a wide range of diseases and to ensure that animal products meet safe standards (EC 2007). In 1982, the Animal Disease Notification System was established for registering and documenting important animal diseases. National authorities responsible for animal health must use the system to notify each other and the European Commission (EC) of outbreaks of contagious animal diseases (EC 2007). The publication of the Commission's White Paper on Food Safety in 2000 marked an important milestone for EU food safety (EC 2007). In 2004, the "Hygiene Package" was adopted, replacing the numerous hygiene Directives with a harmonized, simplified and comprehensive set of rules on hygiene applicable to every stage of the food chain. This legislation, which entered into effect on 1 January 2006, laid down general rules on the hygiene of foodstuffs (Regulation EC 852/2004), as well as specific hygiene rules for food of animal origin (Regulation EC 853/2004), specific rules for the organization of official controls on products of animal origin intended for human consumption (Regulation EC 854/2004) and 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. Among the changes introduced through the Hygiene Package was the requirement that everyone in the food industry carry out in-

house controls and follow the Hazard Analysis and Critical Control Points (HACCP) principles. Regulation (EC) 178/2002 laid down the general principles and requirements of food law, established the European Food Safety Authority and laid down procedures in matters of food safety. Regulation (EC) 882/2004 concerned official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Directive 2002/99/EC laid down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption in 2002.

The Rapid Alert System for Food and Feed (RASFF) has been in place since 1979 and was refined by Regulation (EC) 178/2002, known as the General Food Law. Members of the network are the member states, the EC, the European Food Safety Agency, Iceland, Liechtenstein and Norway. In 2006, legislation on Nutrition and Health Claims was adopted to stop false or misleading claims from being used in the labelling and marketing of food (Regulation EC 1924/2006), and many product-related labelling rules were also introduced. New technology was covered with a specific regulation concerning novel foods and genetically modified food. Novel foods are defined as food and food ingredients that were not used for human consumption to any significant degree before Regulation (EC) 258/1997 entered into force in 1997. Genetically modified organisms (GMOs) are plants, animals and micro-organisms whose genetic characteristics have been artificially modified to create a new property (Regulation EC 1829/2003).

Human and financial resources have an effect on actual food control work and the ability to implement new requirements. Regulation (EC) 882/2004 states that member states must ensure that financial resources are made available for official controls. To ensure this, control fees were imposed on feed and food business operators (FBOs). However, comprehensive food safety legislation directed to both food control officials and FBOs does not enhance or secure the safety of consumers if there are burdens or obstacles that prohibit proper implementation of the legislation.

In Finland, the oldest regulation concerning food dates back to 1879, when health care regulation was established, followed by regulation concerning beverages in 1885 and margarine regulation in 1888 (Mattila 2006). Over the years, food regulation has been renewed entirely. Finland joined the EU in 1995, and the need arose to harmonize national legislation to correspond to EU legislation. This resulted in a new health care act (Finnish Health Care Act 763/1994) and food act (Finnish Food Act 361/1995) in the year of joining the EU. In 2006, national legislation concerning food, food control and food of animal origin was united to form a new food act (23/2006) corresponding to the EU "Hygiene Package". As the EU regulation concerning food is directly applicable legislation in all member countries and national legislation complements it, all officials and operators on food branch must know and apply both regulations. One of the purposes of the EU "Hygiene Package" was to clarify and unify food control inside the EU.

This thesis examines the challenges of resourcing and organizing food control activities as well as the ability of control officials to implement EU food safety legislation promptly and in a regionally uniform

and consistent manner. Particular attention was paid to the possible effects of lacking resources, to the arrangement of food control and to the proper implementation of food legislation. Further, the influence of the above on the uniform treatment of FBOs was evaluated. The ability of food control officials to implement food control regulation was investigated with an emphasis on implementation of EU food safety legislation concerning control plans, quality systems and control fees. As FBOs must comply with all legislation provided, practical problems of FBOs with requirements were examined. If the FBOs cannot implement and comply with the legislation, the legislation loses its purpose and the safety of consumers is compromised. Also manners of detecting, reporting and acting after food fraud at local, national and EU levels should be as homogeneous as possible and were thus investigated. If the manners of detecting, reporting, publishing and carrying out legal consequences of food frauds are not uniform in the EU, the disparity may cause distortion of competition. FBOs would then be treated differently based on their location, and some countries might become more tempting to fraudsters than others.

The approach of this thesis can be described as interdisciplinary, and it considers food control issues in a problem-focused and descriptive manner. It also regards issues of legislation, policy and practice of food control. The aim of the thesis is to determine whether the resources and organization of food control together with implementation, interpretation and understanding of food legislation on a local level by control officials and FBOs influences the uniform implementation of legislation, and thus, the consistent treatment and practices of FBOs. Another objective was to determine whether the patterns of food frauds differ at local, national and EU levels and whether different manners and motives emerge for detecting and reporting food frauds and carrying out legal actions for food frauds at different levels of official control. Because one aim was to identify the potential challenges in practical control work as well as the opinions of control officers and FBOs, the research is highly based on questionnaires and enquiries. Existing socio-economic data, local food fraud cases, Finnish court cases on food frauds, notifications of recalls by Finnish Food Safety Authority Evira, adulterations and frauds reported in the RASFF system as well as published scientific literature on this topic were carefully investigated and analysed.

2 REVIEW OF THE LITERATURE

2.1 PURPOSE OF FOOD CONTROL AND BASIC DEFINITIONS

The purpose of food legislation as well as international treaties concerning food is to comprehensively regulate the food service operations regarding healthiness, safety, control of production conditions and market control. The regulations aim to safeguard public health and to provide consumers food that is safe, unadulterated and honestly presented. This extensive system cannot be based on random or scattered official controls, but should be based on controlled guidelines that emphasize the predictability of risks and the responsibility of FBOs and also function across national borders (Hollo 2008). EU food regulation is strongly based on supranational regulations aimed at freedom of food trade, control of health risks and management of production-related environmental effects. Food safety is based on both official controls and the setting of technical and other requirements for FBOs. Voluntary food safety systems among FBOs combined with careful consumer behaviour also play an important role considering food safety. From the consumer viewpoint, correct information concerning, for instance, the quality, origin or manufacturing method of the product is essential.

The definition of food is essential when defining official control of food regarding public health or other public interests, including free trade and consumer protection. According to Regulation (EC) 178/2002, the definition of food is as follows:

> *"Food (or foodstuff) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. Food includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment."*

Official food control implements food legislation and is performed accordingly. The food control system covers the whole food chain from farm to table (Codex Alimentarius Commission 2006). The food chain consists of primary production (cultivation, livestock and also fishery depending on the regulation) and industrial production and processing. Food control is defined in the Finnish Food Act (2006) as:

> *"Food control means general guidance and advice on food regulations as well as the control measures by means of which the competent authority is able to establish that food, information about it, the procedures and conditions for handling it, and the activities of the food business operator comply with the food regulations."*

2.2 INTERNATIONAL ORGANIZATIONS RELATED TO FOOD SAFETY

The World Health Organization (WHO), founded in 1948, is the directing and coordinating authority on international health within the United Nations' system. WHO experts produce health guidelines and standards, and help countries to address public health issues. There are 194 member states in WHO (WHO 2007). The Food and Agriculture Organization of the United Nations (FAO), founded in 1945, works to reduce hunger, malnutrition and rural poverty (FAO, Themes 2014). The World Food Programme (WFP) of the United Nations has the same goal (WFP 2014). In 1963, a joint FAO/WHO Food Standards Programme was established and the statutes of the Codex Alimentarius Commission were adopted (FAO/WHO 1999). The highest priority of the Codex Alimentarius Commission is to protect the health of consumers and ensure fair practices in the food trade (FAO/WHO, 1999). Codex Alimentarius' Codex of Practice includes the Hazard Analysis and Critical Control Point system (HACCP) (FAO/WHO 1999).

The World Trade Organization (WTO), founded in 1995, aims at removing barriers of free trade (WTO 2014). The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement) were included among the Multilateral Agreements on Trade in Goods, annexed to the 1994 Marrakesh Agreement, which had established the WTO (FAO/WHO 1999). The SPS Agreement acknowledges that governments have the right to take sanitary and phytosanitary measures necessary for the protection of human health. However, the SPS Agreement requires them to apply those measures only to the extent required to protect human health. It does not permit Member Governments to discriminate by applying different requirements to different countries where the same or similar conditions prevail, unless there is sufficient scientific justification for doing so (FAO/WTO 1999). Similar principals were adopted in Regulation (EC) 178/2002, the General Food Law. The TBT Agreement seeks to ensure that technical regulations and standards, including packaging, marking and labelling requirements, and analytical procedures for assessing conformity with technical regulations and standards do not create unnecessary obstacles to trade (FAO/WTO 1999). Under the WTO agreements, countries cannot normally discriminate between their trading partners (WTO 2014). However, some exceptions are allowed under strict conditions, e.g. for environmental or health-related reasons.

The European Food Safety Authority (EFSA) provides scientific advice and scientific and technical support in all areas impacting food safety. It constitutes an independent source of information in this field and ensures that the general public is kept informed. In the European food safety system, official risk assessment is done separately from risk management. As a result, EFSA is an independent European agency funded by the European Union (EU) budget that operates separately from the European Commission (EC), the European Parliament (EP) and EU member states. The scientific findings of EFSA underpin the decisions of the EC, the EP and other EU institutions (EFSA 2015). Participation in EFSA is open to EU member states and to other countries applying EU food safety laws. EFSA is also responsible for co-ordinating risk assessments and identifying emerging risks, providing scientific and technical advice to the Commission in connection with crisis management, collecting and publishing scien-

tific and technical data in areas related to food safety and establishing European networks of organizations operating in the field of food safety. Since EFSA neither performs scientific studies nor possesses labs, instead reviewing the results of tests carried out by other scientific entities, it necessitates a high level of scientific expertise as well as sharing of information (Gabbi & Alemanno 2013).

EC makes proposals for new legislation, but the vast majority of European laws including food regulation are adopted jointly by the EP and the Council (Treaty of Lisbon 2007). The standard decision-making procedure in the EU is known as Ordinary Legislative Procedure (Treaty of Lisbon 2007). This means that the directly elected EP has to approve EU legislation together with the Council (the governments of the 28 EU countries). The Treaty of Lisbon (2007) became applicable from 1st of December 2009, increasing the influence of the EP and also the power of national parliaments as they review proposals for new legislation (Treaty of Lisbon 2007). The EC, in its role as guardian of the European Community Treaties, is responsible for ensuring that Community legislation on food safety, animal health, plant health and animal welfare is properly implemented and enforced in member states (EC 2014). At the service of the commission, the Food and Veterinary Office (FVO) works to assure effective control systems and to evaluate compliance with EU standards within the EU, and in third countries in relation to their exports to the EU. The FVO does this mainly by carrying out inspections in member states and in third countries exporting to the EU (EC 2014).

2.3 BASIC EUROPEAN UNION LEGISLATION ON THE SAFETY OF FOOD

Food control is one of the key elements to ensure safe food for consumers. EU governmental food safety control focus on three areas: product quality and safety assurance, product labelling and product liability. The EU integrated approach to food safety aims to assure a high level of food safety, animal health, animal welfare and plant health within the EU through coherent farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market (EC 2014). EU's prevailing view on food law was laid down in the White Paper on Food Safety (White Paper 2000). The general principle of the White Paper was that all parts of the food production chain be subject to official control. The White Paper on Food Safety was drafted and published in January 2000. It was intended as a consultation document in preparation for the anticipated new food law (White Paper 2000). The White Paper and food legislation has since progressed considerably (Table 1).

The basis of food safety in the EU is laid down in Regulation (EC) 178/2002, the General Food Law. The General Food Law lays down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety. A fundamental principle laid down in the General Food Law is that food products exported to Europe must comply with EU food law or be equivalent to goods produced in the EU in terms of hygiene and safety standards. The objective of the Regulation is to ensure a high level of protection for consumers whilst also taking into account the protection of animal health and welfare, plant health and the environment. The Regulation sets out the general requirements of food law, including food safety requirements,

responsibilities of both food and feed business operators and member states. Regulation (EC) 178/2002 also establishes the principle that the primary responsibility for ensuring compliance with food law rests with the FBO. FBO refers to natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control. Regulation (EC) 178/2002 establishes the principle of risk analysis and its three components: risk assessment, risk management and risk communication in relation to food safety. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. Risk management shall take into account the results of risk assessment and the opinions of EFSA as well other factors that may impact the matter under consideration (Regulation EC 178/2002).

The precautionary principle of Regulation (EC) 178/2002 gives to risk managers an open option when decisions have to be made to protect health but scientific information concerning the risk is inconclusive or incomplete in some way. The precautionary principle is relevant in circumstances where risk managers have identified a reasonable ground for concern that an unacceptable level of risk to health exists but the supporting information and data may not be sufficiently complete to enable a comprehensive risk assessment to be made. When faced with these specific circumstances, decision-makers or risk managers may take actions to protect health based on the precautionary principle while seeking more complete scientific and other data. Such actions have to comply with the normal principles of non-discrimination and proportionality and should be considered as provisional until more comprehensive information concerning the risk can be gathered and analysed. On the other hand the precautionary principle has been criticized for being disproportional with reference to the actual risk involved and for lacking cost-efficiency (Caduff & Bernauer 2006).

Regulation (EC) 178/2002 also contains general provisions for traceability of foodstuff. FBOs must be able to identify any person who has supplied them with a food, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food. To this end, such operators shall have in place systems and procedures that allow this information to be made available to the competent authorities on demand.

A harmonized framework and general rules for the organization of food control were established at the Community level in Regulation (EC) 882/2004. Regulation 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules states that the member states should enforce feed and food law, animal health and animal welfare rules and monitor and verify that the relevant requirements thereof are fulfilled by business operators at all stages of production, processing and distribution. The key elements of Regulation (EC) 882/2004 are to ensure that official controls on feed and food are carried out regularly, on a risk basis and with appropriate frequency. To establish a clear EU framework for a control system systematically setting out the rules to be respected with the aim of greater harmonization and the integration of controls across the entire food and feed chain under the “farm to fork” principle. According to Regulation (EC) 882/2004, a competent authority may delegate specific tasks to official control bodies. The Regulation aims to provide regular training for competent authority staff and to establish appropriate control

methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis in compliance with relevant Community rules or with internationally recognized rules or protocols. It also aims to improve efficiency of the inspection services of the Commission by way of a more transparent, strategic and integrated approach and to establish a community and national reference laboratory network. Regulation (EC) 882/2004 also stipulates the requirement that the competent authorities prepare a single integrated multi-annual national control plan to ensure effective implementation of the Regulation. Based on Regulation (EC) 882/2004, each member state shall designate one or more liaison bodies to liaise as appropriate with the liaison bodies of other member states. The role of liaison bodies shall be to assist and co-ordinate communication between competent authorities and, in particular, the transmission and receipt of requests for assistance. Member states also must organize and develop a Community food safety training strategy to ensure a more harmonized approach. Furthermore, Regulation (EC) 854/2004 concerning official controls on products of animal origin intended for human consumption states that official controls should cover all aspects that are important for protecting public health, and where appropriate, animal health and welfare.

Commission Implementing Regulation 931/2011 sets out specific traceability requirements of Regulation (EC) 178/2002 with respect to food of animal origin. The Regulation applies to food defined as 'unprocessed and processed products' in Regulation (EC) 852/2004. It does not apply to foods containing products of plant origin together with processed products of animal origin. Regulation (EC) 2230/2004 lays down detailed rules for the implementation of Regulation (EC) 178/2002 with regard to the network of organizations operating in the fields within the mission of the European Food Safety Authority. The Regulation sets criteria for the competent organizations designated by the member states in accordance with Regulation (EC) 178/2002, establishes a list of competent authorities and their tasks as well as networking between the relevant organizations of the European Food Safety Authority.

Commission Decision 2004/478/EC concern the adoption of a general plan for food/feed crisis management according to Regulation (EC) 178/2002. The general plan specifies the crisis situations, the procedure leading to the application of the general plan, the establishment of a network of crisis coordinators, the practical procedures for managing a crisis, the role of the crisis unit, the practical functioning of the crisis unit, the link between the crisis unit and the decision-making process, the resolution of the crisis, the management procedures in the event of a potentially serious risk, the communication strategy and the principles for transparency. The management procedures established by the general plan will constitute guidelines applicable to the member states, the relevant authority and the Commission.

Year	Act	Content
1997	Regulation 258/1997	Novel foods and food ingredients
2000	The White Paper	Food safety strategy
2002	Directive 2002/46 (amended in 414/2015)	Food supplements
2002	Regulation 178/2002	General food law
2003	Regulations 1829/2003 and 1830/2003	Genetically modified food and feed
2004	Regulations 852–854/2004	Hygiene package
2004	Regulation 882/2004	Official controls
2004	Regulation 1935/2004	Food contact materials
2005	Directive 2003/89	Allergen labelling requirements
2005	Regulation 2073/2005 (amended by Regulation 1441/2007)	Microbiological criteria for foods
2006	Regulation 1924/2006	Nutrition and health claims
2008	Regulations 1331–1334/2008	Food improvement agents package additives, flavourings, enzymes
2011	Regulation 931/2011	Traceability requirements for food of animal origin
2011	Regulation 1169/2011	Food information to consumers

Table 1. Timeline of some basic EU food safety regulations.

From 2014 onwards Regulation (EC) 1169/2011 on the provision of food information to consumers amended previous legislation on food labelling. The purpose of labelling is to inform the consumer about characteristics such as composition and origin. The regulation makes it mandatory to provide nutrition information at the front of the package of all pre-packaged foods. The obligation to provide nutrition information will apply from 13th December 2016.

European legislation protects consumers against damage caused by defective products. Injured persons can therefore seek compensation with regard to products put into circulation in the internal market according to Directive (85/374/EEC) on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products. The latest amend-

ment of Directive 85/374/EEC describes a product as follows: all movables, even though incorporated into another movable or into an immovable, including electricity, primary agricultural products (products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing) and game (Directive 1999/34/EC). The Directive (1999/34/EC) establishes the principle of liability without fault applicable to European producers. Where a defective product causes damage to a consumer, the producer may be liable. The injured person carries the burden of proof. He must prove the actual damage, the defect in the product and the causal relationship between damage and defect. However, he does not have to prove the negligence or fault of the producer or importer (Directive 85/374/EEC). Rules on general product safety are established in Directive 2001/95/EC. The general product safety directive is intended to ensure a high level of product safety throughout the EU for consumer products and it supplements specific legislation on liability for defective products.

Food legislation is harmonized throughout Europe and should thus be identical in every region and in every member state guaranteeing the safety of consumers, equal treatment of individuals and operators and free movement of food stuff in Europe. EU legislation must be implemented and understood by food control officials and also by the FBOs. If EU legislation is not consistently - with the same contents and time tables - implemented in all member states and regions, the harmonization of legislation loses its purpose, and public safety, uniform treatment of FBOs and free trade may be compromised.

2.4 PRINCIPLE OF EQUAL TREATMENT

The principle of equal treatment is firmly established in most countries and in the conscience of most people (American Declaration of Independence 1776, United Nations 1948, Council of Europe 1950). According to the Constitution of Finland (1999), “Everyone is equal before the law”. Public authorities are therefore obligated to apply the law uniformly and to refrain from unequal treatment or requirements (Administrative Procedure Act 434/2003). According to Regulation (EC) 882/2004, competent authorities shall ensure the impartiality, quality and consistency of official controls at all levels. Hence, all food operators should be uniformly treated by the authorities unless there is a valid reason to treat them differently (Heuru 2003). A valid reason can only be based on objective reasons that serve a legitimate purpose of that particular public authority, which is referred to as the détournement de pouvoir-principle (Heuru 2003). There is always someone who deems that they have a valid reason to treat individuals or operators differently, but it is prohibited to treat individual cases differently (EP 2001); distinction is discrimination when it cannot be based on reasonable and objective criteria. With laws including discretionary rules, the principle of equality is most problematic. The law then does not explicitly state the criteria upon which the officials must base their decisions. Sometimes public authorities make their own internal rules as to how to apply discretion to ensure consistency. Such rules may not, however, breach legislations or treaties concerning equal treatment.

2.5 HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEM AND RAPID ALERT SYSTEM FOR FOOD AND FEED

According to Regulation (EC) 882/2004 EU member states are responsible for enforcing food law, i.e. monitoring and verifying that the relevant requirements of food law are fulfilled by FBOs at all stages of production, processing and distribution. For this purpose, they must maintain a system of official controls and other activities appropriate to the circumstances, including public communication on food and feed safety and risks, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution. Presently, there are 28 member states in the EU: Austria, Belgium, Bulgaria, Cyprus, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom (EU 2015).

Legislation regarding product safety focuses primarily on the organizational measures required to guarantee product quality and safety. Food safety systems generally refer to HACCP (Hazard Analysis and Critical Control Points) or related systems (Untermann 1999). HACCP has its roots in quality management of Japanese products in the 1950s and collaborative development of the United States Army and the United States National Aeronautics and Space Administration (NASA) for the production of safe foods for the United States space programme in the 1960s (FAO 1998). Codex Alimentarius Commission adopted HACCP system in 1993 (FAO 1998). It is a globally recognized systematic and preventive approach that addresses biological, chemical and physical hazards through anticipation and prevention rather than through end-product inspection and testing. The HACCP system is intended to be the primary risk management tool at all stages of the food chain, except primary production (Regulation EC 852/2004). It addresses food hazards as a means of prevention rather than inspection of the finished product. The HACCP system assigns higher responsibility for FBOs and has markedly shaped the working environment of food control officials during the last decade in Europe. Fulfilling all requirements set for official food control necessitates an adequate quantity and quality of personnel. HACCP aims for identification, evaluation and control of significant and potential dangers related to food safety (Regulation EC 852/2004). HACCP systems identify a number of critical control points in business processes for which critical values must be defined. Measurement in these control points must lead to prevention of problems.

The Rapid Alert System for Food and Feed (RASFF) is given a legal basis in Regulation (EC) 178/2002; the system deals with the obligatory notification of any direct or indirect risk to human health, animal health or the environment within a network consisting of national competent authorities, the EFSA and the EC. The Regulation also ensures special powers of the EC for taking emergency measures. RASFF notification is required when a RASFF member has any information about a serious health risk deriving from food or feed. In particular, RASFF members must notify the Commission if they take such measures as withdrawing or recalling food or feed products from the market in order to protect the health of consumers and if rapid action is required. Members must also notify the Commission about

whether or not they agreed with the responsible operator that a food or feed should not be placed on the market if the measure is taken on account of a serious risk. The same applies when the product in question is placed on the market (Regulation EC 178/2002). Regulation (EC) 16/2011 lays down the implementing measures for the RASFF. According to Regulation (EC) 16/2011, there are two main kinds of RASFF notifications: market notifications and border rejections. Contained within market notifications are three types of notifications: alert notifications, information notifications and news, the last pertaining to information judged to merely be interesting for control authorities. Alert notifications are sent when a food or feed presenting a serious health risk is on the market and when rapid action is required. Information notifications are used when a risk has been identified about a food or feed placed on the market, but other members do not have to take rapid action. This is because the product has not reached their market or is no longer present in their market or because the nature of the risk does not require rapid action. A member of the network sends a market notification, called an alert or information notification, when a risk is found in a food or feed product placed on the market. Border rejections concern food and feed consignments that have been tested and rejected at the external borders of the EU and the European Economic Area. The Agreement on the European Economic Area brings together the EU member states and Iceland, Liechtenstein and Norway in a single market (Agreement on the European Economic Area 1995). RASFF notifications define the food products and types of hazards involved such as adulteration/fraud, poor or insufficient controls, absent/incomplete/incorrect labelling, allergens, pathogenic micro-organisms and mycotoxins (in total 26 different hazard categories).

2.6 FOOD CONTROL IN FINLAND

In Finland, several parties are involved in food control. According to the Finnish Food Act (2006) the principal responsibility for practical supervision of food control rests with the local authorities (single municipalities or joint local units with two or more municipalities). At the level of municipalities, this supervision is performed by a body with multiple members, e.g. a committee (Local Government Act 365/1995). In 2015, there were 317 autonomous municipalities in Finland (Statistics Finland 2015a) and 62 joint control units (Ministry of Agriculture and Forestry 2015) taking care of local food control. In practice, the food control is carried out by veterinary officers, sanitary inspectors and public health and environmental engineers delegated by the committee. The local government has a statutory duty to provide adequate resources for food control, and this task is thus usually managed by control units serving a larger area than individual municipalities (Act on Co-operation Areas in Food and Environmental Health Control 410/2009). According to Act on Co-operation Areas in Food and Environmental Health Control (2009) all control units must have minimum resources that correspond to at least 10 full-time positions. These units draw up supervision plans for themselves, and supervision is carried out both systematically and based on reports received by the control units (Finnish Food Act 23/2006).

The Regional State Administrative Agency is responsible for the regional supervision of food control issues (Finnish Food Act 23/2006). The Agency directs the activities of local authorities supervising food control, evaluates the arrangement of food control in municipalities and supervises its implementation. There are six Regional State Administrative Agencies in Finland and each Agency prepares an annual supervision plan on which its activities are based and which takes into account the national environmental health supervision programme that covers food control, animal health and welfare and consumer safety.

The Finnish Food Safety Authority Evira (Evira) is responsible for planning, steering, developing and undertaking food control nationally (Finnish Food Act 23/2006). Evira is also responsible for preparing and steering of a multi-annual national control plan according to Regulation (EC) 882/2004 and Finnish Food Act (2006). Evira's responsibilities include steering the Regional State Administrative Agencies in assessing municipal food control, food control in slaughterhouses, game handling establishments and related establishments, the planning and implementation of the national control of contaminants in food, other national food control duties requiring special expertise, producing guides to good food hygiene practices, functioning as the national contact point for the rapid alert system under the Regulation (EC) 178/2002, approving the training of hunters in health and hygiene, the national information and communication activities, communication about risks and consumer information (Finnish Food Act 23/2006).

The highest supervision of food control is the responsibility of the Ministry of Agriculture and Forestry (Finnish Food Act 23/2006). Other control authorities are the National Supervisory Authority for Welfare and Health, the Finnish Defence Forces, the Finnish Customs and border inspection veterinarians. The National Supervisory Authority for Welfare and Health plans, steers and undertakes control of beverages containing an amount of ethyl alcohol that exceeds 2.8% by volume. The Finnish Defence Forces is responsible for food control in its area and premises in a similar manner as the municipal authorities (Finnish Food Act 23/2006).

The Finnish Customs controls foodstuffs of non-animal origin that is imported from outside the EU or that is supplied to Finland from the EU in connection with unloading and storage of food consignments in Finland, the authenticity of documents concerning non-animal origin food transported as transit goods and the authenticity of documents concerning non-animal origin food that is exported from Finland to destinations outside the EU and international transport of perishable food and the special equipment used in such transport (Finnish Food Act 23/2006). Border inspection veterinarians are responsible for control of foodstuffs of animal origin imported from third countries. Border inspection veterinarians work for Evira (Finnish Food Act 23/2006).

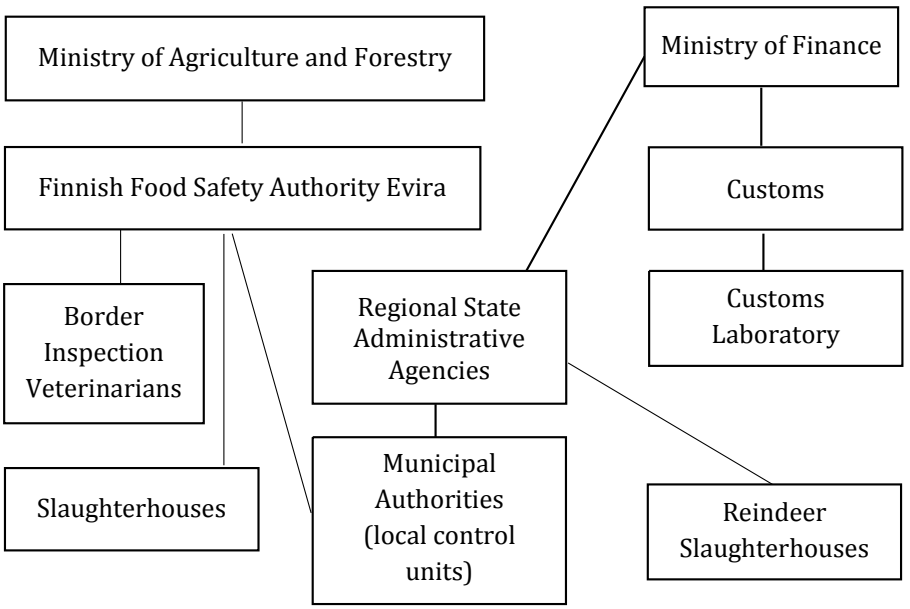

Figure 1. Organization of official food control in Finland.

In Finland, if an FBO has reason to believe that a food imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to recall the food in question from the market where the food has left the immediate control of that initial FBO and inform the competent authorities thereof (Finnish Food Act 23/2006). Actions are taken by Evira when a notification of recall is received. If required, Evira gives its opinion on the adequacy of the planned recall process. Evira sends the municipal food control authorities the notification of recall, and the municipal authorities verify that the recall has been implemented successfully. A copy of the notification is sent to the FBO. If the non-compliance calls for immediate action from the authorities, the subject line of the notification will read "Urgent recall, requires immediate action". Evira draws up a brief press release of the recall and posts it on the internet site of Evira under "Product recalls". Evira also decides whether other EU member states need to be informed through the RASFF system (Regulation EC 178/2002, Evira 2013).

According to the Finnish Food Act (2006) FBOs shall disclose the document on the inspection of the food premises issued by the control authority as required by Evira. Based on the Finnish Food Act (2006), a new food safety information publication system. Oiva, co-ordinated by Evira, was launched in May 2013. The Oiva system is based on the current provisions in food safety legislation. The publication of the Oiva report, which derives from the control visits of municipal food inspectors, is displyed near the entrances of the premises of FBOs. Oiva reports indicate the level of food safety of the FBO by

means of smileys in the report. Another purpose of the Oiva system is to promote uniform food control of FBOs (Evira 2015b).

In addition to EU regulations and the Finnish Food Act (2006), there are several national laws and statutes on official food control, hygiene of food stuffs, transport and sales of food, preparation and handling of food, labels, contact materials, substances and statutes on specific foods strongly based on EU legislation and supplementing it.

2.7 FOOD BUSINESS OPERATORS IN FINLAND

In Evira's register in 2015, the number of approved establishments handling meat was altogether 355, establishments handling fishery products 386, establishments handling milk 109, establishments handling eggs 75 and warehouses of foodstuff of animal origin 127 (Evira 2015a). The number of other food establishments was unavailable, as the notices are given to respective local authorities according to the Amendment of Food Act 352/2011. The food industry employs approximately 33 000 people in Finland, and there are almost 2000 locations of the food industry (Elintarviketeollisuus 2015). Most FBOs in Finland are small- or medium-sized operators; only 1% of FBOs employ more than 250 employees, and 86% of FBOs had less than 10 employees. Of all FBOs, 65% had less than 5 employees (Ministry of Employment and Economy 2014).

2.8 CHALLENGES WITH RESOURCES AND ORGANIZATION OF FOOD CONTROL

New regulation and new tasks may increase the workload of control officers, thus also having an impact on resources of official food control. Nevertheless, new regulation is worthless if lacking resources endanger proper implementation of legislation. Formal assessment of the economic impacts of regulation is an increasing component of the desire of governments for evidence-based policy-making (Traill & Koening 2010). There is a serious shortage of resources in official food control at the local level in Finland (Government Proposal 51/2009). The Finnish Prime Minister's report (VNS 5/2013 vp) states that the poor economic situation of both the state and municipalities will lead to inadequate resources in food control. Further, according to the report (VNS 5/2013 vp) resources for laboratory tests are inadequate, leading to an insufficient level of laboratory analyses, and also the resources for training and funding of research work will diminish during 2013–2017.

The primary functional units of a food control system, at the basic and minimal level, include control officers (inspectors), an analytical service and a regulatory compliance unit (FAO 2000). The most important functional unit of official food control is adequately staffed and trained control officers (FAO 2000). The FAO further (2000) states that lack of food control resources has been a universal challenge over the past years. Most food control agencies, as well as other governmental agencies, suffer from

decreasing budget allocations and are being asked to do more with less. Food control agencies are expected to find more efficient means of doing their work without sacrificing either control or protection (FAO 2000). On the other hand, according to the study of EC (2009), some EU member states have expressed the view that in order to intensify control work the number of staff required to perform official controls should be explicitly defined in EU law. Whatever means to provide adequate resources is chosen, formal consideration of economic and human resources, quantification of these where possible and publication of findings and their underlying assumptions are vital to transparent and accountable policy-making (Traill & Koening 2010).

Communication challenges of the food control authorities are numerous and have been recognized in several countries (Nordic Council of Ministers 1998). It has been stated that clear communication is essential for food control authorities. Without good communication skills, co-operation and joint action between leading officials are impossible, and thus, training in communication is warranted (Nordic Council of Ministers 1998). Transparency without communication is unthinkable. In Finland, Evira has the responsibility for the preparation and overall steering of the multi-annual national control plan. One of the targets in the multi-annual control plan is open communication of all control officials in the food control chain in order to increase the information flow towards consumers and FBOs (Evira 2015b).

Unlike in many other countries, in Finland municipal authorities are responsible for food control at the local level (EC 2009, Government Proposal for Co-operation Areas in Environmental Health Care and Changing the Food Act 51/2009, Finnish Food Act 23/2006). Municipal food control units are organized in co-operation areas, and presently the number of such units is 62 in a total of 317 municipalities (Statistics Finland 2015a). The number of control units has decreased from 277 control units (Government Proposal for Co-operation Areas in Environmental Health Care and Changing the Food Act 51/2009) to 62 control units (Ministry of Agriculture and Forestry 2015) during 2003–2015. Investigations (Government Proposal 51/2009) show that organizing food control to larger co-operation units did not increase the costs for municipalities. If costs rose, it was due to increased tasks required by legislation. Transferring practical food control to the state has been under discussion for years (State Audit Office 1997). According to the study of EC (2009) in member states with decentralized management in food control, the transparency, co-ordination and central responsibility may be compromised. Nationalizing food control tasks is still under consideration, and the Finnish Government Programme in 2011–2014 stated that transferring food control under one state authority must be contemplated in order to ensure adequate and equal food control (VNS 5/2013 vp).

Given the scarcity of public sector resources, concerns about the impact of regulation on competitiveness and the scale of the task at hand, there is also growing interest in co-regulation, with public and private sectors working together to deliver safer food at lower regulatory cost (Martinez et al. 2007). Co-regulation is an approach in which a mixture of instruments is brought to bear on a specific problem like management of food safety, typically involving both primary legislation and self-regulation or, if not self-regulation, at least some form of direct participation of bodies representing stakeholders in

the regulatory decision-making process (Eijlander 2005). An essential element of a co-regulatory approach to governance of food safety is co-operation between the public and private sectors in the process of creating new rules (Martinez et al. 2007). EU food regulation (Regulation EC 178/2002, Regulation EC 852/2004) can be considered as an example of co-regulation, as FBOs are responsible for safety of their products and must have controls that demonstrate that they are managing food safety within their business. Official control is then responsible for approving these internalized rules, monitoring compliance and imposing sanctions when needed (Regulation EC 882/2004).

In addition to regulatory provisions, new methods for ensuring the safety of food and the trust of consumers have been introduced, increasing the participation of FBOs in the form of voluntary standards or codes of conduct. Voluntary traceability and responsibility systems for FBOs have long been an objective of the Government of Finland in order to increase traceability and transparency of the food chain (VNS 5/2013 vp). FBOs producing pork meat have been the forerunners, and they were the first to have a quality manual audited by an independent auditor (VNS 5/2013 vp). There may be increasing potential for regulators to make use of their own means of food safety management, e.g. private standards and codes of practice, as a mechanism to allocate scarce resources (Martinez et al. 2007). However, this would require a fundamental change in culture on the part of control officials, and the challenge for such approaches is the economic and political fallout when wide-scale food safety failures occur (Martinez et al. 2007). Official responsibility in the event of a serious failure in food safety must also be considered. In several member states, public services are being rationalized, and as a part of this, instead of using public servants in food control, the veterinary services are being transferred towards contractual arrangements to reduce the costs (EC 2009).

2.9 IMPLEMENTATION OF EUROPEAN UNION LEGISLATION CONCERNING QUALITY SYSTEMS, CONTROL PLANS AND CONTROL FEES

In Finland, each municipality must draw up a municipal food control plan, as part of its environmental health control plan, taking into account the national food control programme (Finnish Food Act 23/2006). Municipalities are also required to have a quality management system for food control activities (Finnish Food Act 23/2006, Regulation EC 882/2004). Within the EU, the frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by FBOs under HACCP-based control programme or a quality assurance programme, where such programmes are designed to meet the following requirements of feed and food law, animal health and animal welfare rules (Regulation EC 882/2004). Quality control systems among food operators have existed for years and many food operators use the quality standards provided by the International Organization for Standardization (ISO 2005, Manning & Baines 2004). In 2005, the ISO published the first International Standard (ISO 2005) for food safety management systems specifically providing a framework for any food operator in the food chain ISO (2005). It is applicable to all organizations, regardless of size, that are involved in any aspect of the food chain and want to implement the system

(ISO 2005). ISO (2005) specifies the requirements for a food safety management system, combining interactive communication, system management, prerequisite programmes and implementation of HACCP principles. The contribution of both ISO standards and HACCP-based quality control systems has been thoroughly investigated in the literature, with both positive and negative reviews. Many researchers conclude that the added value of systems does not depend on the systems alone, but rather on the degree of their effective implementation (Kafetzopoulos et al. 2013, Psomas et al. 2013). Presently, requirements of International Organization for Standardization (ISO 22000) regarding food safety management are under revision and a new standard is expected in early 2017 (ISO 2015).

As all member states of the EU are obliged to ensure that their official food controls are carried out regularly, on a risk basis and with appropriate frequency, either internal or external audits are needed for verification of this (Regulation EC 882/2004). Audits are also a means to enhance consistency of controls. According to the results of a Finnish study (Läikkö-Roto & Nevas 2014a), the regional officials as auditors considered the audits to be more useful than the municipal officials. In the EU a Commission decision (2006/677) sets out guidelines for auditing national food control authorities on official control. When official food control is audited, the performance of control officials and control authorities is audited. Performance audit is considered to be one of the most effective means for improving performance and quality in the public sector (Daujotaite & Macerinskien 2008). The International Standards of Supreme Audit Institutions (ISSAI), are issued by the International Organization of Supreme Audit Institutions (Intosai) to set implementation guidelines for performance audits (Intosai 2004). According to these standards (Intosai 2004) performance auditing is an independent and objective examination relating to aspects of economy, efficiency and effectiveness, with the aim of leading to improvements in operations.

According to the Finnish Food Act (2006), control officials are entitled to collect fees for control tasks to cover part of the costs of official food control. In 2013, food control in Finland was estimated to cost municipalities approximately 26 million euros per year (VNS 5/2013 vp). Regulation (EC) 882/2004 stipulates that every member state of the EU is obliged to collect food control fees, but enforcement of the regulation has been slow and gradual, with considerable delays in most member states (EC 2009). As the rationale of the fee system is to ensure adequate financial resources to provide necessary staff (Regulation EC 882/2004), thereby easing the aforesaid lack of food control resources, the revenue from fees should be used by the control authority in question. Yet, research has shown (EC 2009) that in the majority of the member states the collected fees were incorporated into the General State Budget instead of the budget of control authorities. Also implementation of collecting the fees differs between and within countries (EC 2009). There is a wide variation in fee rates both between member states and within member states and comparing fees is impossible, as member states have interpreted the terms used differently (EC 2009). As Regulation (EC) 882/2004 does not provide any definition for associated costs of control, there is a variety of costs included or excluded from the fee (EC 2009). Different ways of organizing food control may also have an effect on fee rates and overall implementation of the regulation (EC 2009). According to Regulation (EC) 882/2004, the competent authorities shall

ensure that they carry out their activities with a high level of transparency. For that purpose, relevant information held by them shall be made available to the public as soon as possible. This has not realized entirely, as member states and competent authorities have interpreted the regulation diversely, the fee rates and grounds for fees differ and the situation is not transparent but confusing to FBOs (EC 2009).

In view of the challenges of the fee system, the majority of control authorities of member states in the EC (2009) study preferred a fee system that allows a member state to set the fee rates within a commonly agreed set of rules. Consequently, the EC represented a legislative proposal on May 2013 to review the current system of inspection fees (EC, DG Health and Consumers 2013a). The proposal provide a modernized and simplified, more risked-based approach to the protection of health and more efficient control tools to ensure the effective application of the rules guiding the operation of the food chain. According to the proposal, microenterprises will be exempted from fees, but not from controls, so as not to affect their competitiveness (EC, DG Health and Consumers 2013a). Small- and medium-sized enterprises represent 90% of all businesses in the EU (EC 2015a) and 99% of food and drink businesses (EC 2015a). Small- and medium-sized enterprises are defined in Commission recommendation 2003/361. According to this recommendation, the number of staff in microenterprises is less than 10, in small enterprises less than 50 and in medium-sized enterprises less than 250. The economics and resources of the enterprises also affect the definition. At the beginning of 2016, the Commission proposal was still under review.

2.10 CHALLENGES FOR FOOD BUSINESS OPERATORS IN IMPLEMENTING FOOD LEGISLATION

2.10.1 Challenges with changing requirements

The quantity of European legislation regarding food is overwhelming, and the food sector has become one of the most heavily regulated sectors in the EU (van der Meulen 2013). Legislation obligating FBOs can mostly be grouped into three categories: legislation on the product, the process and the presentation of food products (van der Meulen 2013). Most FBOs will comply with reasonable rules and laws provided that they understand what they must do and believe it is in their best interest to do so (FAO 2000). FBOs face new challenges in the form of new regulations. Regulation (EC) 178/2002 stipulates the general principles and requirements of the EU food law, which emphasizes the responsibility of FBOs in ensuring safety of their products. The primary responsibility for food safety rests with the FBOs (Regulation EC 852/2004), and they are obliged to know and follow food legislation. A harmonized HACCP-system is obligatory for all non-primary FBOs (Regulation EC 852/2004). Thereby FBOs and companies themselves are responsible for the safety of the products they produce, and they must use in-house control of their production. Furthermore, the EU has established legislation specifically to harmonize official control procedures (Regulation EC 882/2004). The regulation of food involves a

complex interaction of a number of different actors within novel systems of supranational governance that are historically determined, relatively new and continuously evolving (Gabbi & Alemanno 2013). The whole concept of food law including laws, regulations and administrative provisions and standards, seems to continuously evolve at all stages (Gabbi & Alemanno 2013). Also an increasing number of legislative measures pursuing quality objectives have been introduced to EU food regulation (Regulation EC 1151/2012). Hence, it can be a challenge for FBOs as well as control officers to keep up with changing regulations and to implement these correctly.

The size of the FBO may also be a factor, as larger FBOs consider systems related to food safety and quality to be a worthwhile investment, while smaller FBOs perceive them as prohibitive burdens (Jayasinghe-Mudalige & Henson 2007). Also the larger the FBO, the greater the awareness of food safety risks (Nevas et al. 2013), and larger FBOs are able to direct resources and funds for training and consultancy for successful implementation of a control system (Panisello & Quantic 2001).

2.10.2 Effect of regulations on practices of food business operators

There have been several studies concerning the knowledge of requirements and practices of FBOs worldwide (Walker et al. 2003a, Walker et al. 2003b, Bas et al. 2006, Gomes-Neves et al. 2007, Jevsnik et al. 2008, Tokuc et al. 2009, Sharif & Al-Malki 2010, McIntyre et al. 2013). FBOs are obligated to follow all of the rules concerning food and food production, and they are assumed to be aware of all statues therein. FBOs must acquire information somehow; according to a recent study, the FBOs saw local inspectors as the most important sources of new information concerning food safety legislation (Nevas et al. 2013). The attitude of Finnish food manufacturing companies has been revealed to be highly positive towards in-house control and HACCP, and in-house controls have been considered to benefit product safety and quality in businesses (Hielm et al. 2006). Food safety training includes legal issues, and undoubtedly, food safety training increases knowledge regarding food safety issues (Lynch et al. 2003), but does not always result in a positive change in food handling behaviour (Howes et al. 1996, Powell et al. 1997). The overall attitudes of the food handlers are usually very positive towards food safety measures and requirements, but they may simultaneously have relatively poor practices (Angelillo et al. 2001, Walker et al. 2003a, Bas et al. 2006, Gomes-Neves et al. 2007, Jevšnik et al. 2008, Tokuc et al. 2008). According to Läikkö-Roto & Nevas (2014), knowledge of food hygiene and attitudes towards official food control among restaurant business operators affect the hygiene in restaurants. Hand hygiene has been tested before and after food safety training and no decrease of enteric microorganisms on the hands was found (Acikel et al. 2008). In Turkey, a study revealed an immediate need for education and increased awareness among food handlers regarding safe food handling practices (Bas et al. 2006). Periodical retraining has also been found to be useful for FBOs (McIntyre et al. 2014).

Operators in different sectors may have different motives for complying with the rules. Farmers in the EU and their compliance with standards have been studied from a point of view other than food legislation (Wieck & Annen 2013). Whereas economic loss of FBOs occurs mainly in the form of lost reputation among consumers and sanctions, the farmers have additional reasons for complying with the

rules. Farmers in the EU are entitled to direct support by the EU under the Single Payment Scheme, the Single Area Payment Scheme and some other specific schemes providing they respect Cross-Compliance regulations where non-compliance is sanctioned by payment reductions (EC 2012). Cross-Compliance regulations include standards of environmental care and public/animal/plant health and animal welfare (EC 2012). The survey of Wieck & Annen (2013) reveals that farmers acted as expected regarding compliance, trying to fulfil all obligations mainly to avoid a penalty of non-compliance in the form of losing their financial support. Thus, in addition to advice, support and an effective inspection regime, incentives may be in place to encourage compliance (Hampton 2004).

In Belgium, the food safety authority has provided incentives for food business operators to set up a certified in-house control system based upon good practices and HACCP principles (Jacxsens et al. 2015). A study revealed that no significant difference could be identified between the certified in-house control system and the non-certified in-house control system in food processing companies regarding their food safety management system and microbiological food safety output. The impact of co-regulation between voluntary and mandatory systems has been investigated by Fares & Rouvière (2010). They suggested that voluntary standards would be more applicable to industries where the food safety risk is low.

The requirements concerning the location of production facilities and transportation routes and structures and maintenance of the facilities as well as the HACCP system were perceived as problematic in small and medium-sized enterprises (Kaario et al. 2007). Several small and medium- sized FBOs experienced the food legislation as difficult to understand in a comprehensive way (Kaario et al. 2007). Documentation is a crucial part of the in-house control system, and the importance of documentation was previously emphasized in a survey by Walker & Jones (2002), showing that the standards of hygiene are better during preparation and cooking in premises with documented hazard analysis systems than in those without. In previous studies, small and medium-sized businesses are often important locations in the transmission of foodborne illness (Border & Norton 1997), and full EU requirements of HACCP may present problems for small and medium-sized multi-product businesses since they lack in-house control knowledge and access to experts (Walker et al. 2003a).

An effective quality management system is one of the most important tasks in the food industry and is a pre-condition for safe foods (Meixner et al. 2011). However, HACCP per se does not make food safe, although its correct and effective application can make a difference (Kafetzopoulos et al. 2013). According to Meixner et al. (2011), human factors (employees and quality managers), the core customer of the food industry, the food retailing sector and system-immanent factors are the most important factors influencing success versus failure of a quality management system. Also changes in product and processes can lead to more pressure on the food safety management system since they include adaptation of working methodology, procedures and training of personnel (Luning et al. 2011).

2.11 CHALLENGES IMPOSED BY FOOD FRAUD ON OFFICIAL FOOD CONTROL

EU White Paper (2000) on food safety establishes the food safety policy in the EU and is based on the risk analysis approach and HACCP. In addition to the previous concerns concerning of resources, slow implentation of new legislation or FBOs' genuine problems in meeting new requirements, food hazards are also caused by frauds committed by FBOs. Frauds and adulteration are a challenge for HACCP-based controls; criminal behaviour is unpredictable and highly creative, with new means continually sought for gaining financial benefits.

For as long as there has been trade of food, there have also been adulterations and frauds (Lasztity et al. 2004). Food safety risks may be caused by technological hazards, i.e. a genuine lack of knowledge about production systems, unintentional safety breakdowns or human or technical failures. But risks may also be caused intentionally by FBOs, i.e. opportunistic malpractice of FBOs also called economic misconduct (Hirschauer & Zwoll 2008). A key factor influencing the degree to which food safety regulations achieve their desired aim is the rate of compliance among food businesses (Martinez et al. 2007). Despite the integrity of the majority of the FBOs and their commitment to consumer protection and consumer confidence, food fraud persists. To address this issue, effective measures are being identified to strengthen European rules and controls, and several of these are reflected in the EU Action Plan to tackle food fraud (EP 2013).

Food fraud is opportunistic in nature and represents a significant challenge to both industry and government (Spink 2011). Spink & Moyer (2011) have identified seven types of food fraud; adulteration, counterfeit product, diversion of products outside of intended markets, over-run (i.e. legitimate product is made in excess of production agreements), simulation, tampering and theft. Each type of food fraud generates different potential levels of monetary gains and the degree of gain is dependent on how well the fraud has been carried out and if detection of the crime occurs (Hirschauer & Zwoll 2008). Traditional food safety approaches may not be the most effective option for detecting or deterring food fraud, as food fraud risk is based on a completely different set of motivations and unconventional adulterants (Spink & Moyer 2011). At the moment, there are many techniques used to detect the presence of adulterants, however, this approach relies on the adulterant or means of substitution being known and no food item can ever be declared truly free of adulteration on this basis (Manning & Soon 2014).

Due to their high market value, meat products are often targets for species substitution and adulteration (Cawthorn et al. 2013). In April 2013, the EC reported meat product adulteration with products containing horse DNA and traces of phenylbutazone (EC 2013). As a result of the horsemeat scandal, several actions were taken in the EU (EC 2013). The Commission made a proposal for reviewing the EU food chain legislative framework, including proposals to strengthen official controls as well as provide a legal basis to impose dissuasive financial sanctions on food fraudsters, which should take into account the financial gain from the fraud. Based on the proposal (EC 2013), the European Food Fraud Network was established in July 2013 with the aim of sharing information in order to deal with cases

of cross-border food fraud more efficiently. A dedicated Information Technology tool, similar to the RASFF, enabling the members of the network to rapidly exchange information and data on potential cases of cross-border fraud was also initiated. Specialized training has been offered based on the proposal from 2014 to food inspectors, police and customs officers and judicial authorities concerning new investigation/control techniques related to food fraud and more effective cross-agency co-operation at the national level. Also the need to develop enhanced laboratory analysis capabilities, through the pooling of knowledge and resources available in the member states, and to create specialized research programmes was acknowledged. Further, a legislative proposal to review the legal framework applicable to official controls along the agri-food chain was submitted, and a study on the legal framework that currently governs the fight against fraudulent and deceptive practices was launched together with team within the Commission to improve co-ordination at the EU level of all services dealing with matters relating to food fraud (EC 2013). Moreover, from June 2016, under Commission Implementation Regulation 2015/262, all member states must maintain a central equine identification database that links to other member states, allowing easier identification of horses barred from slaughter.

The study of Kleter et al. (2009) found between July 2003 and June 2007 altogether 256 food fraud notifications from the RASFF database, the proportion of fraud notifications being 2%. The main fraud-related issues were illegal imports and lack of authorization of establishments and transits. Implicated in frauds were meat, seafood, and composite and mixed products (Kleter et al. 2009). As regions of origin, Asia accounted for 44% and the EU for 22% of fraud-related products (Kleter et al. 2009). Concerning the prevailing reason for recall, Kleter et al. (2009) revealed that during 2003–2007 the total amount of RASFF notifications on unauthorized genetically modified organisms (GMOs) was 171, originating mostly in rice products from the USA and China. The peak of unauthorized GMO notifications occurred in 2006, with more than 80 notifications (Kleter et al. 2009).

In Finland, the decision to take action in case of non-compliance rests, in practice, with the municipal authorities (Finnish Food Act 23/2006). The Finnish food control system has earlier received some negative feedback from the EU: "Enforcement was not adequate either within the remit of the Evira or within the remit of the municipal food control authorities due to the fact that some deficiencies were not noted by the competent authorities or in several cases, although results of non-compliances were registered, deadlines were either not set or not adhered to. Consequently the necessary follow-up actions were not always taken to verify the rectification of the non-compliances detected. The Evira has established an auditing system and, in addition, some limited internal auditing takes place in the milk sector by the Regional State Administrative Agencies. Nevertheless, the system cannot be considered as adequate."(EC, DG Health and Consumers 2013b).

Lundén (2013) states that the use of enforcement measures is often a consequence of FBOs having committed multiple, serious non-compliances, indicating that authorities use enforcement measures especially when a health hazard is obvious or likely to occur. Also other Finnish studies (Jokela et al. 2009, Lepistö et al. 2009, Lepistö & Hänninen 2011) reveal that the use of enforcement measures is

rather infrequent, possibly due to uncertainty concerning the legal measures of applying enforcement measures and the perceptions of food control officials towards enforcement measures. Also in a study conducted in the US recurrent violations accounted for more than half of violations in control reports, suggesting that inspections alone were not effective in promoting fundamental change in establishments with substandard practices (Phillips et al. 2006). Even though most food control officials consider that the use of enforcement measures strengthens food control actions and improves food safety, many find that recommendation and negotiation are sufficient for obtaining compliance (Reske et al. 2007). Procedures for implementing enforcement measures are perceived as heavy, demanding and time-consuming (Jokela et al., 2009; Lepistö & Hänninen, 2011). In the UK, enforcement officials have argued that, for certain types of offences, the sanctions are too low to be preventive, although effective penalties are an essential mechanism in the regulatory system (Martinez et al. 2007). Hampton (2004) also argues that effective sanctions prevent the most negligent FBOs from breaching regulations and provide assurance to compliant businesses that firms trying to gain a competitive advantage through non-compliance will be sanctioned. Moreover, an effective penalty regime can help to build consumer confidence in the food supply chain and enhance public health. On the other hand, in the case of low food safety risk and FBOs with consistently high rates of compliance, recommendations from a control officer aimed at continual improvements in performance can be more effective (Hampton 2004). The Food Standards Agency (2015) in the UK publishes a detailed database on convicted food frauds in order to share information among control authorities, but also to provide information to consumers. An effective penalty regime can help to build consumer confidence in the food supply chain even when penalties are the last resort (Martinez et al. 2007).

3 AIMS OF THE STUDY

The objective of this work was to assess the challenges in implementation of EU legislation at the local level in Finland among food control officials and FBOs and also to investigate national- and EU- level challenges caused by food frauds. Specific objectives were as follows:

1) To determine common features of regions with inadequate food control resources and to evaluate whether the resources and organization of food control affect control work in Finland (I, II, III).

2) To clarify implementation, interpretation and understanding of certain food legislation at the local level among control officials and FBOs in Finland and to determine the possible influence of implementation of legislation on consistent treatment and practices of FBOs (II, III, IV).

3) To identify the challenges created by food frauds at the local and national levels in Finland and in the EU (V).

4 MATERIALS AND METHODS

4.1 4.1. SELECTION OF MUNICIPALITIES (I)

According to Evira (Poutiainen-Lindfors et al. 2004), food control resources are unevenly distributed between municipalities in Finland, with an alarming shortage of food control personnel in some Finnish municipalities. Evira has evaluated resources based on an index classification that focuses on the number of existing personnel and food control objects. An index of resources was calculated for each municipality based on actual human resources used for food control compared with the minimum need for food control resources based on the number and type of surveillance objects in the municipalities as follows:

$$index = \frac{resources\ available}{\sum(no.\ of\ control\ objects \times no.\ of\ inspections \times time\ needed\ \ per\ inspection)}$$

Municipalities with less than half of the required resources in food control were defined as a minor resourced group (n=25). The comparison group (n=25) included geographically close municipalities with similar population size and number of food control objects with more resources than a ratio of 0.5 but still under a ratio of one. Major resourced groups (n=44) had a ratio of 1 or more between need and actual resources, indicating equal or greater resources than calculated need.

4.2 QUESTIONNAIRES (I, II, III, IV)

Altogether four questionnaires were sent during the study period. All questionnaires were built on a University of Helsinki web page by E-lomake® (Eduix/Delta Piktori Oy, Helsinki, Finland). The first questionnaire (I) about food control was electronically sent to food control officials of the minor resourced group (n=25) and the comparison group (n=25) in autumn 2005. The enquiry consisted of 75 questions, including background information, open questions and multiple-choice questions. The main areas of the questionnaire were as follows: i) local food control organization, ii) economic factors of environmental health protection, iii) food control resources and tasks and iv) opinions of respondents on local resources and alternative ways to organize food control. The respondents received the first e-mail message informing them about the electronic inquiry and referring them to the relevant web address. Three reminders were sent. The response rate was 62% (31 replies): 18 responses from the minor resourced group and 13 from the comparison group. Respondents consisted mostly of veterinarians and health inspectors.

An electronic enquiry was also sent to all 184 local food control units that had provided an e-mail address in contact information in the national register in December 2005 (II). The autonomous region of Åland was not included. The enquiry was addressed to the head of each unit. The receivers of the enquiry represented 78% of all food control units in Finland. The enquiry comprised 95 questions, including background information, open questions and multiple-choice questions. The main areas of this enquiry were as follows: a) basic information of the local authority, b) stage of planning of the quality system, c) current stage of the food control plan, d) food control fees and e) personal opinions on the quality systems, control plans and payments of food control. The respondents received e-mail messages and one reminder informing them about the electronic enquiry and referring them to the web address of the enquiry. Out of the 184 local food control units, 60 responded to the enquiry (response rate of 32.6%). Many of them represented more than one municipality, and thus, their responses covered a total of 143 municipalities (34.4% of all Finnish municipalities). Of the 60 local food control units responding (i.e. respondents), 55% represented the local units with less than 20 000 inhabitants and 45% the local units with 20 000 inhabitants or more. The regional distribution of responses calculated for all municipalities situated in each province was the following: Southern Finland 36%, Western Finland 35%, Eastern Finland 31%, Oulu 36% and Lapland 27%.

As a follow-up study, a questionnaire was sent to all 110 local food control units existing in October 2010 (III), except for the autonomous region of Åland. The questionnaire was addressed to the head of each unit, but they were requested to reply on behalf of the personnel of the whole food control unit. As a consequence of regional co-operation and merging of municipalities, the number of food control units had decreased from 184 in 2006 to 110 in 2010. A total of 46 responses was received in 2010, the response rate being 42%. The questionnaire consisted of 54 questions, including background information, open questions and multiple-choice questions. The main areas of this survey were the following: a) the quality system, the food control plan and food control fees charged, b) intra-regional co-operation and c) personal opinions on the changes taking place in the food control organization. The questions referred to the situation at the end of 2010. In order to obtain information for trend analysis, some of the questions were the same as those used in Study II. A single reminder about responding to the questionnaire was sent to the control units.

A questionnaire was sent in October 2006 to all approved meat and fish FBOs found in the register of the National Food Safety Authority Evira at that time (IV). The number of FBOs was 861, of which 164 were EU establishments in the meat sector, 327 low-capacity establishments in the meat sector and 370 establishments in the fish sector. The questionnaire investigated the quality of potential problems of meat and fish FBOs in relation to food legislation.

There were 238 responses altogether (IV), 5 respondents not indicating their business sector. The total response rate was 28%. The response rate of EU establishments in the meat sector was 31% (n=164/51), low-capacity establishments in the meat sector 25% (n=327/81) and establishments in the fish sector 27% (n=370/101). The majority of the respondents (63%) represented establishments that had less than 10 employees. Of all respondents, 22% represented an establishment with 10-49

employees and 11% establishments with 50 or more employees, however, 5% did not indicate the number of employees.

4.3 DATA SOURCES AND OTHER PUBLIC MATERIAL (I, V)

To investigate the reasons for discrepant resources in food control (I), the groups of municipalities were compared regarding their socio-economic position and their organization and practical functioning of food control work. In addition, the annual number of foodborne outbreaks in municipalities in 2000–2004 published by Evira was compared with other data.

Data on socio-economic factors were collected from Evira and Statistics Finland (2005), the Association of Finnish Local and Regional Authorities (2005) and the Ministry of the Interior (2005) and included a total of 50 factors (I). The most important ones were current population and predicted population in 2010, changes in population from 1980 to 2004, net migration %, population density, age structure, political emphasis, industrial structure, education structure, unemployment rate, taxable income €/inhabitant, annual margin €/inhabitant, state grants €/inhabitant, cash €/inhabitant, financial assets €/inhabitant, relative indebtedness %, operating margin, net result for financial year, real property tax, share of corporate rate incomes, net expenditures (€/inhabitant) in social security and health, in environmental health protection, in sports, in child day-care and in basic health care, change % in municipal tax incomes 2001–2002, change % in corporate rate taxes in 2001–2002, objects under municipal food control, operators with in-house control system, index of Evira (resources/minimum need), in-house control % excluding milk-producing plants, whether a municipality was a member of the federation of municipalities and field area.

All food notifications recorded by national food control officers in the EU under the hazard category of "fraud/adulteration" of the public RASFF database in 2008–2012 were retrieved and analysed (V) (376 notifications after the feed, feed additive and food contact material fraud/adulteration notifications were excluded) (RASFF notifications 2008–2012). Evira notifications of recalls related to food fraud in 2008–2012 were also collected and analysed (n = 50) (Evira recalls 2008–2012) (V). The Finnish court case database (Finlex 2012), including the database of the Courts of Appeal 1964–2012 and the Supreme Court of Finland in 1980–2012, was used to identify food frauds/adulterations with a court resolution (V). The keywords used in the search were "food", "food fraud", "food crime" and "health crime". In addition, all documented food fraud/adulteration cases from four large Finnish cities (Helsinki, Espoo, Turku and Hämeenlinna) for 2003–2009 were requested and received from local control officials in 2010. Not all of these cases received from local authorities were prosecuted. District courts of the regions in question were also asked to send details on all court cases concerning food crime, health crime, food fraud food deception, marketing offences and offences connected to import or export of food in 2003–2012. The population under the jurisdiction of these courts comprises 29% of the total population of Finland (Population Register Centre 2012). Cases resolved in district courts are not

registered in the Finlex database. Altogether only 16 documented cases were detected in the extensive search from this area and are referred to herein as local Finnish cases (V).

4.4 INTERVIEW (IV)

Managers of 18 FBOs that had gone through the process of approval for meat or fish establishments in 2005–2006 were personally interviewed during visits to their premises (IV). The interviews were based on the questionnaire sent to all meat and fish FBOs. These FBOs were situated in various parts of Finland, had 1–17 employees and had annual turnover varying from 30 000 euros to 3.5 million euros.

4.5 STATISTICAL ANALYSIS (I, II, III, IV)

Socio-economic parameters for municipalities and questionnaire responses were recorded and analysed separately with the Statistical Package for Social Sciences 12.0. (II), 13.0 (I) and 18.0 (III) for Windows (SPSS Inc.; Chicago, IL, USA). Arithmetic means with standard deviations (SDs) and 95% confidence intervals (CIs) for continuous parameters were calculated, and t-test was performed to analyse differences at the 95% level (p-value < 0.05) between three municipal groups with different resources (minor, comparison and major resourced groups) in food control as well as between municipalities with and without reported food- or waterborne outbreaks (I). A non-parametric Spearman's rank order correlation coefficient with a two-tailed p-value was calculated for cross-correlations between socio-economic parameters (I). A two-step cluster analysis was performed to find clusters of municipalities with similar socio-economic records (I). To analyse the questionnaires, t-test was applied to find differences at the 95% level (p-value < 0.05) between municipalities in the minor resourced and comparison groups, between municipalities according to certain other characters (e.g. education of responsible food control officer and occurrence of food- or waterborne outbreaks) (I) and between "the big local units" and "the small local units" (II and III).

Questionnaire responses were analysed both quantitatively and qualitatively to uncover background information for our findings (I, II, III and IV). Regional differences were calculated based on the regional response rate (II and III).

5 RESULTS

5.1 DIFFERENT RESOURCES AND ORGANIZATION OF LOCAL FOOD CONTROL IN FINLAND (I)

5.1.1 Features of minor resourced municipalities and their comparison groups

Based on the public database, the minor resourced group had a weaker economic situation than the comparison group. A trend of higher population density, net migration percentage and corporate rate income was discovered in the minor resourced group. The share of "other expenditures" in the control unit (i.e. costs other than wages, room rentals, laboratory services, travel, education, lost animals and purchase services) was significantly ($p<0.05$) higher in the minor resourced group (18%) than in the comparison group (4%). The existence of approved in-house control systems in the FBOs in municipalities correlated significantly ($p<0.01$) with the level of resources in food control, as the proportion of approved in-house control systems of all FBOs (excluding milk-producing plants) was in the minor resourced group 64% (16/25), in the comparison group 73% (18/25) and in the major resourced group 81% (36/44). Officials working in the minor resourced group spend less time counselling and guiding FBOs than those in the comparison group, but they did spend more working hours in delivering samples to often distant laboratories personally and in performing different state-mandated tasks.

In the minor resourced municipalities, the councils had no members with background in food control (0%, 0/18 vs. comparison group 15%, 2/13) and less often a member with food industry background (6%, 1/18) than in the comparison group (15%, 2/13). The majority of respondents in minor (72%, 13/18) and comparison groups (69%, 9/13) agreed that the municipal decision-makers were uninformed and not familiar with the field of food control. Furthermore, the official in charge of food control was more often not specialized in food control questions, the allowances and schemes were approved at lower level in the hierarchy and there were more delegations of decision-making to the health inspector instead of the officer in charge in the minor resourced group.

5.1.2 Other possible reasons for minor resources

According to the opinions of respondents, the main reason for inadequate resources in food control was a lack of overall funding (60%, 19/31). Ignorance or uncaring attitude of decision-makers regarding food control also seemed to be a common problem, as 33% (10/31) of respondents indicated a lack of information of decision-makers as the main reason for inadequate or poor resources in food control. The communication skills of the officials in charge of food control were criticized and cited as a reason for poor resources. Open answers from both groups reflected this as weak supervision, with silent and powerless officials in charge who cannot do lobbying on behalf of the sector often mentioned together with overall undervaluation and underappreciation of the branch.

5.1.3 Combination of resources with outbreak data

During 2000–2004 a total of 246 food- and waterborne outbreaks were notified by Finnish municipalities as taking place in 113 different municipalities. Respondents from both the minor resourced group and the comparison group with reported foodborne or waterborne outbreaks were less satisfied with the resources ($p<0.01$), the level of food control ($p<0.05$) and the success of prioritizing of food control ($p<0.05$) than respondents from municipalities without the outbreaks. Ten food- or waterborne outbreaks were reported in the minor resourced group, whereas one of the major resourced municipalities reported a food- or waterborne outbreak in 2000–2004. According to the socio-economic data, the municipalities with outbreaks had significantly ($p=0.01$) smaller environmental health protection (including food control) costs per inhabitant (16 €/inhabitant) than municipalities with no outbreaks (18 €/inhabitant).

5.1.4 Alternative ways to organize food control

Opinions on regional co-operation and organizations, nationalization (i.e. certain tasks becoming the responsibility of governments) and state funding were disclosed in an enquiry from the minor resourced group and the comparison group. Both groups had similar opinions regarding regional co-operation and regional organizations. The respondents largely (84%, 26/31) supported regional co-operation, but most officials (79%, 24/31) believed that increased co-operation would not reduce the costs of food control to municipalities.

Almost half of the respondents had the opinion that nationalization of food and environmental health control (at the time of the study, environmental food and health control included animal welfare, control of animal diseases, control of tobacco, control of chemicals, food control, control of water quality), including food control, would improve equality of citizens (minor resourced group 44%, 6/13 comparison group 46%, 8/18). Approximately half of the respondents in both groups were of the opinion that state authorities had not succeeded in guiding and supervising local food control. The majority (> 70%, 22/31) of both groups answered that the state should ear-mark grants for use in food control.

5.2 REGIONALLY VARYING WAYS OF IMPLEMENTING EUROPEAN UNION LEGISLATION CONCERNING QUALITY SYSTEMS, CONTROL PLANS AND CONTROL FEES IN FINLAND (II, III)

5.2.1 Quality systems of official food control

In 2005, out of 143 municipalities, represented by 60 joint control units, responding, only 24% (n=34/143) had a quality system in use. In the follow-up study in 2010, the situation was better, as 41% out of the 46 responding food control units (19/46) had a quality system in place and the majority (87%, 40/46) of control officers also were of the opinion that quality systems ensured equal treat-

ment of FBOs. In 2005, some regional differences existed; 44% of the municipalities located in Eastern Finland had a quality system in use, whereas none of the municipalities in the Oulu region had a quality system. Municipalities with more 20 000 inhabitants had a quality system in use (33%, 9/27) more often than municipalities with less than 20 000 inhabitants (9%, 3/33). Also in a follow-up study in 2010, quality systems were more common in the large control units (48%, 14/29) than in the small ones, where only 29% (5/17) had one in place.

In 2005, only 62% (n=89/143) of the municipalities already included, or were going to include in the future, bases of risk estimation or the description of surveillance actions in their quality systems. In 2010, 95% of respondents stated that quality systems had facilitated inspections (44/46). The enquiry in 2005 suggests that the biggest challenge was to include the risk assessment in the quality system, especially in the most scarcely populated areas; only 17% of the municipalities from Lapland and 33% from Eastern Finland responded that their quality system included, or would include in the future, the bases for their risk-based decision-making.

Difficulties in creating the quality system in 2005 were indicated to be lack of time (89%, 53/60) and lack of personnel (56%, 34/60). Another problem encountered was lack of knowledge about creating a quality system; only 21% (13/60) of the respondents indicated that lack of knowledge was "not a problem". The lack of instructions and models was considered to be "a rather big problem" or "a big problem" by 39% (23/60) of the respondents in 2005.

When the respondents were in 2005 asked why they had constructed a quality system or were going to construct one, most respondents had a positive view of the quality system. Several open answers (28% of all respondents) emphasized the positive influence of the quality systems on the equal treatment of operators, or on unifying the control work.

5.2.2 Local food control plans

In 2005, 90% (129/143) of municipalities already had local food control plans based on the previous Food Act (361/1995). Lack of time was most often (64%, 92/143) mentioned as hindering creation of food control plans. Although 69% (99/143) of municipalities in 2005 included, or were going to include, risk assessment in the control system, the variation between municipalities was quite large and only 16% (23/143) agreed that an estimation of risk followed by establishing an inspection frequency had been performed for each control object. In fact, 52% (31/60) of the respondents agreed with the statement that risk assessment is difficult and that it creates "a rather big or a big" problem for designing a control plan. In 31% (19/143) of the municipalities, the frequency of inspections was determined by the experience and knowledge of the inspector in 2005. The rest of the municipalities determined the frequency of inspections by using a combination of the aforementioned methods. Furthermore, the decision-makers varied in 2005, as in 41% (59/143) of the municipalities, the risk assessment and the frequency of inspections were decided on solely by their "own" inspector of the objects. In other cases, the risk assessment was performed by the inspector and his/her supervisor together (29%, 41/143),

and in some municipalities (17%, 24/143), by several inspectors together, whereas 13% (19/143) did not mention how the decision was made.

5.2.3 Food control fees

In 2005, the results showed that local authorities in Finland were going to start charging control fees according to the Finnish Food Act (2006) at different times, based on different grounds and in different amounts. Out of 143 municipalities, 17% (24/143) would start collecting fees during 2006, 51% (73/143) in 2007, 3% (4/143) in 2008 and 29% (41/143) did not know when they would start to charge for their control services.

Around 50% (72/143) of the 143 municipalities expressed in 2005 that they had no knowledge of the grounds for the fees to be charged for inspections included in the control plan. Only 7% (10/143) of the municipalities planned to charge according to the proportionate risk in relation to production, i.e. higher risks projected for control objects would result in higher fees. Furthermore, 8% (11/143) of the municipalities planned to base charges on the processing/distribution methods used and the production volume, and 10% (14/143) planned to charge according to the classification provided by Evira for control objects. In addition, 15% (21/143) planned to base charges on working time used and 5% on some other grounds.

In 2005, the amount of the planned fee varied between 21 and 45 euros per hour. The different regions had variable intentions to set charges if the fees were to be based on euros per hour. The differences between municipalities were not detected only in the euros charged per hour, but also on how the municipalities planned to include the time used by the food control officer outside the inspected site of FBO. Of the municipalities, 89% (127/143) responded that the FBOs should also pay for the time needed for each control object by the food control officer outside the inspected site. A minority of the respondents (38%, 23/60) supported the view that control fees have no effect on the in-house control systems. According to 78% (47/60) of the respondents, there will be more complaints concerning the work of inspectors due to control fees.

In 2010, it was clear that the fees were underestimated, as in the follow-up study the range of control fees charged varied from 32 to 56 euros per hour, the median for all control units being 45 euros. In 2005 and 2010, the respondents were unanimous that control fees should be ear-marked for food control purposes. The incomes from food control were treated differently by the local decision-makers; in 2005, in 55% (79/143) of all municipalities the incomes from environmental health protection (including food control) remained in the same unit, and in Western Finland, the proportion was the lowest (41%), whereas in Oulu it was the highest (77%). In 2010, control officers had a positive attitude towards control fees, as most of the 46 respondents supported control fees (94%, 43/46) and believed that they have had a positive effect on the quality or functioning of in-house control systems of FBOs (75%, 34/46).

5.2.4 Personal opinions on evolving requirements

In the open questions in 2005, many respondents considered performing risk assessment to be problematic and they hoped for more guidance or information. More guidance, advice and uniform models were also commonly desired to ensure the equal treatment of FBOs. Audits and accreditations performed by outside organizations were feared to increase the costs of food control, and internal audits were offered as an alternative by several respondents. The attitudes were different in 2010, as at that time more than half of the respondents (52%, 24/46) desired external audits to evaluate the professional qualifications of control officers. In 2005, an increased number of appeals and complaints from the FBOs towards future control work was seen to enhance the equal treatment of FBOs. Some respondents also thought in 2005 that fees hindered fruitful co-operation between FBOs and officials, and several respondents held the opinion that expanded charges will bring more complaints and appeals concerning the control visits. However, the follow-up study in 2010 showed that charging of control fees was not perceived to have increased the number of complaints directed against control officials by FBOs (5%, 2/46), and only 18% (8/46) of respondents felt that fees had diminished the guidance and counselling of FBOs. In 2005, the requirements for quality systems, control plans and fees were believed to improve the quality of in-house control systems and official controls (85%, 51/60), and also in 2010 the vast majority of respondents (88%, 40/46) perceived that quality systems, control plans and fees enhance the quality of food control.

In 2010, food control officers agreed that the collected control inspection fees should be returned to the control unit and that these fees should be standardized nationally to ensure equal treatment of FBOs (80%, 37/46). Almost all respondents in 2010 supported intra-regional co-operation, even though they were of the opinion that such co-operation did not reduce costs or increase resources.

Intra-regional co-operation was highly supported (96%, 26/28) by those respondents who were already participating in the co-operation in 2010. According to open questions of the questionnaire and open comments of respondents, co-operation was supported because it facilitates specializations of skills, even when changes in organization and also in legislation increase the work pressure of control officers.

5.3 CHALLENGES OF FOOD BUSINESS OPERATORS IN IMPLEMENTING AND COMPLYING WITH FOOD LEGISLATION (IV)

The results revealed that Finnish meat and fish FBOs had both a common and a differing understanding of the challenges imposed by the requirements set by food legislation. The most common problems mentioned were related to the layout of production premises and transport routes, control fees, requirements concerning in-house control, structure and maintenance of premises, package labels and the HACCP system.

In open answers, constantly changing rules and legislation were often cited as causing problems as well as different implementation of requirements by the authorities. FBOs of different sizes had different problems. Of the smallest FBOs (less than 0–2 employees, n=61), 43% (26/61) considered that control fees created problems, whereas other groups found control fees much less problematic. Of the biggest FBOs (250 or more employees), 40% (n=2/5) reported traceability, record-keeping and documents, in-house control samples, temperature criteria for products and by-products and waste management to be most problematic. However, several requirements were not perceived as problematic among the biggest FBOs, including the HACCP system (0%) and hygiene requirements for production (0%). Meat inspection, which is quite heavily regulated, was seldom considered problematic among all FBOs (3%, n=8/233).

Among the different sectors, FBOs in the fish sector (n=101) most often (18%, 18/101) mentioned problems in requirements applying to in-house control, whereas EU establishments in the meat sector (n=51) most often had problems in the layout of production premises and transport routes (39%, 20/51). Control fees were most problematic (36%, 29/81) for the low-capacity meat sector (n=81); FBOs in this sector also found the HACCP system to be a problem twice as often as other FBOs (24%, 19/81). More than 11% of both EU meat establishments (6/51) and the low-capacity meat sector (9/81) found traceability to be a problem, while only 6% (6/101) of the fish sector considered it a problem. Record keeping also seems to be less problematic for the fish sector (5%, 5/101). Package labels appear to create problems for all FBOs (17%, 39/233).

Results from the interviews showed that FBOs are largely satisfied with official food control, instructions given by control officials and food safety. There was, however, criticism of varying interpretations of legislation and unequal demands on FBOs. Of the 18 interviewees, 6 mentioned officials making different demands and requirements; when the official changed, the demands and liabilities changed. Several respondents also mentioned that regulations and officials do not take the size of the establishment into consideration when applying regulations. Constant amendments in regulation were said to increase expenses for FBOs.

Problems with the legislation that were mentioned in interviews were mostly the same as in the questionnaire: the structure and location of production facilities, in-house control systems and package labels. Small FBOs, in particular, found the in-house control system and HACCP rather laborious and theoretical. Small FBOs typically used a student from the local educational unit to build an in-house control system as student work. The structure and location of production premises and transport routes caused problems for several respondents, and some FBOs had even closed down their business because of requirements causing excessive costs.

In open questions, the most common concern mentioned by 21 respondents was lack of a common interpretation of legislation among control officials. Officials were said to have varying demands and interpretations both within one municipality and between municipalities. Control fees were also men-

tioned as varying between municipalities. HACCP demands especially were described to differ between officials, and the HACCP system was said to be too laborious and troublesome for many small FBOs.

5.4 CHALLENGES IMPOSED BY FOOD FRAUD ON OFFICIAL FOOD CONTROL (V)

5.4.1 Rapid Alert System for Food and Feed notifications

In the RASFF database in 2008–2012, fraud/adulteration notifications constituted only a small proportion (2%) of all 16 615 notifications reported. Fraud/adulteration notifications were most often reported by the UK (n = 59), Italy (n = 55), France (n= 38) and Germany (n= 30), unlike Finland, which made only one fraud/adulteration notification in 2008–2012. The most common notification type of the 376 RASFF food notifications classified by competent authorities as "fraud/adulteration" notifications was border rejection (77%, 289/376), followed by information notifications (22%, 82/376) and alerts (1%, 5/376). The origin of the food was most commonly Asia (45%, 171/376), followed by the Middle East (16%, 60/376), South America (10%, 38/376), EU (8%, 29/376), Africa (8%, 29/376), Eastern Europe (6%, 22/376) and North America (5%, 21/376). The remaining 6 notifications originated from Oceania or from several or unknown countries (2%). Most common food categories with frauds/adulteration notifications were meat, including poultry and fish and fish products, and nut products and seeds (each having 15% shares of all 376 notifications). Their proportions varied throughout this 5-year period; meat and meat products dominated in 2008–2010, followed by fish and fish products in 2010–2011 and nuts, nut products and seeds together with confectionery in 2011–2012.

Of the 376 RASFF notifications studied, 13 reported two reasons for notification, thus resulting in a total of 389 fraud/adulteration notification reasons. The most common reasons for fraud/adulteration notification were illegal or unauthorized trade/import/transit (25%, 99/389), improper health certificate (23%, 89/389), missing health certificate (17%, 66/389) and fraudulent health certificate (15%, 58/389). Most often the combinations were 1) illegal or unauthorized trade, import or transit/food of animal origin, 2) improper health certificates/nuts, nut products and seeds, fish and fish products and fruits and vegetables, 3) absent health certificate/confectionery, nuts and fish and fishery products and 4) fraudulent health certificate/seafood. Although some of the improper, expired or missing documents may be due to administrative error, competent authorities have classified them under the category of adulteration/fraud and not, for example, under poor or insufficient controls or labelling absent/incomplete/incorrect (examples of other hazard categories available in the RASFF database), and they are therefore considered as frauds or adulterations in this analysis. Fraudulent or adulterated parcels or lots were most commonly either destroyed (26%, 103/389) or redispatched (26%, 103/389) or access to the market was prevented by other means (official detention or seizure) after

detection. In 10% of cases (39/389), the product was withdrawn from the market. No mention of prosecutions was found in the register.

5.4.2 Notifications of recalls by Finnish Food Safety Authority Evira

Similarly to the RASFF results, most of the notifications of recalls published by Evira in 2008–2012 comprised direct public health risk (79%, 189/239) and were not considered as fraud/adulteration. Public health risks were either due to food safety/quality reasons, such as salmonella, heavy metals or mycotoxins (51% of all notifications, 122/239), a component added to the food that could potentially cause an allergic reaction (23% of all notifications, 55/239) or missing/wrong/misleading labelling (5% of all notifications, 12/239). Of the 239 notifications of recalls published by Evira in 2008–2012, 21% (50/239) were linked to a similar definition of fraud or adulteration as in RASFF cases. Food products reported were food supplements (22), rice vermicelli (7), sweets (3), chaga mushroom or other plant products (6), drinks (3), muesli (3), spices (1), snacks (2), meat (1) and seeds/seed oil (2). Non-domestic ready-to-eat products were linked to 90% (45/50) of all fraud/adulteration notifications.

The most common reason (52%, 26/50 notification reasons) for recall in the Evira fraud/adulteration notifications was unauthorized genetically modified rice or use of plants not authorized as novel foods, followed by unauthorized food ingredients or substances (30%, 15/50), unauthorized irradiation (16%, 9/50) and non-compliance with hygienic rules of establishment (2%, 1/50). Fraud/adulteration originated from domestic primary production in 3 cases (unauthorized use of a chaga mushroom, Inonotus obliquus, as a novel food) and processing in 2 cases (unhygienic premises and unauthorized use of a chromium substance).

5.4.3 Local Finnish cases

Documented local Finnish cases of intentional food fraud/adulteration revealed the indifference of FBOs towards the orders given by control officials. In the majority of cases (56%, 9/16), FBOs continued forbidden activities even after several warnings from control officials until more severe actions, such as destruction of products or indictment, were brought to bear. Products in reported cases were most often (88%, 14/16) meat or meat products or fishery products. Unlabelled, falsely labelled or missing documents (63%, 10/16) formed the most frequent fraud type in all product categories.

Consequences of frauds were public health risks, deceit of consumers and benefit at the expense of other FBOs. Of the 12 cases prosecuted in court, the FBO was accused and found guilty of a health crime, i.e. endangering consumer health, in 83% (10/12); imprisonment was imposed in only one case. Of fraud cases, 25% (4/16) did not end up in the judicial system. However, also in these cases fraudulent products were withdrawn from the market, destroyed or premises were closed and an injunction was placed against FBOs by the decision of the food control officer.

5.4.4 Comparison of patterns at European Union, national and local levels

The products in both RASFF (92%, 358/389) and Evira (90%, 45/50) fraud/adulteration reports originated most often from outside the borders, whereas local Finnish cases mainly dealt with domestic production (71%, 11/16). In RASFF notification reasons, 33% (128/389) comprised illegal or unauthorized trade, practice or adulteration/tampering, whereas the rest (67%, 261/389) concerned frauds in documentations. Similarly, missing, fraudulent or improper documents were most commonly reported in local Finnish cases (63%, 10/16). By contrast, the pattern was very different in Evira notifications, where unauthorized food, ingredients or process constituted 98% (49/50) of all fraud notification reasons. Both in RASFF fraud notifications (50%, 195/389) and in local Finnish cases (88%, 14/16), the majority of notifications concerned food of animal origin, while in Evira fraud notifications food supplements dominated (44%, 22/50) and food of animal origin was reported only once (2%, 1/50).

5.5 SUMMARY OF EFFECT OF VARYING IMPLEMENTATION OF REGULATIONS OR REPORTING OF FRAUDS ON THE PRINCIPLE OF EQUAL TREATMENT (I, II, III, IV, V)

In some regions of Finland, the human resources used for food control are less than the minimum required based on the number and type of surveillance objects, resulting in different levels of food control (I). In these municipalities, also decision-making was more often delegated to a health inspector instead of the officer in charge (I). When the officer in charge was on his annual holiday, there was most often (89%) no one replacing him (I). Authorities in these municipalities do not spend as much time in counselling and guiding FBOs as the authorities in other regions (I). Almost half of all respondents thought that nationalization of food and environmental health control would improve equality of citizens (I). Larger control units were also supported (I, II and III). The level of food control was found to be inadequate in the minor resourced areas, where there were also less approved in-house control systems among FBOs and more food- or waterborne outbreaks (I). Control authorities implement food legislation requirements concerning control plans, quality systems and control fees at varying time points and with varying contents (II-IV). Quality systems are seen to improve the quality of inspections (88%), and to ensure equal treatment of FBOs (87%), yet only 41% of control units had a quality system in place in 2010 (III). Control units started collecting control fees from the FBOs at varying time points: 17% started collecting fees in 2006, 51% started in 2007, 3% started in 2008 and the rest (29%) had no knowledge about when they would start collecting fees from the FBOs. Grounds for fees were different among control units (II and III); some control units charge FBOs only for the time spent on actual inspection and some charge also for time spent by the officer outside the inspected site (II). The amount of fees charged from the FBOs per hour varies regionally between 32 and 56 euros (III). Control officials desired standardized fees to ensure equal treatment over the whole country (II and III). FBOs felt that control officials have varying interpretations of food safety legislation; when the

official changed, the demands and liabilities changed (IV). Officials had different demands and interpretations within one control unit and between control units. Small FBOs saw requirements of food legislation as more difficult and burdensome than medium-sized FBOs. FBOs of microenterprises (staff 1 to 9) felt that the requirements concerning the size of the production facilities as somewhat excessive (IV). Control fees are more problematic for small FBOs than others (IV). An inclusive HACCP system was too cumbersome for small FBOs (IV). Countries inside the EU report food frauds to the RASFF system with varying frequency (V). RASFF and Evira fraud notifications concerned mostly products originating from outside the EU, whereas fraud cases with court conviction involved mostly domestic production. All fraud cases in Finland do not end up in the judicial system even when there is a significant public health risk (V).

6 DISCUSSION

6.1 PRINCIPLE OF EQUAL TREATMENT (I, II, III, IV, V)

Comprehensive and harmonized food safety regulation has no importance if it is not implemented, interpreted and understood in a uniform manner by control officials and also by the FBOs throughout the EU. If different regions have varying requirements or interpretations of legislation, it results in different levels of demands towards FBOs and might even have an influence on the competitive position of FBOs and public health. FBOs inside the EU are treated differently if similar non-compliances result in legal actions and penalties in some countries and only withdrawal from the market in other countries, as is case between Finland and the UK (Food Standards Agency 2015). The principle of equal treatment is firmly established in the EU (Council of Europe 1950). In practice, though, treatment of citizens with similar cases may vary between member countries. This is possible because the implementation of EU legislation into national legislation is the responsibility of the authorities in each member country and the procedure for implementation is not harmonized (Mäenpää 2003). The principle of equal treatment requires consistency in decision-making. The requirement of consistency does not, however, justify general decisions without paying attention to specific features of each case such as risk for consumer health, nature of operations or size of the FBO. Actions of authorities must also be in proportion to the objective pursued (Administrative Procedure Act 434/2003). The national control plan of Finland for 2015–2019 (Evira 2015b) also emphasizes the importance of equal treatment in control work when using public power in the form of binding orders or decisions towards FBOs. Written process descriptions, codes of conduct, chain auditions and several models for documents are offered by Evira to increase uniformity of food control (Evira 2015b).

Regionally and even within a single control unit, varying implementation or interpretation of legislation was discovered (I-IV). In some cases, when the control officer changed, the requirements or interpretation of legislation changed (IV). Food control resources in Finland differ regionally (I), possibly compromising also the level of controls. Food control fees, control plans and quality systems are taken into use at different times and with regionally divergent contents (II, III). In addition to regional location, the size of the FBOs has been noted to affect the consistency of orders given by inspectors to correct non-compliances, as small FBOs reported not being able to negotiate about non-compliances, whereas bigger FBOs were able to negotiate (Nevas et al. 2013). Inadequate resourcing of local food control inevitably leads to strict prioritizing in targeting the inspection visits and less frequent inspection visits to certain food production establishments (Nevas et al. 2013). This also may have an impact on the opinions of FBOs on the benefits and equality of food control. According to Läikkö-Roto et al. (2016), tacit knowledge of food control tasks exists in control units. When tacit knowledge is not shared, it decreases the efficiency and uniformity of the food control and may lead to variable practices. Even insufficient sharing of knowledge among personnel with the decision-making authority inside the control unit was recently discovered (Läikkö-Roto et al. 2016). This might compromise the legal

rights of FBOs when the needed competence in the decision-making process is not ensured, especially if the power of making decisions is delegated to someone lower in the hierarchy (I).

Effective food control systems are essential to protect the health of consumers. EU regulations regarding food control have brought changes to several national food control legislations (EC 2014). It is vital that these rules are fully respected by all operators in the sector. The competent authorities in the member states must have the appropriate technical knowledge, including awareness of the Community rules on food legislation, food hazards and market mechanisms, to enable them to effectively verify compliance with the Community rules (EC 2014). The national authorities also need adequate training and regular updating of their knowledge in the area of food safety, as has been recognized by Regulation (EC) 882/2004.

6.2 EFFECT OF RESOURCES AND CONTROL ORGANIZATION ON FOOD CONTROL (I, II, III)

Knowledge, training and proper implementation of new legislation can become insignificant if the resources in actual food control work are too scarce to allow performance of tasks adequately to ensure the safety of food and the health of consumers. Limited resources in local food control may affect the ability of control officials to guide and advise FBOs as stipulated in Regulation (EC) 882/2004 due to shortage of time. Lacking resources may also affect the ability of local control officials to specialize in certain tasks or sectors, and thus, provide the expertise needed by FBOs. According to the results of this study (I), weak economic condition of the region was one explaining factors for inadequate human resources. In 2008, the European economy was in the deepest recession since the 1930s (EC, DG Economic and Financial Affairs 2009). In 2015, the pace of financial recovery and economic growth remains slow (EC, DG Economic and Financial Affairs 2016). In Finland, the gross domestic product (the value of all final goods and services produced in a year) was 36 457 €/inhabitant in 2008 and 37 559 €/inhabitant in 2014 (Statistics Finland 2015b), indicating no recovery from the recession in 2008. Even in a poor economic situation, decision-makers must acknowledge the importance of food control for the safety of consumers and allocate adequate funds to control work. If the resources in food control are scarce, the safety and trust of consumers may also weaken and affect the food market. Even though the respondents regarding local food control resources (I) represented only a small portion of local authorities, it is clear that the knowledge and respect of local decision-makers of food control might affect funding, and thus, resources and functioning of local food control. The importance of food control for decision-makers should thus be promoted. Recently, the Regional State Administrative Authorities in Finland assessed the human resources for official food controls in Finnish municipal food control units as insufficient (Evira, 2012, 2013, 2014), but also in the Regional State Administrative Authorities human resources in food control were insufficient, resulting in less education and training for municipal food control officials (Evira 2014). According EC (2009), some member states

expressed the view that in order to intensify control work the number of staff required to perform official controls should be explicitly defined in EU law.

According to Study I, some local food control officers felt that their branch of work was somehow underappreciated in the municipal organization and in decision-making, and this was mentioned to have a negative impact on the resources allocated to control work. A feeling of underappreciation can clearly affect the motivation of personnel, and according to Läikkö-Roto et al. (2016) motivation and well-being of operative staff on-the-job are essential for high-quality and efficient official food control. When the staff of any organization is satisfied with their job and committed to the organization, they also feel more connected to their work (Høigaard et al. 2012, Powell & Meyer 2004, Yalabik et al. 2013). According to a recent Finnish study, even when food control units in Finland invest in sufficient prerequisites for official food controls, challenges remain with regard to adequate resources and creation of appropriate working conditions in units (Läikkö-Roto et al. 2016).

Communication skills of officials in charge with municipal decision-makers were criticized by themselves, and poor lobbying skills was mentioned as a reason for inadequate financial resources allocated to food control (I). Good communication and strong internal co-operation within control units with adequate management skills were also desired (Läikkö-Roto et al. 2016). Better communication between decision-makers and food control officers as well as inside control units is therefore needed, especially when leading food control officers described themselves as "passive and silent" (I). Petticrew et al. (2004) and Speybroec et al. (2015) also noted that interaction and communication between scientists and decision-makers in general is crucial and that the language of communication should be clear and transparent in order that parties understand each other's concerns. Anders and Schmidt (2011) reported that most regulatory approaches to risk prioritization developed to date are based on measures of health outcomes and do not systematically account for other factors that may impact decision-making such as the economic, market-level and social dimensions of food safety. Therefore, open communication between all parties is needed and would increase transparency, and hence, uniformity of control actions. One of the main targets of the national control plan of Finland in 2015–2019 is open communication of authorities in the whole control chain towards FBOs and consumers (Evira 2015b). Although the number of municipalities compared (I) was modest, new information on the bases of inadequate food control resources was discovered.

In Finland, larger food control units with several municipalities are highly supported by food control officials (II, III). Larger areas with common instructions, standards and active auditing methods and open communication could reduce at least regionally uneven treatment of FBOs and should thus be further evaluated. Larger control units with intra-regional co-operation also facilitate specialization in certain work, but apparently do not ease the lack of resources among control officials or decrease costs for participating municipalities (III). In contrast, a study conducted by Ryhänen & Ketola (2008) revealed that the greatest challenges for food control personnel in intra-regional co-operation in 2008 were increasing burden of bureaucracy, mistrust, lack of openness between participating municipalities and poor transfer of information. It is also possible that the local knowledge and the knowledge of

control objects is better in smaller control units, resulting in more precisely targeted inspections, saving time and resources. This aspect should be further evaluated in larger control units.

6.3 IMPLEMENTATION OF REGULATIONS CONCERNING QUALITY SYSTEMS, CONTROL PLANS AND CONTROL FEES IN FINLAND (II, III)

According to EU (Regulation EC 882/2004) and national legislation (Finnish Food Act 23/2006), food control units shall compile and implement quality systems to provide operative staff information and instructions about issues such as their tasks, responsibilities and duties, their work objectives, control methods and techniques and the actions taken following controls. Further, official controls are to be carried out regularly, on a risk basis with appropriate frequency based on the risk assessment of each FBO (Finnish Food Act 23/2006). Local authorities are to have also a control plan that covers all FBOs and establishments (Finnish Food Act 23/2006). The results show that legislation concerning control plans, quality systems and control fees is implemented with considerable delay, at regionally different time points and with different contents in Finland (II, III).

Different and varying contents of food control plans directly impact FBOs in frequency of control visits and subsequent fees (II, III). The contents of control plans vary regionally, and more than half of the respondents (52%) found risk assessment of control objects to be difficult (II). Also the determination of frequency of inspections was performed with different methods (II), and in 2010 over half (57%) of the respondents felt that there was insufficient guidance for risk-based controls (III). The vast majority of food control units perceived that quality systems and control fees facilitate inspections and have a positive effect on the quality or functioning of in-house control systems of FBOs. Quality systems were also seen to enhance equal treatment of FBOs (III). Even when the control unit has a quality system in place, there may be insufficient commitment from inspectors to result in high-quality systems or operating procedures (Läikkö-Roto et al. 2016). Quality systems in food control became mandatory in Finland in March 2006 (Food Act 23/2006); however, in 2010 only 41% of local food control units responding to an enquiry and 32% of respondents participating in intra-regional co-operation had a quality system in place (III). The results indicate that larger control units are not more effective in implementing new regulations; implementation appeared to be done more effectively in smaller control units. On the other hand, the results also suggest that extra administrative tasks during the organizational change take time away from control work. Thus, the efficiency of implementing new legislation in both small and large control units should be investigated further.

One way of evaluating adequateness of risk-based food control, thus unifying the control, is auditing the control unit. In Finland, the obligation to guide and evaluate the municipal food control is assigned to the Regional State Administrative Authorities by law (Finnish Food Act 23/2006). A recent study (Läikkö-Roto & Nevas 2014a) reveals that municipal officials are not satisfied with the expertise of the auditors concerning official food control in practice and do not find the audits very useful. Audits performed by outside organizations were feared to increase the costs of food control, and internal audits

were offered as an alternative (II). In order to evaluate the effectiveness of the entire food control chain, Evira has launched a chain auditing method (Evira 2015b).

According to Regulation (EC) 882/2004, member states may collect fees to cover the costs occasioned by official control. As local food control authorities in Finland (single municipalities or joint local units with two or more municipalities) are in charge of food control in their own area, they can independently decide the amount of fees. Large variation in fees, the basis of the fees and the starting time of collecting fees exists (II, III). Regulation (EC) 882/2004 leaves it up to member states to define the fee system, and great incoherence in the fee calculation, basis of fees, fee collection, use of revenues and enforcement of fees between member states has been discovered (EC 2009). According to EC (2009), in member states with decentralized management the central competent authority is not always in control and effective coordination is not always ensured even though Regulation (EC) 882/2004 implicitly refers to a central authority as having the ultimate responsibility for effective coordination. With divergent bases and levels of fees between member states, regions and sectors, even within control units and depending on the size of FBO (II, III and IV, EC 2009, Läikkö-Roto et al. 2015), the question arises of distortion of competition and uneven treatment of FBOs. In Finland, standardized control fees are seen to increase equal treatment of FBOs (II, III). To achieve more coherent control fees, the EU has proposed grounds for common minimum fee levels to improve the transparency and accountability of fees (EC 2009). Without transparency of fee systems and bases thereof, including the obligation of member states to report them to the EC, it is impossible to estimate the effects of control fees on free competition and distortion of the market.

6.4 CHALLENGES OF FOOD BUSINESS OPERATORS WITH REGARD TO FOOD REGULATION (IV)

Harmonized food legislation is insignificant unless it is properly understood and complied with by the FBOs who are responsible for the safety of their products. The attitudes of the FBOs towards food control may also have an impact on the realization of official food control and safety of food. The results and previous studies show that food safety is a concern of FBOs, and FBOs in general are satisfied with official food control and instructions and advice given by control officers (III, Nevas et al. 2013). Even with the modest response rate and limited operating sector of FBOs, it seems clear that several requirements of food legislation cause extra efforts to FBOs of all sizes and fields of business (III). Small and medium-sized meat and fish FBOs in Finland consider things like layout of production premises, transport routes, structures and maintenance of premises and building materials as problematic for their operations (IV). According to Green & Kane (2013), control officials are more likely to pay attention to visually apparent and rule-based physical (walls, floors, ceilings, etc.) non-compliances rather than effectively checking and discussing the HACCP system to reveal significant risks. Assessing a risk-based problem that is embedded in the system of food production and involves discussing and contemplating the system with the staff, rather than simply reporting what is seen, might also create a

challenge for the control officer (Fairman & Yapp 2005). This might partially explain why physical items play such a large role among FBOs' problems. Detailed and practical common instructions with practical examples concerning premises would be beneficial for the FBOs and control officials, facilitating inspections and unifying requirements. The results are also alarming, as discovered shortages may also impose significant health risks. Some of the FBOs also had to discontinue their operations because of the expense of the required amendments (IV). In addition to the expense of fixing the premises to meet hygiene requirements, indifference to requirements may be why the premises did not meet code to begin with, with FBOs instead concentrating on achieving the highest possible profit.

Both the control officers and FBOs requested more models, guidance and assistance with quality systems and risk assessment (II, III, IV, Nevas et al. 2013). With evolving legislation and new requirements, it is essential that uniform instructions and models to assist with new requirements are given without delay by the policy-makers. In Finland, Evira aims to increase and facilitate the training of control officers by using multiannual training calendars and remote access to training sessions (Evira 2015b).

6.5 FOOD BUSINESS OPERATORS AND HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEM (IV)

Even though a harmonized HACCP-based system has been obligatory for all non-primary FBOs since 1998, it is still one of the requirements causing problems for FBOs (IV). Several FBOs used outside consultants to plan a HACCP system instead of using their own personnel (IV). HACCP systems include continuous records and safety checking for surveillance purposes as well as for updating the system. If outside experts are used to create the HACCP system, it is possible that the system will remain unfamiliar and useless to the FBO. This happens especially when there is no person in charge of the HACCP system in the operation (Nevas et al. 2013). If HACCP demands vary between control officials (IV), updating the system may also be frustrating for the FBO. Previous studies also suggest that the implementation of the HACCP system varies strongly across countries, food industry sectors and types of firms (Caduff & Bernauer 2006). Small businesses seem to have more difficulties with regulation and they see compliance as an integral aspect of the enforcement process; they believe that unless an enforcer has identified a certain non-compliance, they are in compliance with the law (Fairman & Yapp 2004). In contrast, a recent study by Luning et al. (2015) demonstrated that also small and medium-sized enterprises managed to have advanced food safety management systems and achieved good food safety outputs. Larger FBOs are noted to be more aware than small FBOs of the risks associated with their processes (Nevas et al. 2013), and they also consider systems related to food safety and quality as an effective investment, while small FBOs consider them to be prohibitive burdens (Jayasinghe-Mudalige & Henson 2007, Nevas et al. 2013). Since most (65%) of the FBOs in Finland have less than five employees (Ministry of Employment and Economy 2014), and at a European level 99% of food and drink business operators (EC 2014) are small or medium- sized, the challenge is considerable. Because

the practical implementation of the HACCP and especially the definition of the critical control points in the food industry are usually complex structured tasks in small and medium-sized FBOs, new automatic decision support tools have been introduced that enable automatic identification of critical control points in processes (Bertolini et al. 2007). The critical control points are identified with a software system using a database of hazards connected to food ingredients and process steps (Bertolini et al. 2007). Challenges among small and medium-sized FBOs have been noted, as in 2013 the EC proposed a package of measures reducing administrative burden for operators and simplifying the regulatory environment. Special consideration was given to the impact of this legislation on small and medium-sized FBOs, which were exempted from the most costly and burdensome elements in the legislation. It is estimated that the package will enter into force in 2016 (EC proposal 2013/0140, COD). Special attention should, however, be paid to the safety of consumers. Since most of the FBOs in the EU are small or medium-sized FBOs (EC 2014) and are at least in Finland struggling with HACCP requirements, the effect of mitigating food safety requirements for these FBOs may have considerable effects on food safety, and thus, further research is warranted after implementation of the package.

In Finland, with the amendment of the Finnish Food Act (2011), the obligation for approval of food establishment in advance was limited to FBOs handling products of animal origin according to Regulation (EC) 853/2004. Requirement for approval of premises before starting any operations or business was seen as too laborious for small FBOs with low-risk activities (Government Proposal 293/2010 for amending Food Act), and a notice of starting operations was considered sufficient. The impact of this amendment on food control work is considerable, as before the change the number of establishments needing approval before starting their operations was 48 000 and after the amendment the number dropped to 1200 (Government Proposal 293/2010 for amending Food Act). With the same amendment, the obligation for approval of control officers for FBO's in-house control systems was removed, with the intent of focusing on risk-based controls in arrears. A connection between low number of approved in-house control systems and outbreaks was discovered (I). Thus, it would be interesting to determine whether the amendment affects the quality of FBO's in-house control systems, food safety or even the number of outbreaks.

Technical barriers, including all practices, attitudes and perceptions that negatively affect the understanding, and hence, the proper and effective implementation and maintenance of the HACCP principle, have been studied by Panisello & Quantick (2001). According to Panisello & Quantick (2001), identification of technical barriers is essential also because of increasing global trade, including developing countries; the problems of small FBOs with the HACCP system may be incurred by large FBOs in developing countries due to the lack of technical resources at the plant level or the government may lack sufficient resources to verify HACCP plans at the national level. With increasing global and internet trade, the inability or reluctance of some FBOs to properly implement the HACCP system will create a challenge for those FBOs complying with requirements and trying to retain their reputation and gain profit, as the products they buy may not have the expected quality.

6.6 FOOD FRAUD (V)

HACCP-based food control is about controlling scientifically proven significant risk. But if the risk is based on fraud and economically motivated adulteration, traditional methods may not offer all answers or critical control points, producing a great challenge for official food control. Food fraud incidents differ from traditional food safety threats since they are not predictable by traditional food safety risk assessments or intervention strategies. Although there are few reported fraud cases in Finland and food frauds are seldom brought to the court, at the EU level the frequency in reporting food frauds is variable (V), challenging EU food control overall. A lack in control resources may have a negative influence on detecting frauds and also instigating legal actions. Different interpretation of the concept of fraud or varying legal systems between EU member states may also create differences in detecting or reacting to frauds. Divergent activity in reporting fraud cases and starting legal actions may result in a heterogeneous approach towards non-compliances of FBOs. Food frauds that were prosecuted in Finland handled mostly products of domestic origin, whereas in RASFF and Evira fraud notifications the product originated mostly from outside the EU (V). It is possible that the threshold to start legal actions towards FBO is lower when the defendant is domestic rather than directing legal actions towards a multinational enterprise with a home office abroad, creating challenges with territorial jurisdiction. A lack of resources may result in omission of more laborious enforcement methods towards foreign FBOs, while domestic FBOs with the same non-compliances are penalized. There is no definition of food fraud in EU legislation, nor do any specific tools or mechanisms exist to counter the criminally relevant facts that are to be brought to prosecution in accordance with applicable national rules. The present situation creates a challenge for harmonized EU food control legislation, and more detailed and practical common instructions on the definition of food fraud are needed. Advanced detection methods and other deterrence strategies are also needed to prevent and detect food fraud and unconventional adulterants. The new technical methods and strategies required formulate a new economic challenge for official control, which is already struggling with scarce resources. For instance, at the time when melamine was added to infant formula and other milk products in China, there was no mechanism for the detection of melamine in dairy products because it was not an expected additive (Everstine et al. 2013). Some researchers (Traill & Koenig 2010) claim that because of existing legislation and costs to FBOs in the form of lost reputation, food fraud is unlikely to occur in developed countries. However, adulteration and frauds have continued to evolve to evade and challenge existing testing methodologies, requiring continual updating of methods and resources to develop new methods (Everstine et al. 2013, Cutarelli et al. 2014, Sun et al. 2014).

In most RASFF fraud notifications (92%), the origin of food was outside the EU (Asia, Middle East and South America most commonly) and concerned food deriving from animals (V). These results are in line with those reported by Bouzembark & Marvin (2016) for the years 2000–2013. Since only 8% of RASFF fraud notifications were of EU origin, the EU food control system seems to tackle mostly frauds originating from third countries. A study conducted by Trienekens & Zuurbier (2008) discloses that FBOs from developing countries and emerging economies have problems complying with quality and

safety standards and regulations, especially due to the proliferation of standards in Western markets. It seems clear that in order to keep food safe and compliant with standards and regulations, FBOs universally need clear, uniform and update instructions on requirements. Even though HACCP systems are mainly applied in exports from developing countries, these systems are fragile and the high refusal rate of products from these countries due to, for example, pesticides residues was exposed (Trienekens & Zuurbier 2008). Inadequate preventive inspections and education of standards together with a weakly developed sanction system were also mentioned as complicating food control in some developing countries (Trienekens & Zuurbier 2008). If official food control in the country of origin is inadequate or the standards are different, the control officials at borders and at the destination of the product are faced with the extra challenge of discovering possible non-compliances. The quality of products does not, however, explain the number of fraud notifications, and unawareness of regulations does not prevent sanctions. Therefore, a non-compliance due to lack of information concerning requirements can also be recorded as a fraud.

In line with our study, previous research has shown that in 2005 RASFF notifications of illegal imports of animal products unsuitable for marketing were on the rise (Kleter et al. 2009). Meat or meat-based products can be tempting objects for fraud, especially if there is juxtaposition between the cost of production and the price that the supply chain customer or end user is prepared to pay for the product (Manning & Soon 2014). A study undertaken in South Africa on processed meat products (n = 139) disclosed that 68% of samples contained species that were not declared on the product labelling (Cawthorn et al. 2013). In accordance with that study, Potter et al. (2012) revealed that meat products were the second most common subjects of all product recalls in USA, the Republic of Ireland and the UK in 2004–2010. With the global food supply chains, it is possible to adulterate food in a country where regulatory and market controls are limited and the product is cheaper and to cause economic disruption or public health consequences at the other side of the world (EP 2013). With the increase of globalization in trading and online shopping, the amount of counterfeit goods and fake products concerning all categories of goods has increased significantly (Li 2013), and thus, uniform and effective means of controlling and preventing food frauds are needed worldwide.

EU member states will be asked to fully integrate anti-fraud checks into their national control plans and to ensure that financial penalties in these cases are set at amounts sufficiently high to work as preventive means (EC proposal 2013/0140, COD). The horsemeat incident in 2013 showed weaknesses in communication among control authorities with their counterparts in other member states in ensuring enforcement in cases of violations having cross-border impact (EC 2015b). As a consequence of weak communication between member countries, 28 national food fraud contact points were added and they operate in each EU member state to ensure cross-border co-operation on matters related to potential food fraud (Food Fraud Activity Report 2014). In Finland, co-operation between Evira, customs, police, prosecution, tax authorities, competition authority, consumer authority and the Ministry of Agriculture and Forestry has been increased in order to inhibit food fraud (Evira 2015b). New techniques have also been introduced to predict possible frauds and ease the workload of control officials.

Recently, a tool to assess the food fraud notifications in RASFF and to predict the type of fraud based on the country of origin and product category was developed using Bayesian Networks modelling (Bouzembark & Marvin 2016). The model predicted 80% of food fraud types when food fraud type, country of origin and food category had been reported before in RASFF (Bouzembark & Marvin 2016). However, predicting intentional adulteration is challenging and may lag behind because of unconventional and ever-changing adulterants and perpetrators. The wide range of substances that can be used in food fraud coupled with the impossibility of analysing them all, requires new testing methods such as mass spectrometry (Di Stefano et al. 2012), analysis of stable isotopes in foods (Kelly & Bateman 2010, Rock 2012), spectral fingerprinting, chromatographic fingerprinting and electrophoresis fingerprinting (Casale et al. 2010, Zhang et al. 2011) and DNA barcoding (Maralit et al. 2013). New testing methods obviously require training and both human and financial resources in official food control. DNA tests, sequencing and databases can be developed for all meat types and will make it possible to trace the meat to the individual animal type, breed and locality of origin along with isotope analysis, but the price of tests prohibits its use in ongoing quality assurance (Manning & Soon 2014).

Finnish court cases concerned mainly products of animal origin (V). As leading control officers in charge of enforcement methods are usually veterinarians in Finland (I), it is possible that they are more familiar with products of animal origin or more likely the health risks in these cases were estimated as high. Since products in notifications of Evira were mostly products like food supplements, further sanctions were also perhaps considered unnecessary. However, fraudulent food supplements without significant health risk may bring about considerable profits for the FBO without official sanctions in Finland. Furthermore, 30% of Evira's fraud notifications handled unauthorized additives, and in the UK non-approved food additives lead to fines incurred by FBOs when detected (Food Standards Agency 2015). Sanctions and definitions of food fraud are thus inconsistent and unequal towards FBOs inside the EU and need to be more unified or at least made more transparent.

Similar to Evira's notifications (V), the products studied in the Finnish Customs Laboratory (2014) most often non-compliant with the provisions were food supplements and special foods (dietetic foods, fortified foods) (46%), followed by flavourings (17%) and cocoa, coffee and tea (16%). The reason for non-compliance was most often labelling (33%), pesticides (20%) and additives (13%). In 5% of non-compliances, an inconsistency in the composition of the product and legislation was recorded to be the reason (Finnish Customs Laboratory 2014).

Missing, fraudulent or improper documents were the most commonly reported fraud reasons in RASFF notifications (67%) and local Finnish cases (63%) (V). In 2014, frauds discovered in the EU were also mostly related to non-compliances of labelling, falsified documents and substitution, such as replacement of a higher value species with a lower value species, and these frauds mostly concerned meat products (Food Fraud Activity Report 2014). Meat products and false documents may be a tempting combination because of the price of the product and because of the difficulty for the control officials and consumers to identify the product after it is processed or chopped and frozen (V). Following the discovery of horsemeat in beef products in Europe in 2013, restoring consumer confidence through

improved traceability, sourcing local ingredients, providing clearer and correct labelling and stating the origin of meat on package was suggested (Barnett et al. 2016). Several technologies suitable also for preventing frauds in packaging have been developed; these include holograms, colour-shifting ink, security thread, watermarks and sequential product numbering (Li 2013). New technologies for preventing and detecting frauds would be beneficial for control officials and also for law-abiding FBOs suffering financial losses due to fake products on the market.

In the majority of documented local Finnish fraud cases, the FBOs continued forbidden activities even after several warnings from control officials (V). Despite the modest amount of examples and cases without court handling only from four cities, the result is alarming. The same phenomenon has been noted in previous studies (Phillips et al. 2006, Lundén 2013). The indifference of FBOs towards requirements may be caused by the cost of amending their activities, the ineffective enforcement methods and sanctions or inconsistent interpretations of legislation by control officials (IV). In Finland, municipal authorities are also responsible for control of environmental protection. The state of affairs in Finland in environmental protection control concerning enforcement methods appears similar to that of food control. Enforcement methods in environmental protection control are used on very rare occasions, and the threshold to start legal actions is high among control officials (Laakso et al. 2003). Starting enforcement methods is without exception considered a complicated, long and exhausting process among control officers, and the reluctance for enforcement has sometimes led to endless discussions and instructions given to passive operators with a chain of non-compliances (Romppanen 2009).

In Finnish court cases, the FBOs were most commonly accused and found guilty of a health crime, i.e. endangering public health (V), and local control authorities use enforcement measures mainly in cases where the occurrence of a health hazard is obvious or probable (Lundén 2013, V). A recent study shows that enforcement measures appear to be an effective way of ensuring that FBOs correct their food safety violations, although the enforcement processes were rather long in some cases and required recurrent enforcement (Kettunen et al. 2015). Several control units with no enforcement measures were also discovered (Kettunen et al. 2015), possible indicating dissimilarities in using legal actions between control units. Previous Finnish studies (Jokela et al. 2009, Lepistö et al. 2009 and Lepistö & Hänninen 2011) similarly disclose that the use of enforcement measures is rather infrequent, possibly due to uncertainty concerning the practices of applying enforcement measures and the uncertain or guarded perceptions of food control officials towards enforcement measures. It is possible that the FBOs are aware of the long-lasting and laborious nature of enforcement methods and therefore continue their forbidden activities hoping that further actions will not be taken by control officials. However, the negligent attitude of FBOs towards regulation and orders given accordingly may seriously endanger public health. According to the Finnish national control plan (Evira 2015b), the use of enforcement methods and correction of non-compliances may be monitored by a new electronic information system in the future. Depending on the information provided by the information system, it is likely to unify enforcement procedures in Finland. In Finland, veterinarians usually are the originators

of enforcement actions (I), and precaution or inexperience in legal actions may exist among the reasons for varying and few enforcement actions. Accordingly, it has been stressed by the European Parliament (EP 2013) that the attitude of enforcement authorities should move from an administrative and veterinary approach towards a more law enforcement approach, which has proven successful in a number of member states. Enhanced education of food legislation among law students in Finland would also generate more experts, perhaps more court cases and law literature. Measures that have a direct economic impact on FBOs appear to be effective (Kettunen et al. 2015), and the possibility of officers being allowed to issue on-site fines to FBOs has been discussed as an option for enhancing on-site effectiveness of food control actions (Lepistö 2008). The right to determine on-site fines would, however, require great uniformity, consistency and transparency of actions of control officials to be equitable.

EP (2013) states that the complexity and cross-border character of the food chain in combination with the national character of controls and diverse enforcement may result in a large amount of food fraud going undetected. Undetected food fraud creates a challenge for control officials and consumers in the form of risk to public health and asymmetric information. It also challenges honest FBOs in the food chain, as they need know what they are buying and want to pay the right price for the product in order to gain profit and to retain their reputation and market share. The economic gain of fraud is further enhanced by an often ineffective sanction regime: relatively low sanctions and large differences between member states (EP 2013). Only 16 court cases concerning food were found in an extensive data search in Finland (V). The situation concerning court cases is quite different from the UK, where the Food Standards Agency provides detailed information about food law prosecution outcomes in a public database (Food Standards Agency 2015). The database covers food safety-related prosecutions obtained by the Food Standards Agency and local authorities in England, Wales and Northern Ireland. The database includes, among other information, the names of the FBOs, identification of specific regulation offended, description of the offence and sentence given together with the costs of the prosecution to the FBOs (Food Standards Agency 2015). In the UK, there are specific prosecutors for food-related offences. The objective of the database is primarily to knowledge-share among enforcement authorities, but it also provides information for the consumers. There were 420 convictions in the database in the time period of January-October 2015. Out of the convictions, 90% (377/420) were in the category of food hygiene and breached Regulation (EC) 852/2004 on the hygiene of food stuffs (Food Standards Agency 2015). Recurrent non-compliances with hygiene improvement notices were often mentioned, and several offences were performed by the same FBO, indicating that indifference of FBOs towards the orders of control officials is not only a Finnish phenomenon (V). The rest of the offences in the UK concerned labels (insufficient or fraud), out-of-date products, non-approved food additives, insufficient traceability, substitution of products and meat frauds. The fines varied between 100 and 20 000 pounds. One FBO was sentenced to prison for two years, and only one FBO was conditionally discharged (Food Standards Agency 2015). It seems that even consumers are being treated differently depending on their country of residence when comparing the situation in Finland and UK, at least regarding the information obtained.

The state of affairs in Finland and in the UK shows that the FBOs are treated differently inside the EU at least concerning detection of non-compliance and legal actions after detection. From RASFF fraud notifications (V), 59 originated from the UK and only one from Finland. The population of the UK (65 million) is more than ten times that of Finland (5.5 million) (Eurostat 2015). Is it possible that smaller EU countries like Finland have less frauds or are only those fraudsters caught that cross borders of bigger EU counties with better resources to reveal frauds? Major variations in contributions by EU member states to the RASFF database, which did not correlate with import tonnage, size or population of the member state, were also discovered by Taylor et al. (2013). EP (2013) has acknowledged that food fraud generally occurs where the risk of getting caught is minimal and sanctions are low. EP (2013) suggests that the member states should set penalties for food fraud which are at least double the estimated amount of economic gain sought through the fraudulent activity and even higher penalties, including criminal law penalties, for fraudulent cases in which public health is deliberately endangered or in cases of fraud involving products aimed at vulnerable consumers. In the event of repeated offences, the registration of the FBO should also be withdrawn (EP 2013).

Even though the food business today is heavily regulated and food is probably safer than ever, challenges remain. At the local, national and global levels, the prevention, detection and definition of food fraud require uniform and comprehensive approach. Common and practical instructions for defining food fraud are needed. Multiple disciplines and data sources, including extensive and active co-operation and communication between countries, scientists, different authorities and also FBOs, are essential. Compliant and honest FBOs can also play an important role in improving communication among legitimate producers, standardizing and recommending testing methods and performing regular product testing at retail, thus improving customer confidence in products (Everstine et al. 2013). Identifying common patterns of food fraud cases helps with risk evaluation and with devising common and coincident prevention strategies and deterrence. Additional research in detecting food frauds, sharing information about these frauds and unifying the reporting and penalizing of these frauds is required. Methods to prevent and detect malicious tampering of the food chain, i.e. bioterrorism, should also be further investigated.

7 CONCLUSIONS

1. Common features of regions with inadequate food control resources were identified as weaker economic condition in general, stronger business activity, higher population density and large net migration. The decision-makers were uninformed regarding the needs of food control, there were few food experts among the decision-makers and the official in charge of food control was more often not specialized in food control questions. The allowances and schemes of food control were approved at a lower level in the municipal hierarchy, and an inability of the officer in charge of lobbying funds for the food control branch was often mentioned. The decision-making inside the food control organization was more often delegated to the health inspector instead of the officer in charge and more time was spent on state-mandated tasks or tasks such as delivering samples to long-distance laboratories personally. Resources affect control work, as authorities working in municipalities with inadequate resources did not spend as much time in counselling and guiding FBOs as municipalities with better resources. Inadequate resources negatively affected the level of food control, as in 2002 only 8% of respondents from the respective areas thought that the level of food control was adequate. The number of approved in-house control systems was lower in municipalities with inadequate resources, and the number of food- or waterborne outbreaks was higher. Regionally varying resources in food control result in regionally uneven levels of food control and possibly also uneven treatment of food business operators. Regional co-operation was highly supported by control officials and was seen to enable specialization and distribution of tasks and to increase uniform treatment of FBOs.

2. EU legislation concerning quality systems, control plans and control fees is implemented at regionally different times, with significant delay and with different contents, affecting uniform treatment of FBOs. Control officials believe that quality systems enhance equal treatment of FBOs and facilitate inspections. The majority of control officials had difficulties in creating a quality system because of lack of knowledge and lack of instructions. In 2005, the biggest challenge with quality systems was to include risk assessment in the quality system. Control officials support standardized fees to ensure regionally equal treatment of FBOs. The frequency of inspections was determined on different grounds between the regions, resulting in varying treatment and control fees for FBOs. Regulations concerning quality systems, control plans and control fees are seen to improve the quality of food control and in-house control systems of FBOs. FBOs in the meat and fish sectors have problems with implementing and understanding EU food legislation. The most common challenges for all FBOs are related to layout of production premises and transport routes, control fees, requirements concerning in-house control, the structure and maintenance of premises and transport routes, package labels and the HACCP system. Constant changes in rules and legislation and control officials different and varying demands and interpretations of legislation create problems for FBOs. Small FBOs consider requirements of food legislation more cumbersome than bigger FBOs. Borders of the municipalities may determine the quality and level of food control, the implementation of legislation and requirements set, the guidance of FBOs and the costs of controls for FBOs, resulting in uneven treatment of FBOs.

3. Member states in the EU report food frauds in a highly variable fashion. This makes it difficult to define whether the difference is genuine and based on an accurate number of frauds or whether it is the result of different interpretations of the concept of fraud, lack of resources or some other underlying reason. In addition to different activity in reporting food fraud, also enforcement methods and sanctions differ between member states, creating heterogeneous treatment of FBOs and consumers and challenging control officials dealing with FBOs at border inspection sites. At the local level in Finland, fraud cases mostly dealt with domestic production, whereas at the national level (Evira notifications) and the EU level (RASFF fraud notifications) the products originated mostly from outside the borders of the EU. This may indicate that enforcement methods towards overseas or multinational FBOs are considered problematic by control officials. Violations in documents were most often in question in RASFF notifications and Finnish local cases. New methods are needed to unify documentations and for control officials to be able to identify false documentation without difficulties. In Evira notifications, the reason for fraud was most often unauthorized food, ingredients or processes and most often concerned food supplements. With food fraud in Finland, the product is most often withdrawn from the market, whereas in the UK FBOs are prosecuted in court for similar offences, resulting in different treatment of FBOs inside EU member states and possibly enabling distortion of competition. In Finnish local cases and RASFF notifications, food of animal origin dominated, indicating a need for advanced but expensive methods to identify ingredients, e.g. methods to identify the origin and species of meat products. Food frauds are seldom prosecuted in Finland and FBOs are often indifferent towards orders given by control officials, resulting in recurrent violations and endangering public health. FBOs' attitudes towards control officials indicate that enforcement methods are not effective or rapid enough to prevent recurrent violations. Effective methods for detecting and reporting frauds and more uniform penalties for FBOs committing food fraud are needed.

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